

Eye Bank Association of Australia and New Zealand Inc.



**EBAANZ Medical and Quality Standards
for Eye Donation and Eye Tissue Banking**

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Introduction

The Eye Bank Association of Australia and New Zealand Inc. (EBAANZ) was formed to promote cooperation, communication, consistency and reliability of service between Eye Banks for the benefit of donors, donor families, ophthalmic surgeons and tissue recipients.

The five Eye Banks in Australia and one in New Zealand are members of the Association.

Restoration of sight by transplantation of a healthy, viable cornea from a recently-deceased donor is the only option for people with advanced or end-stage corneal disease. Sclera from donated eyes may be used surgically for repair and reconstruction. The provision of these valuable tissues over many decades by Eye Banks has led to renewed quality of life for thousands of people, and has resulted in major efficiency and cost benefits to the health care industry. It has also enabled the donation wishes of many thousands of people to be fulfilled.

These Medical and Quality Standards have been developed to assure consistently high levels of quality, safety, proficiency and ethics in dealing with eye tissue for transplantation. Herein are defined the minimum standards of practice in the donation, retrieval, testing, preservation, and distribution of eye tissue as determined by the ophthalmological medical community in Australia and New Zealand. They are guided by similar Standards produced by the Eye Bank Association of America and the European Eye Bank Association and, in a broader context, well-established international standards for tissue donation and banking. Thus, these Standards encompass and reflect current international best-practice in eye donation and banking.

The Standards are written with a Quality Systems approach in mind and are designed to supplement (not replace) formal regulatory codes which may specify additional specific requirements for Good Tissue Practice as required by Government agencies.

It is also important to acknowledge in this Introduction those aspects of normal Eye Banking practice that are *not* specifically addressed by these Medical and Quality Standards, but nevertheless form an integral and indivisible part of the donation process. Eye Banks, being the first Donation Services, have by necessity been required to cover *all* aspects of donation including, but not restricted to - direct interaction with medical staff and families to obtain eye donor history for donor screening, obtaining consent for donation and performing services associated with follow-up to donor families, and responsibility for hospital and community donation programmes. These services, as well as the surgical, scientific and administrative aspects of eye tissue processing addressed in this document, are performed by professionals trained in these fundamental facets of eye donation services. Policies and procedures concerning these aspects of the donation process are addressed by each individual Eye Bank's Quality System, and may vary according to regional differences in practice.

In addition, the donor coordination services performed in association with other donation agencies or services, such as those that are primarily responsible for organ donation, tissue donation and/or those which may exist as part of Coronial institutions, must also comply with the minimum requirements specified in these Standards. The services provided through these beneficial and mutual partnerships include elements of donor screening, consent, and testing. The Eye Banks, as the distributors ultimately responsible for the safety, quality and supply of the eye tissues for transplantation, must seek and require assurance from these partnerships that practices conform to EBAANZ Medical and Quality Standards.

General Principles

1. The Eye Bank/Donation Service will ensure it complies with all relevant Federal and State legislation and regulations in the development and execution of policies and practice.
2. At all times a fundamental principle and aim is to maintain the dignity of the donor, the dignity of the donor's family and the dignity of the prospective recipient. The professional's ethical (and legal) duty of care is derived from this principle.
3. The Eye Bank/Donation Service will provide corneal and other human eye tissue with maximum safety and minimal risk to the service's staff, hospital staff and recipient patients.
4. A fundamental principle of all tissue banking is to prevent the introduction, transmission and spread of communicable disease or infection.

However, these principles and goals are subject to the limitations of human tissue donation, variability in biological systems and material, and the practice of medicine. Thus, as for donation of other major organs:-

- No two donations are the same, and each item of tissue acquired is unique and variable.
- Testing or evaluation of such individual tissues is restricted to tests that do not lead to its destruction. Minimal manipulation is required for eye tissue to remain viable and healthy.
- Eye tissue is not sterile, nor (as living tissue) can it be subject to terminal sterilisation or to an absolute guarantee of absence of potentially infectious micro-organisms.
- Extensive screening is performed to preclude from transplant any tissue which is potentially hazardous because of possible transmission of disease or infection; however risk of transmission can never be completely eliminated.
- There are no absolutely defined criteria for the acceptance or rejection of tissue - the final decision regarding surgical use rests with the surgeon for each individual and unique case. In reaching a decision on acceptance or rejection of tissue for surgical use, the surgeon is guided by the Eye Bank/ Donation Services' testing and reports.

Unlike blood and most other forms of donated bodily tissues, very little 'processing' or long-term storage of eye tissue can occur. Eye tissues cannot be tested for functional ability in the laboratory or have tests performed to monitor viability or presence of contaminants that will compromise the tissue itself. Therefore, the aim of eye tissue 'processing' is to preserve the viability and function of the tissue, reduce residual colonisation of normal ocular flora and avoid introducing contaminants. Each unit of tissue is retrieved, stored and distributed as an individual item, and is not pooled or transplanted in multiple units. No definitive test of functional ability is able to be performed, except by transplantation and subsequent biological function in the recipient; therefore no direct validation of processes can be achieved except by monitoring clinical outcome.

These Standards also reflect that there are different methods employed to store and preserve eye tissue, which are all medically approved and clinically proven, and that eye tissue may be used for different surgical purposes.

Surgical use of corneas for transplantation (*keratoplasty*), and hence the type of donor tissue supplied, can vary according to the presenting indication of the recipient, the preferred method of the surgeon, and urgency of surgery. The most common form of keratoplasty (*penetrating keratoplasty*) utilises the full thickness of the donor cornea, including the vital inner cell layer (endothelium) i.e. the whole thickness of the cornea is replaced. Various forms of *lamellar keratoplasty* (*of either anterior or posterior cornea*) are also performed. Anterior lamellar procedures replace only the anterior portion of the recipient's cornea with equivalent partial thickness donor tissue i.e. the recipient's endothelium remains. Posterior lamellar procedures replace the endothelium of the recipient's cornea with donor endothelium. These techniques are becoming more common, and can be seen as advantageous to the recipient. This has implications for Eye Banking in the selection of donor eye tissue and the preparation of the tissue for surgery.

Therefore, Eye Banking must accommodate these differing requirements for surgical use, which may mean that different 'qualities' of tissue can be supplied e.g. a cornea with an unsuitable endothelium may be used for cases of anterior lamellar keratoplasty. Corneas are also able to be used as a purely structural tissue, where perforation of the cornea is an emergency, and a cornea not meeting normal quality requirements is acceptable to 'save the eye'.

Finally, it must be appreciated that many aspects of the process of providing eye tissues are based on medical and surgical procedures in addition to the scientific and technical procedures employed in the laboratory. Such medical and surgical procedures are difficult to standardise with any degree of certainty, and professional judgment must be employed in any given situation. This can be compared directly to many of the donor screening, retrieval and evaluation processes that occur in the case of vascularised whole organ donation. It is not possible to encompass these aspects of Eye Banking in written Standards where technical direction is no substitute for professional experience and judgment. However, professional practice must still be based on the general principles and minimum standards provided by this document.

These Standards will be reviewed annually, updated if necessary and approved by EBAANZ member Eye Banks. The compliance date for any changes is three months following the date of this document.

1

QUALITY SYSTEMS AND ASSURANCE

1.1 General

The aim of using a Quality System in Eye Banks is to maximise 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.

The Eye Bank shall have a formally established quality assurance programme (hereafter called Quality System) that defines and documents a series of systematic processes that are to be followed by all those working in the organisation. These processes shall be designed to ensure that quality is evident in every part of the organisation 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 Quality System shall include ongoing monitoring and evaluation of activities, identification of problems, and implementation of plans for corrective actions.

1.2 Resources for a Quality System

- Adequate resources shall be provided at all levels to ensure effective and efficient delivery of the Eye Bank's Quality System. The Eye Bank shall identify and provide adequate resources, including the assignment of trained personnel, for management, performance of work and process verification activities and internal audits.

1.3 Procedures and Documentation

- A Quality System depends on the implementation of 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.
- A Policy and Procedures (Quality) Manual shall be produced which includes standard operating procedures (SOPs) and associated documents for all activities which affect the safety or quality of eye tissues and shall include (but not be limited to) a detailed description of the following:
 1. The procedures used for consent for donation, donor suitability assessment, eye tissue retrieval, processing, preservation, packaging, labelling, storage, quarantine, evaluation, distribution, and recall of, eye tissues.
 2. Record keeping, adverse reaction reporting and notification.
 3. The procedures used for facility establishment, maintenance, cleaning and environmental monitoring (if performed).
 4. The procedures used for equipment maintenance, cleaning, calibration and validation.
 5. Procedures for corrective and preventative actions to be implemented should errors or non-conformances occur, and to effect continuous quality improvement.
 6. Copies of publications cited in support of the policies and procedures.
 7. A description of the required tests, procedures and tolerance limits applied.
 8. Quality assurance activities.

1.4 Responsibilities for Quality

- The responsibilities and reporting relationships of all key personnel shall be defined and documented.
- The Medical Director of the Eye Bank (as defined in Section 2) shall have overall responsibility for the policy of the Quality System. This must be relevant to the Eye Bank's goals and the needs of the health sector it supplies.
- The Quality Manager of the Eye Bank (as defined in Section 2) shall have responsibility for the policy implementation and operation of the Quality System.
- All members of staff shall be trained in accordance with the Quality System and be responsible for

the quality of their work.

1.5 Approval, Review and Audit

- Procedures, documents and forms shall be reviewed and approved by the Quality Manager or other authorised 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 operations and records. These should be performed at least annually, and by a person familiar with, but not directly responsible for, the processes being audited.

1.6 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 materials not in current use shall be clearly distinguishable from those in current use.
- Critical materials shall be stored in a manner that ensures the integrity and status of the material is maintained.

1.7 Process Controls and Changes

- Eye Banks shall document in their Policy and Procedures (Quality) 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:
 - performance of specific tests, trials or procedures
 - risk assessment for potential effect on safety and quality
 - previously published studies
 - 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.

2

PERSONNEL AND TRAINING

2.1 General

- The Eye Bank shall have sufficient staff to perform duties relating to eye tissue donation, retrieval, processing and distribution in accordance with the volume of tissues expected to be obtained, and the nature of the Eye Bank's specific service requirements.
- Staff shall possess the educational background, experience and/or training sufficient to ensure assigned tasks are performed in accordance with established Quality procedures.
- The Eye Bank shall establish and maintain a current organisational chart that defines the role and reporting responsibilities of all staff.
- The Medical Director, Manager and Quality Manager shall be appointed by the Eye Bank's Board of Directors, Trustees or other governing body.
- When the Medical Director, Manager or Quality Manager is not available a deputy shall be designated who is capable of fulfilling the responsibilities on an interim basis.

2.2 Key Responsibilities

With recognition that Eye Banks may be different in regard to staffing levels, structure and specific allocation of responsibilities -

- a. the specific titles given are intended as an indication of the role and are not prescriptive. Individual Eye Banks may allocate their own titles to these responsibilities.*
- b. the following key responsibilities may be undertaken by the same person e.g. Manager and Quality Manager, however the preference is for separate individuals to undertake these responsibilities.*

The purpose of this Standard is to ensure that there are identifiable people within the organisation that fulfill these key responsibilities.

2.2.1: Medical Director

- The Eye Bank shall have a Medical Director.
- The Medical Director shall 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 eye disease. If the Medical Director has not served a corneal fellowship, then the Eye Bank shall have and document a consulting relationship with an Ophthalmologist who has.
- The Medical Director of each member Eye Bank shall attend the Annual General Meeting of EBAANZ at least once every three years.
- The Medical Director shall oversee and provide advice on all medical aspects of the Eye Bank operations. These include but are not limited to:
 - Formulation, approval, and implementation of medical policies and procedures.
 - Oversight of training of staff with regard to donor screening, tissue retrieval, tissue preservation and tissue evaluation.
 - Understanding of the principles of the infectious disease screening and testing methods employed, and the interpretation of test results.
 - Participation in establishment and operation of the Quality System. This shall include approval of any changes to the Quality System.
- The Medical Director may delegate responsibility for donor screening, tissue retrieval, preservation, and tissue evaluation to qualified Eye Bank personnel; however, the Medical Director shall ensure that the Eye Bank operates in compliance with these EBAANZ Medical Standards and all relevant Federal and State legislation and regulations.

- An Eye Bank has three months to replace a Medical Director who has resigned.

2.2.2: Manager

- All policies and procedures of the Eye Bank shall be under the supervision of a Manager (or an equivalent person who fulfills these responsibilities).
- The Manager shall be responsible for all administrative operations including ensuring compliance with these Standards. The Manager shall be the individual responsible for the day-to-day operation of the Eye Bank, and implementing the policies of the governing body. This will include, but is not limited to:
 - Responsibility for all personnel and training of staff to ensure adherence to these Standards and other regulatory standards.
 - Keeping up to date with new developments, professional guidelines and related research.
 - Other Management responsibilities as prescribed by the Eye Bank's governing body.
- The Manager, if not a Registered Medical Practitioner, shall consult with the Medical Director as well as other medical and regulatory authorities in carrying out prescribed responsibilities as necessary or required..
- The Manager shall provide all staff members with adequate information to perform their duties safely and competently.

2.2.3: Quality Manager

- All policies and procedures relating to the Quality System of the Eye Bank shall be managed by the Quality Manager (or equivalent person who fulfils these responsibilities).
- These responsibilities should include design, implementation and maintenance of the Quality System, specifically in relation to:
 - Documenting policies and procedures and associated document control.
 - Ensuring agreements or contracts for services with third parties are established and maintained.
 - Regular audit and review of the Quality System to effect continuous quality improvement
 - Recording of deficiencies, non-conformances and any reported adverse reactions, and to ensure corrective and preventative actions are assessed, actioned and reviewed.
- The Quality Manager shall have the necessary independence and authority to ensure that quality measures are employed as defined by the Quality System while still acting in accordance with the policies and procedures of the Eye Bank.

2.2.4: Scientific Staff / Donor Coordinators / Administrative Staff

- The governing body and/or Manager shall appoint scientific/technical staff, donor coordinators and administrative staff as appropriate to their needs, and ensure that staff have the appropriate qualifications and training for the performance of their job responsibilities. The Manager shall ensure that there are a sufficient number of qualified staff to promptly and proficiently perform all procedures that form part of their responsibilities.

2.3 Training and Continuing Education of Personnel

- Training and continuing education programmes shall be developed in accordance with identified needs for each role or responsibility.
 - Programmes shall be documented and include on-going training and assessment.
 - Personnel shall be trained in the Quality System, Medical Standards and all Federal and State legislation and regulations relevant to their responsibilities.
 - Records shall demonstrate that each staff member is trained for the work practices and Quality Procedures they are authorised to perform. There shall be records to show that all personnel have acknowledged any subsequent changes to procedure(s).
 - Personnel shall not be permitted to sign or initial a document unless they have been trained and assessed as competent in the work practices associated with the signature, and in the significance of their signature.

- The Eye Bank should provide educational opportunities such as in-service education programmes, attendance at meetings, seminars, and workshops for all personnel at a frequency that is reasonable and appropriate for the needs of the individual staff member.
- The Eye Bank shall institute and document a competency assessment program for all staff. This should include any action to be taken if expected competence was not achieved.

3

BUILDINGS AND FACILITIES

3.1 General

- The Eye Bank shall have sufficient space, equipment, and supplies to perform the volume of laboratory services required with optimal accuracy, efficiency, asepsis, timeliness and safety.

3.2 Eye Bank Laboratory(s)

- 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.
- There shall be easy access to 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 Environmental Conditions

- The Eye Bank shall establish and document requirements for the environment to which tissue is exposed. The quality of air shall be defined for each type of processing area and this will depend on the nature of the process, the tissue and the degree of handling and exposure of the tissue.
- Eye tissue retrieval shall be performed in as clean an area as practicable using techniques to reduce contamination. There is no requirement for a defined air quality or monitoring thereof.
- Following preliminary evaluation and decontamination, open-container processing and handling of eye tissue shall be performed in an accredited biohazard safety cabinet, or an accredited operating theatre, or in a room where the air quality is controlled and documented.

4 EQUIPMENT

4.1 General

- Documented procedures shall be established to maintain all equipment that may affect the safety and/or quality of tissue or reagents (critical equipment).
- The Eye Bank shall:
 - Identify all critical equipment that may affect tissue safety and/or quality.
 - Specify details of the equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.
 - Specify cleaning and routine maintenance schedules and procedures for each piece of critical equipment.
 - Maintain appropriate maintenance, certification, 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.
 - Identify the calibration status of critical measuring equipment, and ensure that calibration is performed against a traceable standard.
 - Ensure that the handling and maintenance of critical equipment is such that the accuracy and fitness for use are maintained.
- If more than one variant of an item of critical equipment is employed for tissue processing or evaluation, records shall identify which specific item is used for each unique tissue.

4.2 Storage Equipment

This section applies to those items of equipment used to store eye tissue intended for transplantation, and also applies to those equipment items for storage of reagents that may affect the safety and quality of tissues (if appropriate to that reagent). Due to the nature of storage required this could apply to refrigerators, incubators or freezers. Therefore the generic term "tissue storage equipment" is used in this section.

- The Eye Bank laboratory shall have tissue storage equipment with a device, visible without opening the equipment item, for continuously recording temperature variations. The temperature recording device should reflect the temperature of the stored tissue under normal storage conditions appropriate to that tissue.
- Temperature variations shall be recorded daily and remain within the range appropriate to that stored item (or to the reagent). This range shall be specified in the Eye Bank's Policy and Procedures (Quality) Manual. These records shall be kept for a minimum of three years.
- The continuous temperature recorder shall be calibrated against a reference thermometer as defined by the appropriate regulatory agency at least once a year.
- The tissue storage equipment shall be maintained for the use of tissue and reagents and shall contain clearly defined and labelled areas for all tissue stored i.e. quarantined tissue, surgical tissue awaiting distribution, research tissue; and defined areas for reagents.
- Eye Banks shall detail required cleaning intervals and documentation in their Policy and Procedures (Quality) Manual.
- In the event of a power failure or malfunction, there shall be provision for immediate notification and action to be taken, which may include an emergency power supply to maintain essential storage temperatures within the range specified.

4.3 Biohazard Safety Cabinet

- 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 cabinet shall be monitored at regular defined intervals for air quality.

4.4 Surgical Instruments

- Adequate instrumentation shall be available to provide for aseptic removal of whole eyes and corneas.
- Instruments employed may be of single-use, disposable type, or those which are re-used.
- Re-usable instruments shall be inspected frequently enough to assure that they function properly, and shall be suitably decontaminated and cleaned prior to sterilisation and re-use.
- All sterilised instruments shall be identified by sterilisation dates, sterilisation method and appropriate expiration dates that are current.
- The Eye Bank shall provide documentation of appropriate sterilisation.

5

INFECTION CONTROL AND PERSONNEL SAFETY

5.1 Infection Control

- Eye Banks shall employ general principles of infection control in their work practices to minimise the potential for contamination of personnel, contamination of tissues, and cross-contamination between different donor tissues.

5.2 Health and Safety

- The Eye Bank shall operate under the Health & Safety requirements, including current Universal Precautions for health care workers as specified by relevant Federal and State legislation and regulations, and local rules or guidelines (if applicable).
- Eye Banks shall include in their Policy and Procedures (Quality) Manual specific reference to Universal Precautions for the safe handling of human blood and tissues. This should also form part of the training programme for new staff.
- The Eye Bank shall establish and document procedures for required personal protection items and apparel to be worn by staff while handling deceased persons and tissues.

5.3 Waste Disposal

- Human tissue and waste items shall be disposed of in such a manner as to minimise any hazard to Eye Bank staff, other personnel and the environment, and to comply with all relevant Federal and State legislation and regulations, and local rules or guidelines (if applicable).
- Dignified and proper procedures shall be used to dispose of human tissue and these must be documented.

6

RECORDS AND DOCUMENT CONTROL

6.1 General

- All processes and associated activities in the donor screening, tissue retrieval, preservation, and tissue evaluation, testing and distribution of eye tissue shall be documented and the documents controlled.

6.2 Policy and Procedures (Quality) Manual

- The Eye Bank shall maintain its own Policy and Procedures (Quality) Manual that details all aspects of its specific donor screening, consent, retrieval, processing, testing, storage, evaluation, distribution and quality assurance practices. This includes:
 - Standard operating procedures
 - Specifications, such as donor criteria and tissue evaluation criteria
 - Standard forms used in eye tissue donation, processing, storage, testing and distribution
- The Policy and Procedures (Quality) Manual shall be reviewed at regular intervals.
- Each procedure shall be reviewed, approved, signed and dated by the Quality Manager or other authorised person prior to issue. This process shall ensure that:
 - the relevant issues of appropriate documents are available at all locations where operations essential to the effective functioning of the Quality System are performed
 - invalid or obsolete documents are removed from points of issue or use, to prevent unintended use
 - obsolete documents are retained for knowledge preservation and legal purposes and that these are suitably identified and stored

6.3 Donation and Processing Records

- Records shall be confidential, secure, accurate, complete, legible and indelible.
- Each unit of tissue shall have a unique identifiable code and be traceable from donor to recipient, while protecting the donor's anonymity.
- Records shall document the following minimum information:
 - Record of authorisation/informed consent for donation
 - The date, and where applicable, the time the procedure was performed
 - The identity of the person performing and/or authorising critical procedures
 - Any inspection checks and quality control tests performed

6.4 Revisions and Additions

- Revisions of records shall be made with a single line drawn through the altered text.
- The revision(s) shall be initialed and dated by the individual making the revision(s).
- Additions to records shall be initialed and dated by the individual making the addition(s).

6.5 Storage and Retention

- The minimum periods of retention for all categories of documents shall be specified.
- The complete records pertaining to each donor tissue, including donor information and testing, shall be retained for a minimum of twenty years after the tissue is distributed.
- Documents shall be stored and retained so they are retrievable in facilities that provide a secure and suitable environment to prevent damage, deterioration or loss.

6.6 Confidentiality

- All Eye Bank records and communications between the Eye Bank and its donor families, recipients and health professionals shall be regarded as confidential and privileged.
- Access to donor identity and medical information shall be restricted to Eye Bank staff, other donation agencies where appropriate, and to inspectors from regulatory agencies.
- A system shall be established to ensure that records containing confidential donor and recipient information are secured from unauthorised access.

6.7 Computerised Records

- If an Eye Bank uses a computerised system for quality purposes other than archiving of records that have also been retained as hardcopy, then it shall ensure that validation of the process is performed.

7

CONSENT FOR DONATION

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.

7.1 General

- Donation of eye tissue cannot proceed unless legal authority to remove tissue is established under the relevant Federal and State legislation and regulations. Details of this authority shall be documented in the Policy and Procedures (Quality) Manual.
- In most instances, this authority is obtained by the receiving of informed consent from the potential donor, the donor's next-of-kin, or authorisation of a Designated Officer or Coroner (when they are legally in possession of the body).

7.2 Method of Consent

- Obtaining of legal consent prior to eye tissue retrieval is essential.
- Consent procedures and forms shall conform to applicable Federal and State legislation and regulations, and documentation of consent shall be retained.
- In Coroner's cases, the Eye Bank shall adhere to the consent regulations specified by the Coronial legislation in its country or state.
- In each case, the consent designation and restrictions, if any, shall be followed.
- In some Eye Bank jurisdictions there may be a legal requirement for verbal consent to be witnessed and/or permanently recorded.
- In no case shall coercion or monetary inducement be offered to obtain consent.
- Consent may be obtained by Eye Bank Coordinators, other donor Coordinators, directly by medical or hospital staff, or by any individual designated by an institution and trained to represent the option of eye donation to the family of the deceased.
- Informed consent is defined as *the authorisation to remove tissues for agreed purposes based on the amount of information that a reasonable person would likely attach significance to.*
- For an eye donation consent to be informed, it should contain the following elements:
 - Permission for removal of eye tissue either as whole eyes, or as corneas only (as applicable).
 - Information as to the tissues which can potentially be used for transplantation, or research (as applicable)
 - The purposes for which these tissues will potentially be utilised
 - Information concerning the donation process e.g. location, timing, viewing of the body
 - The requirement for blood testing of the donor to test for infectious diseases or tissue typing purposes
 - The possible requirement for further medical information to be obtained, and permission for this e.g. from GP, specialist
 - Information concerning potential unsuitability of tissue for transplant, and uses for which permission is given in these instances e.g. research, clinical training, return of tissue, disposal
 - Permission for use of tissue for research, clinical training or education should be obtained as a separate explicit consent
 - Information on follow-up options and notification of outcome
 - That there shall be no cost to the donor and/or their family for any expenses relating to donation
 - Information on possible use for cosmetic procedures or applications involving commercial gain (*only if this is applicable to the tissue(s) being consented*)
 - Ability and time for person to ask questions and receive clear answers

7.3 Documentation of Consent

- Consent shall be obtained in writing (by a signed Consent Form), verbally (by telephone) or by audio or audio-visual means. In all cases, documentation of the consent shall be made and the consent retained as part of the donor records.
- A Consent Form, or documentation of verbal consent, 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 shall include (but is not limited to) the following minimum information:
 - The identity of the donor
 - The identity and relationship of the consenting person, including name and address
 - A description of the type of tissues for which consent is given to retrieve
 - A description of the general purposes for which retrieved tissues may be used, which may include transplantation, and/or research, and clinical education (if applicable)
 - The identity, position and institution of the consenter (person obtaining consent)

8

DONOR SCREENING AND CONTRAINDICATIONS

8.1 General

- 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.
- Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation includes:
 1. Serologic testing
 2. Physical assessment of the donor
 3. Eye tissue evaluation
 4. Donor history evaluation: this shall include donor information obtained from at least one of the following:
 - Coroner, Pathologist or certificate of death
 - Police investigation report
 - Family interview
 - Medical record or hospital chart
 - Treating physician or General Practitioner interview
 5. Medical Director overview to review any donor information where questions arise in the above areas. In these cases, individual donor suitability shall ultimately be determined by the Medical Director. This shall be documented.

8.2 Contraindications

- Defined in the table below are the MINIMUM set of contraindications for use of eye tissue for transplant purposes.
- Individual Eye Banks may have exclusionary criteria in addition to this list.
- Some criteria listed as generally exclusionary may be acceptable depending on the storage method used for tissue preservation - see explanatory notes at end of table.

Screening of donors shall be conducted for the following disorders, which are potentially health-threatening for the recipient(s) or pose a risk to the success of the surgery, and shall not be offered for surgical purposes:

8.2.1: Penetrating Keratoplasty

Classification	Disease or process
General	<ul style="list-style-type: none">• Death from unknown cause - <i>but suitable if the death certificate or autopsy report is only pending an unresolved differential cause of death where all the alternatives are NOT contraindications.</i>

Infectious disease^{1,2}	<ul style="list-style-type: none"> • Acquired immune deficiency syndrome (AIDS) • Encephalitis - active, viral, or encephalitis of unknown origin • Hepatitis - active, viral • Human T-cell lymphotropic virus (HTLV-1 or HTLV-2) • Human immunodeficiency virus (HIV-1 or HIV-2) - clinical diagnosis or seropositive • Leprosy - active • Malaria - active • Meningitis - active, viral, or meningitis of unknown origin • Progressive multifocal leukoencephalopathy • Rabies • Reye's syndrome • Rubella, congenital - but past acute infection is not a contraindication • Smallpox - recognisable signs or symptoms within the last 14 days • Subacute sclerosing panencephalitis • Syphilis - active • Tuberculosis - active • Typhoid - active <p><i>Where active is listed, past resolved infection may be acceptable.</i></p>
Infection³	<ul style="list-style-type: none"> • Active systemic viraemia • Active systemic fungaemia
Infectious disease - high risk⁴	<p>Human immunodeficiency virus (HIV) or Hepatitis high risk (any potential donor that exhibits one or more of the following):</p> <ul style="list-style-type: none"> • Persons who have performed intravenous, intramuscular or subcutaneous non-prescribed drug use within the previous 12 months (or where history or examination gives cause to suspect non-medical intravenous drug use) • Men and women who have engaged in sex for money or drugs within the previous 12 months • Men who have had sex with another man in the previous 12 months • Persons who have received human-derived blood clotting factors e.g. for haemophilia in the previous 12 months • Any person who has had sex in the previous 12 months with any of the above four categories • Persons who have had close contact with another person having viral hepatitis within the previous 12 months, <i>except for hepatitis A</i> • Persons who have had sex in the previous 12 months with a person known or suspected of having HIV or any non-A viral hepatitis • Recipient of blood or other human-derived transfusion/infusion product outside Australasia within the previous 12 months • Persons with tattooing, body piercing or scarification, or acupuncture within the previous 12 months in a unregulated Australasian facility or non-Australasian facility (piercing done at home should be assessed by the Eye Bank and may be acceptable) • Children <13 years of a mother with HIV or AIDS, or at high risk infection from HIV, but only if the child shows evidence of infection • Incarceration within a prison within the previous 12 months (<i>assessed by Eye Bank if involves only remand of less than 7 days, or where the incarceration was in a facility not described as a prison</i>). • Jaundice, unexplained, or hepatomegaly unexplained. Note hepatomegaly may not be apparent unless an autopsy is performed. • Known exposure within the previous 12 months, by percutaneous inoculation, contact via a mucous membrane or non-intact skin, to blood from a person with known or suspected HIV, or HBV or HCV infection • Persons who have had gonorrhoea or syphilis within the previous 12 months or have been treated for one of these diseases in the previous 12 months <p>Human immunodeficiency virus (HIV) high risk where the following cannot be explained by other disease processes (any potential donor that exhibits one or more of the following):</p>

	<ul style="list-style-type: none"> In the previous 12 months, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting >1month, unexplained temperature >38.6°C for >10days, unexplained persistent diarrhoea, unexplained persistent cough or shortness of breath, or opportunistic infections.
Malignancy	<ul style="list-style-type: none"> Hodgkin's Disease Leukaemia Lymphoma Lymphomatoid granulomatosis Lymphosarcoma Myeloma Myeloproliferative disease Polycythaemia vera - primary (<i>secondary polycythaemia is acceptable</i>)
Neurological disorder	<ul style="list-style-type: none"> Chronic idiopathic demyelinating polyneuropathy Creutzfeldt-Jakob Disease (CJD) or prion disease any type Amyotrophic lateral sclerosis (motor neurone disease) Multiple sclerosis Huntington's chorea Guillain - Barre syndrome
Neuro-degenerative - high risk⁵	<ul style="list-style-type: none"> Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown aetiology. Blood relatives of persons diagnosed with CJD of any type. Recipients of human pituitary-derived hormones from 1963 to 1985. Recipient of human-derived dura mater tissue at any time.
Eye Disorders and Surgery⁶	<ul style="list-style-type: none"> Ocular/intraocular infection - active inflammation giving rise to clinically diagnosed endophthalmitis (keratitis, conjunctivitis, retinitis, choroiditis, iritis, uveitis, vitreitis, scleritis) at the time of death. Malignant tumours of the eye e.g. retinoblastoma, melanoma, adenocarcinoma Corneal disorders including keratoconus, keratoglobus, dystrophy Corneal opacity, scarring, or pterygium, which involves the central optical area of the corneal button (may be considered for posterior lamellar procedures) Corneal surgery e.g. radial keratotomy, laser refractive surgery: photorefractive keratectomy (PRK) or laser in situ keratomileusis (LASIK)
Notes:	<p>¹ Bacterial endocarditis and bacterial meningitis may be suitable depending on the case and if organ culture storage of corneas is performed with concomitant microbiological testing.</p> <p>² Where active is used this normally means current at time of death and confirmed by clinical examination, serological or confirmatory testing.</p> <p>³ Localised non-systemic infections, and infective processes that have clinically resolved may be considered. Each case needs to be assessed by the Eye Bank. Generalised bacteraemia is not contraindicated if organ culture storage of corneas is performed with concomitant microbiological testing.</p> <p>⁴ Close contact is defined as sexual contact or contact which may result exchange of body fluids, which includes living in the same household.</p> <p>⁵ Recipients of synthetic growth hormone or dura mater are acceptable. Dementia resulting from cerebrovascular disease, brain tumour, or trauma, and toxic- or metabolic-induced dementia may be acceptable.</p> <p>⁶ Defects or disorders of the eye should be assessed by the Eye Bank so</p>

that the importance can be considered. Many defects or disorders, and many surgeries on the eye e.g. for cataract removal, glaucoma, retinal therapy are not contraindications, where corneal tissue is screened by endothelial microscopy. They should not be considered contraindications to donation but the cornea assessed for suitability of intended surgical procedure.

8.2.2: Anterior Lamellar or Patch Keratoplasty

- Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma e.g. aphakia, iritis, is acceptable for use. Death to preservation time may be extended.

8.2.3: Posterior Lamellar / Endothelial Keratoplasty

- Criteria are the same as listed for penetrating keratoplasty except that tissue with local non-infectious anterior pathology that does not affect the posterior stroma and endothelium is acceptable for use. Surgeons should be notified of any such pathology prior to placing the tissue for transplant.

8.2.4: Epikeratoplasty

- Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the corneal endothelium e.g. aphakia, iritis, is acceptable for use. Death to preservation time may be extended.

8.2.5: Scleral Tissue

- Criteria are the same as listed for penetrating keratoplasty except that tissue with local eye disease affecting the cornea is acceptable for use. Death to preservation time may be extended.

8.3 Documentation of Donor Information

- Donor screening forms and/or copies of medical charts, Coroner review forms and initial autopsy results shall be completed and retained on all donated eye tissue as part of the donor record.
- Names of persons providing donor screening information shall be recorded.

8.4 Donor Age

- The lower age limit for donation of eye tissue for transplantation shall be two years.
- The upper age limit shall be left to the discretion of the Medical Director, since no definite relationship has been established between the quality of donor tissue and advanced age.

8.5 Interval between Death, Enucleation, Excision and Preservation

- Acceptable time intervals from death to enucleation or excision, or from excision to preservation may vary according to the circumstances of death, interim means of storage of the body and/or method of corneal preservation.
- It is generally recommended that corneal preservation occur as soon as practicable after death.
- All time intervals for each donor i.e. the time of death to the time of enucleation and preservation and/or the time to corneal excision, shall be recorded.

8.6 | Living Donors

- Eye tissue that is removed and processed for transplantation from a living donor shall have the same standards applied as for all cadaveric tissue. e.g. the same donor medical history screening and testing etc., except of course that cause of death is not relevant.

9

RETRIEVAL AND PROCESSING OF EYE TISSUE

9.1 General

- Retrieval may be either by removal of the whole eye (enucleation) or by removal of only the corneoscleral button (*in situ* excision).
- Ultimate responsibility for Eye Bank staff or other personnel to perform retrieval procedures rests with the Medical Director or Manager in authorised to do so.

9.2 Surgical Retrieval

- The Eye Bank shall have retrieval procedure(s) documented in their Policy and Procedures (Quality) Manual.
- The Medical Director and Manager shall be responsible for assuring that Eye Bank personnel comply with all applicable procedures for the retrieval of tissue. Adequate guidance should be given to others who may perform retrieval on behalf of the Eye Bank at remote sites.
- The donor shall be positively identified by cross-check with a tag or other label on the body, or by positive identification by hospital or mortuary staff.

9.2.1: Enucleation Procedure

- Enucleation is a surgical procedure, and as such, may vary according to factors unique to each situation.

9.2.2: In Situ or Laboratory Removal of Corneoscleral Button

- Corneoscleral excision is a surgical procedure, and as such, may vary according to factors unique to each situation.
- Excision of the corneoscleral button shall be performed using aseptic technique by individuals specifically trained for *in situ* retrieval and/or laboratory removal of the corneoscleral button.
- Laboratory removal shall be performed in a biosafety cabinet or in an operating room.
- For *in situ* excision, the eye shall be examined with the use of a penlight or portable slit-lamp prior to excision.
- Povidone-iodine solution (or other validated decontamination reagent) shall contact the surface of any ocular tissue intended for transplantation at least once between the time of the donor's death and tissue preservation i.e. prior to *in situ* excision or of whole globes in laboratory. Excess decontamination solution should be irrigated from the ocular surface prior to preservation.

9.3 Transport of Eye Tissue to Eye Bank

- Packaging of tissue shall ensure adequate protection from damage or deterioration during transport of tissue to Eye Bank. Packaging may vary according to:-
 - the type of tissue
 - method of transport
 - distance from retrieval site

9.4 Lamellar Tissue Preparation and Laser Assisted Preparation

- Preparation of tissue for lamellar keratoplasty (anterior or posterior) may be performed using manual or automated methods.
- Lasers may be used to prepare corneal tissue in which unique tissue architecture is required. This

can include shaping for penetrating, anterior or posterior keratoplasty.

- Such preparation must be performed in either a) an accredited biohazard safety cabinet; or b) an accredited operating room/theatre; or c) in a room where air quality is controlled and documented.

10

EXAMINATION AND EVALUATION OF EYE TISSUE

10.1 General

- The suitability of any individual cornea may depend on the intended surgical use of the cornea. Therefore the ultimate responsibility for accepting any individual cornea for surgery rests with the transplanting surgeon. e.g. a cornea that does not meet normal endothelial quality criteria for penetrating keratoplasty may be used for tectonic or anterior lamellar keratoplasty.
- In this section, “examination” refers to the method of inspection; and “evaluation” refers to an assessment of quality; either qualitative, quantitative, or both.

10.2 Examination and Evaluation Methods

10.2.1: Gross Examination & Evaluation at Retrieval

- The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination and scleral colour e.g. jaundice. This examination may be aided by use of a penlight or portable slit-lamp.

10.2.2: Laboratory Slit-lamp Examination & Evaluation

- Prior to storage the cornea should be examined by slit-lamp for epithelial, stromal and endothelial pathology, for example: scars, oedema, significant arcus, striae, epithelial defects, endothelial guttae or disease, polymegathism, pleomorphism, infiltrates or foreign bodies.
- The relative importance of slit-lamp examination and evaluation will vary depending on the storage method employed. Microscopic examination of the cornea at the end of the storage period (if possible) may provide information of more immediate relevance to the release of tissue for transplant.
- Slit-lamp examination and evaluation shall be documented.
- Eye Banks should perform slit-lamp evaluation after lamellar or laser-assisted preparation of tissue to detect any damage to the corneal endothelium, or surgical detachment of Descemet’s membrane that may have occurred during preparation.

10.2.3: Endothelial Cell Examination & Evaluation

- The endothelium of the excised cornea shall be examined by specular microscopy or light microscopy. Evaluation should include an assessment of cell morphology and determination of cell density.
- When it is not possible to obtain an endothelial cell density or endothelial image, this requirement may be waived on a case-by-case basis by the Medical Director or Manager if authorised to do so.
- Eye Banks may choose to perform pachymetry and/or endothelial evaluation after lamellar or laser assisted preparation of tissue.
- Endothelial cell examination and evaluation is not required for those corneas intended to be used only for anterior lamellar procedures.

10.2.4: Examination of Sclera

- Although there are no absolute criteria for evaluation of scleral quality, scleral shells should be visually examined for gross defects before storage and distribution.

STORAGE AND PRESERVATION OF EYE TISSUE

There are various methods of storing and preserving eye tissue that differ in temperature of storage, preservation media employed and recommended maximum length of storage time. Individual Eye Bank's may use only one, some or all of these methods. The method employed may depend on the ultimate intended surgical use of the tissue.

11.1 General

- All eye tissue intended for transplantation shall be stored in quarantine until results of HIV, HBV, HCV and any other relevant donor screening tests have been recorded as non-reactive.
- Eye Banks shall precisely document their procedures for storage and preservation of eye tissue in their Policy and Procedures (Quality) Manual.
- Aseptic technique shall be practiced during handling of tissue that is appropriate to the method of storage and preservation of that tissue.
- Reagents and solutions used for preservation shall be of a grade or quality approved for human use, or if this is not possible, a grade or quality where the safety and efficacy can be validated.
- Corneal storage medium shall be used and stored according to the manufacturer's recommendations for temperature, expiry date and other factors.
- Lot numbers for storage medium or reagents shall be recorded in the documentation of processing for each unique tissue to allow traceability and recall.
- Antibiotics, antimycotics, and/or other labile reagents may be added to the storage medium immediately prior to tissue preservation, ensuring aseptic technique is used.
- The date of preservation shall be indicated on all stored eye tissue.
- A "use by" date shall be indicated on all tissue distributed for transplantation.
- The maximum recommended storage time for each method may be extended with the approval of the Medical Director and agreement with the transplanting surgeon.

11.2 Methods of Preservation

It must be recognised that while maximum storage times are recommended for the various methods of preservation, it is in most cases preferable to transplant eye tissue before these maximum times are approached in order to optimise surgical outcome. Availability of eye tissue, clinical requirements and surgical need may determine the storage time for each individual eye tissue.

11.2.1: Whole Eye Preservation

This refers to whole eyes that are stored under refrigeration between 0 to 10°C for a short term, usually in a 'moist chamber' system. They are sent to the surgeon in this state and the cornea is not excised by Eye Bank staff.

- The maximum recommended storage time by this method is 48 hours, but this may be extended upon the approval of the Medical Director and agreement with the transplanting surgeon.

11.2.2: Hypothermic Preservation of Corneas

This refers to excised corneas stored under refrigeration between 0 to 10°C for a short or intermediate term.

- Eye Banks shall use an appropriate hypothermic corneal storage medium in accordance with manufacturer's recommendations.
- The maximum recommended storage time by this method where a viable endothelium is required is 14 days (depending on the medium used) but this may be extended upon the approval of the Medical Director and agreement with the transplanting surgeon. A longer period is acceptable if the endothelium does not need to be viable which shall be decided by the Medical Director.

11.2.3: Organ Culture (Normothermic) Preservation of Corneas

This refers to excised corneas stored by incubation between 28 to 37°C for an intermediate or long term.

Culture Phase:

- Eye Banks shall use an appropriate normothermic corneal storage medium in accordance with manufacturer's recommendations.
- Eye Banks performing organ culture preservation shall adhere to aseptic technique during processing of tissue after retrieval.
- Eye Banks performing organ culture preservation shall employ methods of microbiological testing of the storage medium to test for the presence of microbiological contaminants. These results shall be retained as part of the tissue records.
- The maximum recommended storage time by this method is 30 days (depending on the medium used) but the storage time may be extended upon the approval of the Medical Director and agreement with the transplanting surgeon.

Transport Phase:

- Eye Banks performing organ culture preservation may elect to transfer the cornea into a 'transport' medium in order to thin the cornea prior to transplantation. This transfer process shall be performed in an aseptic manner in a biohazard safety cabinet.
- The maximum recommended time in transport medium by this method is 5 days (depending on the medium used) but this may be extended upon the approval of the Medical Director and agreement with the transplanting surgeon.

11.2.4: Cryopreservation of Corneas

This refers to excised corneas stored by freezing at sub-zero temperatures between -75°C to -196°C for long-term storage, for the purposes of tectonic (structural) keratoplasty only. It is recognised that the functional integrity of the corneal endothelium will be lost, and Eye Banks may elect to remove the endothelium before storage by this method.

- Eye Banks shall use an appropriate cryopreservation medium in accordance with regulatory requirements.
- The maximum recommended storage time by this method is two years but this may be extended upon the approval of the Medical Director and agreement with the transplanting surgeon.

11.2.5: Preservation of Sclera

Sclera are used surgically as a structural tissue where viability is not important.

- There are various methods of preserving sclera, including the use of 70% or greater ethyl alcohol, sterile glycerin, cryopreservation and gamma irradiation. Eye Banks shall preserve scleral tissue using aseptic technique, using one of these methods.
- Details of the preservation method shall be documented in the Policy and Procedures (Quality) Manual.

12

SEROLOGY AND MICROBIOLOGY TESTING

12.1 General

- The Medical Director shall prescribe tests and procedures for measuring, assaying or monitoring properties of eye tissues essential to the evaluation of their safety for transplantation, and to conform to all relevant Federal and State legislation and regulations.
- Results of all such tests or procedures, together with evaluations based on these findings, shall become part of the record of all tissues processed.
- Infectious disease testing shall be performed by a laboratory certified under the applicable regulatory body according to all relevant Federal and State legislation and regulations.
- Testing of donor blood for specified infectious agents shall be performed with *in vitro* diagnostic devices that comply with regulatory requirements.

12.2 Serologic Testing

12.2.1: General

This section specifies the EBAANZ- required serologic tests which shall be performed on each donor from which tissue is designated for surgical use.

- A blood sample from the donor shall be tested - this may be either:
 - a. a post-mortem sample procured as soon as practicable after the time of death, or at the time of tissue retrieval, or
 - b. a pre-mortem sample procured within 7 days prior to death
- A hard copy of serological results, or verbal confirmation of results (using a process to allow traceability, cross-checks and eliminate ambiguity), 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 non-reactive for each mandatory infectious disease, and all other requirements are met.
- EBAANZ recognises the use of neutralisation assays or confirmatory tests as scientifically valid e.g. NAT testing, and may be utilised where initial screening assays are equivocal.
- All tissue intended for transplantation shall be stored in quarantine until results of mandatory tests are known.

12.2.2: Plasma Dilution Donor Evaluation

- 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:
 - a. 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
 - b. the Eye Bank shall establish an algorithm for calculating the effect of plasma dilution on the donor sample and demonstrate that it is less than the designated limit.

12.2.3: Mandatory Testing

- Mandatory tests are those which are the minimum requirement for release of tissue for transplantation.
- Blood (serum or plasma) must test non-reactive to the following infectious diseases:
 - Human Immunodeficiency Virus Types 1 and 2: anti -HIV-1 , anti-HIV-2
 - Hepatitis C Virus (HCV): anti-HCV

- Hepatitis B Virus (HBV*): HBsAg

*HB surface antigen is the minimum marker required to be tested, however two further markers (HB core and HB surface antibody) may be tested to more precisely determine infectivity status.

- *Serology testing for HTLV-I and HTLV-II is not required for eye tissue donors.*
- *Serology testing for syphilis is not required for eye tissue donors.*

12.2.4: Non-required Laboratory Results

- If laboratory results of *non-required or conflicting* serologic tests for infectious disease are reported for tissue for transplantation to the Eye Bank, they shall be taken into account in determining suitability for eye tissue transplantation. Guidance shall be sought from the Medical Director.

12.2.5: Non-surgical Donor Eye Tissue

- If donor tissue is provided for purposes other than transplantation e.g. research, clinical training etc, and if that donor tissue is not screened or tested for HIV, hepatitis B or hepatitis C, a label stating that screening for these has not been carried out or stating “potentially hazardous biologic material” or some other designation shall be attached to the container used for the donor tissue storage and/or transport.

12.3 Microbiological Testing

12.3.1: General

Eye Banks may perform microbiological tests on the donor tissue and/or the preservation medium, if this is applicable to the storage method being utilised for that tissue.

- Eye Banks performing microbiological testing of tissue and/or storage medium shall establish and document procedures for these tests in their Policy and Procedures (Quality) Manual.
 - a. Microbiological testing in Eye Banks performing the hypothermic storage method is not mandatory for the release of tissue.
 - b. Microbiological testing of the storage medium is mandatory for release of tissue in Eye Banks performing the organ culture storage method.
- Results of such tests shall be interpreted and reported according to a policy and procedure established by the Medical Director and documented in the Policy and Procedures (Quality) Manual.
- Microbiological testing shall be performed by a laboratory certified under the applicable regulatory body according to all relevant Federal and State legislation and regulations..
- Any positive microbiological culture should have the organism identified to at least the genus level.

12.3.2: Microbiological Tests

If performed, microbiological tests may include, but are not limited to, the following:

A: Test(s) of storage medium for organ-culture (normothermic) storage

- Microbiological tests shall be performed on a sample of the organ culture medium for each cornea during the storage period. Aseptic technique shall be used when performing such sampling.
- This test shall be performed several days into the storage period, and/or at a point near distribution of the cornea e.g. at the time of terminal evaluation and transfer of the cornea into transport medium.

B: Surgical Cultures

- Surgeons may elect to perform a microbiological test of either the donor tissue remaining after corneal trephination (i.e. the 'donor rim') and/or of the storage medium in which the cornea is received. If either of these tests are performed, the Eye Bank may request that the results are reported to them by the surgeon and be retained as part of the records for that tissue.
- Eye Banks shall request that positive results in cases of post-operative infection, that are in the opinion of the surgeon likely to be attributable to the donor tissue, should be reported to the Eye Bank as an adverse reaction.

13

UNIQUE IDENTIFICATION, LABELLING AND TRACEABILITY

13.1 General

- Each eye tissue shall be stored in an individual labelled container with unique identification at all times. i.e. no pooling of tissue can occur.
- The Eye Bank shall assign a unique identification code (which may be a combination of alphanumeric and/or numeric characters) that allows for the tracking of each individual tissue from the donor to the recipient and vice versa, and if applicable, the tracking of archived serum samples and quality control specimens to the donor.

13.2 In-process Labelling and Traceability

- Eye tissues shall be labelled for unique identification and tracking during all phases of retrieval, processing, preservation, storage and distribution.

13.2.1: Temporary Labelling at Retrieval

- Final unique tissue numbers may not be known at the point of retrieval. Therefore at the time of retrieval, a temporary label such as the donor's identification code, name or other identifier should be affixed to each tissue container.

13.2.2: Permanent Labelling at Processing

- Once the tissue has been transported back to the laboratory for final processing and storage, a permanent label shall be attached specifying the unique tissue code.

13.3 Documentation to Enable Traceability

- As a minimum Eye Banks shall keep accurate records of:
 - the identity of the donor
 - the unique donor identification code
 - the types of tissues retrieved and processed
 - the unique tissue identification code(s) for all tissues derived from each donor
 - the distribution of all tissues according to the unique tissue identification code(s)
 - the personnel involved in procedures
 - the identification of the recipient
 - the dates of retrieval and transplantation

13.4 Labelling for Distribution and Transplant

- This applies to the labelling of the final container in which the tissue is sent for transplantation. Each corneal or scleral tissue container shall be clearly and indelibly labelled to include at least the information below:
 - Name of distributing Eye Bank
 - Eye tissue identification code
 - Type of tissue
 - Type of preservation medium

14

DOCUMENTATION OF DONOR EYE TISSUE

14.1 General

- Forms for retaining donor and recipient information shall be established and shall be readily accessible for inspection by an applicable regulatory agency. These records shall be retained in a secure fashion for a minimum of twenty years.
- Donor screening forms shall contain adequate information regarding the donor's cause of death and medical and social history.

14.2 Minimum Information to be Retained

- Eye Bank records shall include the following minimum information:
 - Name of source Eye Bank (if tissue sourced from another Eye Bank)
 - Unique donor and tissue identification code(s)
 - Name of donor
 - Date of birth of donor (or year of birth where no precise date of birth is known)
 - Cause of death
 - Death date and time
 - Enucleation or in situ excision date and time
 - Type of preservation medium
 - Lot numbers of preservation medium (and other reagents if used)
 - Preservation date and time
 - Slit lamp report (if performed)
 - Results of evaluation by microscopy
 - Names of persons performing donor screening, consent, retrieval, processing, evaluation, and release
 - Printed results of all required serologic tests
 - Printed results of microbiological tests (if performed)
 - Utilisation of tissue i.e. surgical, research, training, quality control etc
- And if tissue was sent for surgical use:
 - Date, time and method of transportation
 - Name of surgeon receiving/transplanting tissue
 - Place and date of transplant
 - Name of recipient
 - Date of birth of recipient (or year of birth where no precise date of birth is known)
 - Adverse reaction reports (if received)
 - Follow-up reports (if received)

15

UTILISATION AND RELEASE OF EYE TISSUE

15.1 Suitability for Transplantation

The Eye Bank shall specify whether any tissue intended for transplantation meets the criteria for penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, and/or tectonic use.

15.2 Utilisation of Eye Tissue

- Records for each unit of eye tissue retrieved and processed shall contain information on the final utilisation of that tissue i.e. either
 - distributed for transplantation into a recipient
 - used for research/clinical training/education or other purpose
 - discarded
- Records should indicate the reason if tissue is not distributed, or ultimately used, for transplantation.

15.3 Release of Eye Tissue

- Prior to distribution of tissue for transplantation, authorised staff shall review and document that the medical and laboratory information is in accordance with these Standards.
- Before tissues are released for transplantation, all pertinent records concerning donor screening, testing and quality control shall be reviewed and found to be complete and accurate.
- The Eye Bank shall establish and document their criteria for release of tissue for transplantation, which shall include (but is not limited to) the following:
 - Donor screening suitability
 - Slit-lamp and microscopic evaluation criteria
 - Non-reactivity for required serological tests
 - Acceptable results of microbiological tests (if performed)
- The Eye Bank shall establish and document a system of checks in the Policy and Procedures (Quality) Manual to ensure that all required donor screening, inspection checks, tests and evaluations have been performed, that results conform to criteria for release, and that authorising signature(s) are in place.
- In particular, a system shall demonstrate that tissues not suitable for release can be distinguished from those which conform to requirements and may be released.

15.4 Exceptional Release of Eye Tissue

Exceptional release is defined as *the distribution of a unit of tissue because of an unusual or urgent clinical need that circumvents normal release procedures.*

This would normally involve release of tissue before some or all of the required tests have been reported.

- The Eye Bank shall establish and document procedures to be followed in cases where exceptional release of tissue is advocated, either on a case-by-case basis or by pre-established criteria.
- Exceptional release of tissue shall require approval of both the Medical Director and of the transplanting surgeon and conform to any applicable regulatory requirements.
- Documentation accompanying the tissue shall state:
 - which donor and/or testing information is available at the time of release
 - which donor and/or testing information is not available, and a guideline as to when this information will be available
- Final test results or donor screening information shall be forwarded to the transplanting surgeon upon receipt by the Eye Bank.

- Documentation of exceptional release shall be retained in the donor records.

16

DOCUMENTATION TO ACCOMPANY EYE TISSUE

16.1 General

- Documentation shall accompany tissue for transplantation, and shall comprise two components:
 - 1) An **Eye Tissue Report**, containing information specific to the tissue being sent
 - 2) a **Package Insert**, containing general information of importance to the surgeon
- Information contained in the Eye Tissue Report and Package Insert can remain as separate forms, or be contained on the one form as long as each component is easily discernable; otherwise separate forms are advised

16.2 Eye Tissue Report

- The Eye Tissue Report shall contain the following minimum information:
 - Name of distributing Eye Bank
 - Address and telephone number of Eye Bank
 - Unique tissue identification code
 - Type of preservation medium
 - Age of donor
 - Death and preservation dates and times , and/or death-to-preservation interval and storage interval
 - Results of the mandatory serological tests i.e. that HIV, HBV and HCV results were non-reactiveand in addition for corneal tissue:
 - Results of microbiological tests (if performed)
 - Results of endothelial evaluation by microscopy (indicate if not performed)
 - Type of keratoplasty that tissue is suitable for i.e. penetrating, anterior lamellar, endothelial lamellar etc
 - If a cornea is pre-cut, clearly indicate the type of pre-cut method performed or the indicated use (e.g. endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser-assisted keratoplasty, etc.)
 - If prepared for laser-assisted penetrating keratoplasty:
 - Morphology and dimensions of cut
 - Post-cut endothelial microscopy report (if performed)
 - If prepared for lamellar anterior or endothelial keratoplasty:
 - Estimated thickness of transplant portion
 - Estimated diameter of cut
 - Post-cut endothelial microscopy reports for tissue intended for endothelial keratoplasty (if performed)

16.3 Package Insert

- The Package Insert shall include the following minimum information:
 - Recommended storage temperature for specific type of tissue (cornea, sclera, whole eye) and type of storage method. Specific emphasis should be made in regard to conditions under which tissue should NOT be stored after arrival at the transplant unit.
 - That the surgeon should check for integrity of the seal and immediately report to the Eye Bank any evidence of possible tampering.
 - For corneas:- that colour change of storage medium outside a specified range may indicate an unacceptable change in pH, in which case the tissue should not be used and reported immediately to the Eye Bank.
 - If microbiological tests were *not* performed by the Eye Bank, a statement to that effect.
 - The form shall also advise the receiving surgeon that the tissues are delivered with no absolute guarantee of safety or efficacy, or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for intended use.
 - The form shall advise the transplanting surgeon that the distributing Eye Bank must be notified in writing of recipient information, for the purpose of tracking the tissue from the donor to the recipient, when tissue is transplanted (this may be achieved through the return to the distributing Eye Bank of the Australian Corneal Graft Registry Form or the New Zealand

Corneal Transplant Registry Form)

- That serologic tests (and microbiologic tests if applicable) were performed by a testing laboratory certified under regulatory requirements.
- It must be advised if all or any of the tests performed have not been validated.

17

PACKAGING AND TRANSPORT

17.1 Packaging and Sealing for Transport

- Procedures shall be established and maintained to ensure that:
 - The tissue is presented in a container designed to maintain quality and prevent contamination.
 - The tissue is capable of being presented in an aseptic manner.
 - Each tissue shall be individually packaged and sealed with a tamper-evident seal.
 - Packing shall be done so that the packaging insert and tissue label do not become wet.
 - The Eye Bank shall use a validated packaging method so as to maintain the temperature of the tissue at an acceptable level while in transit.
- The exterior of the transport container (if a third party is used for delivery) should clearly display:
 - the name, address, telephone number of the Eye Bank distributing the tissue
 - the name, address, telephone number of the Transplant Unit receiving the tissue
 - the type of tissue
 - recommended storage conditions
 - any special handling instructions

17.2 Transport

- Transport from Eye Bank to Transplant Unit may be performed by:-
 - hand delivery by Eye Bank personnel or,
 - the use of a third party, usually transport company/courier
- The Eye Bank shall establish and maintain procedures that account for the different modes of transport used, to ensure that the quality of the tissue is maintained. These procedures should take account of factors such as time in transit, temperature conditions and tracking of the tissue.

18.1 General

- Eye Banks shall establish and document a system of eye tissue distribution that is applicable to their health service, that conforms to all relevant Federal and State legislation and regulations, and 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, colour 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.
- Bookings for supply of 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 is 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 e.g. parts of a whole scleral shell supplied cannot be divided by the surgeon and used in multiple recipients.
- 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.

18.2 Recipient Information

- The Eye Bank shall obtain recipient information from the transplanting surgeon on each eye tissue used for transplantation.
- This information shall include the following (as a minimum):
 - Recipient's name
 - Date of birth (or year of birth if a precise date of birth is unknown)
 - Diagnosis i.e. indication for transplant
 - Name of surgeon receiving/transplanting tissue
 - Date of surgery
 - Location of surgery
 - Post-operative complications (tissue-related) if reported.

18.3 Recipient Follow-Up

- 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.

18.4 Cost Recovery

- With the recognition that 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 surgeons, individuals or institutions to recover costs of retrieval, processing, storage and distribution of tissues, provision of the service, and development of banking techniques.

19

ADVERSE REACTIONS, RETURN AND RECALL OF EYE TISSUE

19.1 General

- The Eye Bank's Quality System shall provide for the documentation and investigation of errors, complaints and adverse reactions that may affect the safety and quality of eye tissues provided for transplantation.

19.2 Adverse Reaction Reporting

An adverse reaction is defined as *an undesirable or untoward complication in a recipient consequent to, or reasonably related to, transplantation of tissue, which requires non-standard clinical treatment or intervention.*

- The Eye Bank shall establish and document a procedure in their Policy and Procedures (Quality) Manual for the receiving surgeon to notify the Eye Bank of any adverse reactions arising from the transplantation of eye tissue.
- A reportable adverse reaction is any communicable or other disease potentially transmitted by and/or attributable to transplantation of donor eye tissue or biologic dysfunction of the eye tissue. This includes:-
 - Infection - as manifested by endophthalmitis, keratitis or systemic viral disease
 - Biologic dysfunction - such as primary graft failure, donor corneal dystrophy or evidence suggestive of prior refractive surgery.
- If systemic infectious disease such as HIV, hepatitis, syphilis or CJD develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the Eye Bank, and to regulatory agencies if required.
- 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).
- Adverse reaction reports shall be available for inspection by regulatory agencies, and be retained for a minimum period of twenty years.

19.3 Return of Eye Tissue

- If tissue is unable to be used for transplantation after distribution, the Eye Bank shall establish and document in its Policy and Procedures (Quality) Manual a procedure for determining suitability of that tissue for:
 - re-distribution for transplantation (which may include re-assignment and possible use for anterior lamellar or tectonic surgery)
 - other use such as for research, clinical training or education
- Documentation shall record all available information as to the status and conditions under which the tissue has been handled and stored while away from the Eye Bank. In particular, attention should be paid to:
 - Integrity of the tamper-evident seal and container for evidence of tampering or contamination
 - Environmental conditions under which the tissue has been stored
- Documentation shall record the reason for the return, all investigations performed to determine tissue quality, and the ultimate disposition of the tissue. These records shall be retained as part of the record for that tissue.

19.4 Recall of Eye Tissue

Recall is defined as *the requested return of tissue known or suspected to be non-compliant to quality procedures.*

- The Eye Bank shall establish and document in its Policy and Procedures (Quality) Manual criteria and procedures to be followed in circumstances where the tissue has been found to be (actually or potentially) unsafe for transplantation.
- Information or test results received by the Eye Bank after release of tissue that indicate a potential risk to the health of the recipient e.g. HIV, viral hepatitis, CJD constitute a recall and shall be reported to the Medical Director and the transplanting surgeon as soon as possible. Similarly, information or test results that indicate the transplant has a high likelihood of failure will constitute a recall.
- The Medical Director is ultimately responsible for determining compliance in notification of tissue recall because of possible transmission of a notifiable disease to applicable Federal, State and /or local regulatory agencies.
- Upon notification of a recall, the Eye Bank shall promptly notify all consignees to whom tissue (that might be affected) from the same donor was distributed.
- Tissues from the same donor not already released and/or distributed for transplantation shall be quarantined pending resolution of the recall.
- If the tissue has already been transplanted, the notification, in-house actions and notification to transplant surgeons shall be considered as a potential adverse reaction investigation in accordance with these Standards.
- All information relating to a recall of eye tissue shall be retained for a minimum of twenty years beyond the date of distribution of the tissue.

20

SUPPLY OF EYE TISSUE FOR NON-SURGICAL PURPOSES

Eye Banks may facilitate the supply of eye tissues for the purposes of research, clinical training and/or education. This may be for uses required by the Eye Bank itself, or for other researchers or medical practitioners.

20.1 Types of Non-Surgical Eye Tissues

- Tissues for non-surgical purposes may include (but are not limited to):
 - those which do not meet donor screening, testing or evaluation criteria and cannot be distributed for transplantation
 - other structures in the eye that are not able to be transplanted e.g. lens, retina
 - those which are derived directly from donors screened as not suitable for donation for transplant purposes
 - surgical tissue derived from recipients e.g. the defective cornea removed during surgery
- Eye Banks may also require tissues to validate their quality control systems and/or processes.

20.2 General

- As for tissues for surgical use, authorisation for the donation and use of ocular tissues for research, clinical training or educational use shall be received from an authorised person by a process of informed consent. Informed consent for use of tissue for quality control purposes may or may not be required, subject to applicable Federal, State and /or local laws and Regulations.
- Documentation concerning the distribution, use and traceability of each tissue distributed for non-surgical use shall be retained by the distributing Eye Bank as part of the record of that tissue.
- The Eye Bank shall ensure anonymity of the donor to any individual or institution receiving tissue for non-surgical use, and that any details which may identify the donor are not provided.
- The Eye Bank shall ensure that provision of tissue for research or clinical training purposes is on condition that any applicable regulatory requirements such as Ethical Approval have been fulfilled.
- If donor tissue is provided for non-surgical purposes and if that donor has not been tested for HIV, HBV or HCV, a label stating that such testing has not been carried out or stating potentially hazardous biologic material (or some similar designation) shall be attached to the container in which the tissue is provided.

DEFINITIONS AND TERMINOLOGY

This list contains definitions and terminology used in these Quality and Medical Standards.

Adverse Event/Reaction

An undesirable effect or untoward complication in a recipient consequent to, or reasonably related to, transplantation of tissue, including disease transmission, infection or biological dysfunction.

Anterior lamellar keratoplasty

Transplantation of the anterior stroma of the cornea, but not the posterior stroma or endothelium.

Aseptic Technique

The measures used to prevent contamination of tissue by microorganisms during handling and processing.

Audit

A documented activity which is aimed at verifying that the applicable element of the Quality System has been established, documented, and implemented in accordance with requirements. Usually a review of procedures, records, equipment, materials, facilities, personnel functions is performed to evaluate adherence to written standards and operating procedures. External audits are performed by applicable regulatory agencies.

Autopsy

An examination of the body after death to determine the cause of death and/or to discover and describe pathological processes present in the body at the time of death.

Batch or Lot

A defined quantity of material, reagent or product processed in one series of processes that is intended to have uniform character and quality within specific limits, which is produced according to a single processing method during the same processing cycle.

Cadaver

A dead body, or corpse.

Cadaveric donor

A person who donates organs and/or tissues after death for the purpose of transplantation into another person.

Calibration

Checking an inspection, testing, or measuring instrument against another instrument or standard that is of known accuracy to national / international standards. The aim of calibration is to detect, and adjust any variation in the instrument being checked, in order to maximise accuracy.

Competency

The ability of an employee to acceptably perform tasks concomitant with his/her role for which he/she has been trained.

Competency Assessment

The evaluation of the ability of an employee to acceptably perform tasks that form part of their role.

Complaint

A written or oral report of deficiencies related to the identity, quality, reliability, delivery, safety, effectiveness or performance of a tissue, or dissatisfaction with aspects of service delivery.

Consent

See Informed Consent.

Container

A receptacle that is used to contain tissues and is in direct contact with the tissue.

Corrective action

Action that is taken to eliminate the cause(s) of an existing non-conformance in order to correct that

non-conformance, and prevent it from recurring.

Cross-contamination

Transfer of infectious agents from one tissue to another tissue.

Cryopreservation

The storage of tissues to a set temperature below 0°C with or without the addition of a cryoprotectant. Cryopreservation does not necessarily imply maintenance of viability or structural integrity.

Decontamination

Chemical or physical treatment which reduces, removes inactivates or destroys potential pathogens on the surface of an item, but does not necessarily destroy all microbial forms.

Deviation

An event that is a departure from a procedure or normal practice.

Disposition

The final destination of tissue, including use for transplantation, research, clinical training, education, quality control or discard.

Distribution

Transportation and delivery of tissues for surgical use in a recipient.

Distributing Eye Bank

The Eye Bank that provides tissue to the end-user i.e. transplanting surgeon. The distributing Eye Bank is responsible for obtaining recipient information, post-operative follow-up information and reporting any adverse event/reaction to the source Eye Bank.

Donor

A living or recently-deceased person from whom organs or tissues have been removed. In the case of eye donation, this is almost invariably a deceased person.

Donor Family

The next-of-kin of the donor. May be formally or informally defined.

Donor Referral Source(s)

Entities such as hospitals, Coronial services, hospices and individual allied health care professionals who identify potential donors and refer them, or their next-of-kin, to the Eye Bank.

Donor Screening / Donor Suitability Assessment

The process of determining the suitability of a specific individual for eye (tissue or organ) donation based on available information. This includes, but is not limited to medical and social history, physical examination, and autopsy finding (if an autopsy was performed).

Endothelial Keratoplasty

Transplantation of the endothelium of the cornea, with or without an amount of carrier posterior stroma.

Enucleation

Retrieval/recovery of the whole intact eye globe.

Evaluation (of tissue)

The assessment of eye tissue, either *in situ*, or in the laboratory, to determine conformance to predetermined criteria.

Exceptional Release

The distribution of a unit of tissue, because of urgent or unusual clinical need that circumvents normal release procedures. Requires approval of both the Medical Director and transplanting surgeon.

Expiry Date

The date after which instruments, supplies, reagents or tissues are usually deemed no longer suitable for use for a particular purpose.

Eye Bank

A unit, service or organisation that is responsible for the activities of donor screening, retrieval, processing, preservation, storage, testing, packaging and delivery of suitable eye tissue for

transplantation. May also be involved in directly maintaining donor programmes consent for donation, donor family support and in provision of tissues for research.

Eye Donor

A person who by the circumstance of circulatory or brain death, can donate eye tissue for transplantation such as corneas, sclera, and other eye tissues for research or clinical education. Such donors can present in many situations such as hospitals, Coroners, hospices, rest-homes or directly from the community.

Eye Tissue

Tissues derived from the human eye. Eye tissue that can be transplanted includes corneas and sclera. Other eye tissues such as lens, retina and other structures can be used for research or other educational use.

Finished Tissue

Tissue that has been fully evaluated, enclosed in its final container, labelled and released for distribution. Such tissue will have been determined non-reactive for standard serological and microbiological tests performed.

Form

A document required to perform or assist with the tasks referenced in a Quality Procedure or Work Instruction.

Graft

A tissue, whether whole or in part, that is used surgically in transplantation.

Haemodilution

See plasma dilution.

Identification Number

See Unique Identifying Number.

Infectious Material

Blood, tissue, organ or body fluid or secretion from a human (living or dead) potentially containing infective organisms, to which a worker may become exposed.

Informed Consent

A process by which information concerning the donation process is presented to a potential or to the donor's next-of-kin or other legally recognised representative with an opportunity for them to ask questions, after which specific approval is documented. Relevant legislation and professional donation guidelines govern informed consent.

Label

Any written, printed or graphic material on, or affixed to, a container or package of tissue.

Laser-assisted Keratoplasty

Corneal transplantation surgery in which the corneal architecture is shaped by a laser. This can include shaping for penetrating, anterior or posterior keratoplasty.

'May'

Used to refer to an acceptable method that is recognised but not essential.

Medical/Social History Interview

A documented dialogue in person or by telephone with an individual who would be knowledgeable about the potential donor's relevant medical history and social behaviour that might lead to increased risk for infectious disease or dysfunction of tissue. Usually a close relative or other person with affinity relationship. May also be performed with a GP or primary treating physician.

'Must'

Used to indicate a mandatory requirement.

Next-of-kin

The person(s) most closely related to a deceased individual as designated by applicable law, or by family determination. Legal precedence would apply if dispute occurs.

Non-conformance

A deficiency in characteristic, measured quantity, documentation, or procedure which may render tissue unacceptable to specified requirements.

Organ Culture

The storage and maintenance of corneas *in vitro* in a nutrient medium at 28° - 37°C for periods up to 30 days.

Also called *normothermic storage*.

Organ donor

A person who can donate solid vascularised organs such as heart, lungs, liver, kidney and pancreas, as well as other tissues. These donors always present to, and are maintained in, an Intensive Care Unit.

Package

A labelled carton or other receptacle containing one or more containers of tissue and accompanying forms and labelling.

Package Insert

The written material accompanying tissue which bears general information about the tissue, testing performed, directions for use, and any applicable instructions or warnings.

Plasma Dilution

A decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from transfusion of blood or blood components, and/or infusion of fluids e.g. colloids and/or crystalloids.

Posterior Lamellar Keratoplasty

See *Endothelial Keratoplasty*.

Pre-Cut Tissue

Corneal tissue for transplantation in which lamellar dissection or shaping has been performed by the Eye Bank (either manually or assisted by keratome or laser) prior to distribution to the end-user.

Preservation

The combination of conditions and procedures that conserve the quality of tissues during specified storage periods, and prevent or retard biological or physical deterioration.

Preservation Medium

See *Storage Medium*.

Preventative action

Action taken to eliminate the cause(s) of a potential non-conformance in order to prevent it from occurring.

Primary Graft Failure

Corneal oedema or other dysfunction present from the time of keratoplasty that does not resolve in the weeks subsequent to the surgery and in which there is no other known operative or post-operative complication or underlying recipient condition that would explain the dysfunction. This, for instance, does not include endothelial dislocation in endothelial keratoplasty. Usually results in re-grafting of the patient.

Procedure

A series of steps, which when followed, is designed to result in a specific outcome.

Process Control

A system of checks and balances incorporated into Quality Procedures involving critical operations to prevent errors.

Processing

Procedure(s) employed after tissue retrieval and before distribution in the final container, including dissection of tissue, physical, chemical or mechanical treatment, preparation of components from su tissue, testing, labelling and associated record keeping.

Product (as applicable to therapeutic goods)

Result of activities, or processes. Product may be, or may include service provided, in addition to

physical materials, parts, components etc. In the case of the Eye Bank, eye tissue for transplantation.

Quality

The conformance of tissue or a process with pre-established specifications or Standards.
All the characteristics of the product conforming to requirements.

Quality Assurance

A positive declaration to provide confidence that the product shall consistently conform to requirements.

Quality System

A planned and documented pattern of the resources, methods, and actions to provide confidence that the product will consistently conform to specified requirements.

Quality Procedure (Standard Operating Procedure)

A written document/method detailing the specific policies and instructions to be used by staff and personnel. This includes, but is not limited to, procedures to assess donor suitability, and to retrieve, process, preserve, test, evaluate and distribute tissue. It also includes methods to maintain and review a Quality Assurance System.

Quarantine

The status of retrieved tissue isolated physically or by a system whilst awaiting a decision on suitability for release or rejection based on completion of testing procedures. Such systems are designed to prevent the premature release of tissues for transplantation.

Recall

The requested return of tissue known or suspected to be non-compliant to the quality procedures of the bank, in accordance with the instructions contained in an advisory notice.

Recipient

The person into whom donor tissue is transplanted/implanted/grafted.

Retrieval/Recovery

The surgical removal of eye tissue from a donor.

Safety

A quality of tissue indicating handling according to Standards, and substantial freedom from the potential for harmful effects to recipients. Also, the condition of being protected from risk or injury associated with occupational exposure.

Screening/Serology Tests

Laboratory tests approved by regulation, which screen for infectious disease such as presence of HIV, Hepatitis B and Hepatitis C.

'Shall'

The same as 'must' i.e. a mandatory requirement.

'Should'

Used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there may be effective alternatives.

Source Eye Bank

The Eye Bank that retrieves eye tissue from a donor following donor screening, and who usually performs storage, testing and evaluation of the tissue. The source Eye Bank maintains all donor and testing records, but is required to pass this information on to the distributing Eye Bank if they so request.

Standard Operating Procedure

See Quality Procedure.

Status

The classification of any material or tissue in relation to their acceptance or otherwise, for use, further processing or distribution. Terms used include 'Quarantine', 'Released', 'Hold', or 'Rejected'.

Sterile

Condition of a product that is free of detectable, viable micro-organisms.

Storage

Maintenance of tissue in a state ready for transplantation or other future use.

Storage Medium (Preservation Medium)

The reagent used to preserve tissue for its intended future use.

Therapeutic Goods

Goods that are in any way for therapeutic use, or for use as an ingredient or component in the manufacture of therapeutic goods.

Time of Death

For the purposes of eye banking, the time of cessation of heartbeat, cardiac death, asystole or cross-clamp time.

Tissue

Material of human origin, as a functional group of cells. Definition for therapeutic purposes distinguishes tissue from organs, blood or reproductive tissue.

Tissue Release

The process which enables a tissue to be released from quarantine status by the use of systems and procedures to ensure that the finished product (tissue) meets its release specifications and is acceptable for transplant purposes.

Tissue Report

The written material accompanying tissue which bears specific information about the donor (although unidentifiable), processing information, donor and tissue testing and evaluations performed.

Traceability/Tracking

The ability to trace or track a product, or batch of products by means of **unique** identification. For tissue, the ability to trace the tissue during any step of its donation, retrieval, processing, testing, storage and distribution. It also implies the capability of identifying the medical personnel receiving/transplanting the tissue, and the ability to identify the recipient.

Transfer

In relation to corneal tissue preserved by the organ culture method, the process by which a cornea is removed from storage, evaluated and placed into specialised medium for transport to transplant centre.

Transplantation

The surgical removal of compromised host tissue and grafting of donor tissue into a recipient.

Transport Medium

In relation to corneal tissue preserved by the organ culture method, a specific medium containing a thinning agent, capable of maintaining cellular viability during the transport of tissue from the bank to transplanting hospital.

Universal Precautions

Treating body fluids/materials as if infectious and emphasising work practice controls such as hand washing, protective clothing and needle stick injury precautions.

Unique Identifying Code

A unique code (composed of numeric and/or alphanumeric characters) assigned to any individual donor or tissue, (whether retained as whole or divided from that originally retrieved) to ensure traceability and confidentiality.

Validation

Establishment of documented evidence that provides a high degree of assurance that a specific process will consistently produce a result meeting its predetermined specifications and quality attributes. A process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use.