Eye Bank Association of Australia and New Zealand (EBAANZ)

Medical Standards

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Contents

A1.000 INTRODUCTION AND PURPOSE

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.

The purpose of these medical standards is not only to provide interpretation in meeting the requirements of the code of Good Manufacturing Practice (cGMP) and the relevant Therapeutic Good Orders (TGOs), but to also allow the EBAANZ medical standards to be independent of TGA guidance and regulation.

The cGMP and TGOs have been interpreted within these standards. This includes reformatting, editing, and specific additions. For direct information from the TGA, one should refer to the documents cited here:

- Therapeutic Goods (Standard for Human Cell and Tissue Products—Donor Screening Requirements) (TGO 108) Order 2021
- ARGB Appendix 12 - Guidance on TGO 108: Standard for Human Cell or Tissue Products - Donor Screening Requirements
- Australian code of good manufacturing practice for human blood and blood components, human tissues and human cellular therapy products

A1.200 Scope

- 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. They are guided by well-established international standards including the Eye Bank Association of America and the European Eye Bank Association. Thus, these Standards encompass and reflect current international best-practice in eye donation and banking.

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

  - Recovery
  - Processing

- Storage
- Tissue evaluation
- Donor eligibility determination
- Distribution

- These standards shall be reviewed at least annually and revised as necessary to incorporate current research findings, legislative changes and improved clinical practice.

B1.000 Quality Systems and Assurance

B1.100 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.

B1.200 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.

B1.300 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.

B1.400 Responsibilities for Quality

- The responsibilities and reporting relationships of all key personnel shall be defined and documented.
- The Medical Director of the Eye Bank 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 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.

B1.500 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.

B1.600 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.

B1.700 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:
    1. performance of specific tests, trials or procedures
    2. risk assessment for potential effect on safety and quality
    3. previously published studies
    4. 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.

C1.000 Personnel and Training

C1.100 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.

C1.200 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.

C1.100 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:
    1. Formulation, approval, and implementation of medical policies and procedures.
    2. Oversight of training of staff regarding donor screening, tissue retrieval, tissue preservation and tissue evaluation.
    3. Understanding of the principles of the infectious disease screening and testing methods employed, and the interpretation of test results.
    4. Participation in establishment and operation of the Quality System. This shall include approval of any changes to the Quality System.
- An Eye Bank has three months to replace a Medical Director who has resigned.

C1.200 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:
    1. Responsibility for all personnel and training of staff to ensure adherence to these Standards and other regulatory standards.
    2. Keeping up to date with new developments, professional guidelines and related research.
    3. Other Management responsibilities as prescribed by the Eye Bank's governing body.
- The Manager shall consult with the Medical Director as well as other medical and regulatory authorities in carrying out prescribed responsibilities as necessary or required.

C1.300 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 development, implementation, and maintenance of the Quality System, specifically in relation to:
    1. Documenting policies and procedures and associated document control.
    2. Ensuring agreements or contracts for services with third parties are established and maintained.
    3. Regular audit and review of the Quality System to effect continuous quality improvement
    4. 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.

C1.400 Scientific Staff / Donor Coordinators / Administrative Staff

The governing body and/or Manager shall appoint 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 enough qualified staff to promptly and proficiently perform all procedures that form part of their responsibilities.

D1.000 Training and Continuing Education of Personnel

- Training and continuing education programmes shall be developed in accordance with identified needs for each role or responsibility.
    1. Programmes shall be documented and include on-going training and assessment.
    2. Personnel shall be trained in the Quality System, Medical Standards and all Federal and State legislation and regulations relevant to their responsibilities.
    3. 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).
    4. Personnel shall not be permitted to sign documentation unless they have been trained and assessed as competent in the work practices associated with the signature.
- The Eye Bank should provide and/or support educational opportunities such as in-service education programmes, attendance at meetings, seminars, and workshops for all personnel.
- 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.

E1.000 Buildings and Facilities

E1.100 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.

E1.200 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 enough grounded outlets for operating laboratory equipment.

E1.300 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.
- Eye tissue retrieval shall be performed in as clean an area as practicable using aseptic techniques. 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.

F1.000 Equipment

F1.100 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:
    1. Identify all critical equipment that may affect tissue safety and/or quality.
    2. 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.
    3. Specify cleaning and routine maintenance schedules and procedures for each piece of critical equipment.
    4. Ensure 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.
    5. Identify the calibration status of critical measuring equipment and ensure that calibration is performed against a traceable standard.
    6. 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.

F1.200 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.

F1.300 Biological 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.

F1.400 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.

G1.000 Infection Control and Personnel Safety

G1.100 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.

G1.200 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.

G1.300 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.

H1.000 Records and Document Control

H1.100 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.

H1.200 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:
    1. Standard operating procedures
    2. Specifications, such as donor criteria and tissue evaluation criteria
    3. 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:
    1. the relevant issues of appropriate documents are available at all locations where operations essential to the effective functioning of the Quality System are performed
    2. invalid or obsolete documents are removed from points of issue or use, to prevent unintended use
    3. obsolete documents are retained for knowledge preservation and legal purposes and that these are suitably identified and stored

H1.300 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:

1. Record of authorisation/informed consent for donation
2. The date, and where applicable, the time the procedure was performed
3. The identity of the person performing and/or authorising critical procedures
4. Any inspection checks and quality control tests performed

H1.400 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).

H1.500 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.

H1.600 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.

H1.700 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.

I1.000 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.

I1.100 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).

I1.100 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:

1. Permission for removal of eye tissue either as whole eyes, or as corneas only (as applicable).
2. Information as to the tissues which can potentially be used for transplantation, or research (as applicable)
3. The purposes for which these tissues will potentially be utilised
4. Information concerning the donation process e.g. location, timing, viewing of the body
5. The requirement for blood testing of the donor to test for infectious diseases or tissue typing purposes
6. The possible requirement for further medical information to be obtained, and permission for this e.g. from GP, specialist
7. 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
8. Permission for use of tissue for research, clinical training or education should be obtained as a separate explicit consent
9. Information on follow-up options and notification of outcome
10. That there shall be no cost to the donor and/or their family for any expenses relating to donation
11. Information on possible use for cosmetic procedures or applications involving commercial gain (only if this is applicable to the tissue(s) being consented)
12. Ability and time for person to ask questions and receive clear answers

I1.200 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:
    1. The identity of the donor
    2. The identity and relationship of the consenting person, including name and address
    3. A description of the type of tissues for which consent is given to retrieve
    4. 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)
    5. The identity, position, and institution of the consentor (person obtaining consent)

J1.000 Donor Screening and Contraindications

J1.100 General

The suitability of an individual for eye tissue donation shall be documented.

All donors shall be identified by name and another unique identifier.

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.

J1.200 Medical and Social History

- Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation shall include but not be limited to:
    1. Communicable disease testing
    2. Eye tissue evaluation
    3. Donor history gathering to an extent to which it is possible to make an acceptable judgement on donor risk. Sources of information may include but not be limited to:
        a. Medical record or hospital chart;
        b. Donor Risk Assessment Interview;
        c. Physical assessment of the donor to identify risk factors for potential infection with transmissible diseases, the extent of which is in keeping with the overall risk profile of the donor;
        d. Death Certificate;
        e. Coroner or Pathologist's report on the physical assessment of death; or
        f. Treating physician or General Practitioner interview/report
        g. Medical Director oversight 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, and this shall be documented.

J1.300 Interval between Death, Enucleation 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. Suitability shall be defined by the eye bank's Medical Director.
- 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.

J1.400 Documentation

- Donor screening forms and/or copies of medical charts, Coroner or pathologist's reviews and testing results shall be retained on all donated eye tissue as part of the donor record.

J1.500 Ineligibility Criteria for Donor Selection

- Criteria for the ineligibility of donor selection are mandated by the Therapeutic Goods Administration through the current Therapeutic Goods Order.
- This section contains the minimum donor selection ineligibility criteria as defined by TGO108 that pertain to contraindications for the selection of donors with the intent for transplant use (Table 1)
- Included is EBAANZ guidance pertaining to how certain criteria can be met (Table 2).
- Included is EBAANZ guidance pertaining to risk factors for donor deferral that are in extension to, and that have not been considered in TGO108 (Table 3).
- This is not an extensive list. The EBAANZ donor selection guideline should be referred to for further acceptance and deferral criteria, including explanations.

Table 1:	
Medical and social history criteria	Period of ineligibility
a person who is infected with: a) HCV; b) HIV-1; or c) HIV-2	permanently ineligible
a person who is infected with: a) HTLV-1; or b) HTLV-2	permanently ineligible
a person who has potentially been exposed to: a) HCV; b) HIV-1; or c) HIV-2	ineligible until such time as the person is demonstrated not to be infected
a person who has potentially been exposed to: a) HTLV-1; or b) HTLV-2	ineligible until such time as the person is demonstrated not to be infected
a person who is infected with, or has potentially been exposed to, HBV	ineligible until such time as the person is demonstrated to be: a) immune from HBV infection; or b) not infected with HBV, as confirmed by NAT
a person who has received an injection of any substance in connection with a use that is not a: a) therapeutic use; or b) cosmetic use where the injection is delivered as part of a procedure that is conducted under the professional supervision or direction of a medical or dental practitioner	ineligible for a period of at least 5 years from the last injection received by the person
a person who has been a recipient of viable animal cells or tissues	permanently ineligible
a person who is at risk of prion disease because the person has been, or has potentially been, exposed to the putative causative agent of one of the family of pathogenic transmissible spongiform encephalopathies, including: a) genetic (familial) exposure; b) environmental exposure, including living in or visiting England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time between 1 January 1980 and 31 December 1996; or	permanently ineligible

c) iatrogenic exposure, including receiving a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man at any time on or after 1 January 1980	
a person who has been a recipient of human pituitary-derived hormone	permanently ineligible
a person who has experienced any of the following events, which may give rise to a risk of acquiring a blood borne transmissible infection: a) mucosal splash with blood; b) needle stick injury; c) tattooing; d) body piercing; or e) acupuncture or dry-needling, unless performed using sterile, single-use needles	a) where the person tests negative for HCV using NAT—ineligible for a period of at least 4 months from the event; or b) where the blood samples of the person has undergone serology testing in accordance with subsection 11(4), and the donated tissue was placed in quarantine in accordance with subsection 11(15)—no ineligibility period applies; or c) in all other circumstances—ineligible for a period of at least 6 months from the event
a person who has been a recipient of allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues that did not conform with this instrument	a) where the person tests negative for HCV using NAT—ineligible for a period of at least 4 months from the date the person received the allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues; b) in all other circumstances—ineligible for a period of at least 6 months from the date the person received the allogeneic blood, blood components, human derived clotting factors, organs, cells or tissues
a person who has engaged in sexual activity that puts the person at an increased risk of acquiring infectious diseases that could be transmitted through blood, cells or tissues	ineligible for a period of at least 3 months from the date the person last engaged in the sexual activity

a person who has been imprisoned for a consecutive period of 72 hours or longer	ineligible for a period of 12 months from the date of release of the person from prison
a person who has a symptomatic infection, fever or infectious illness	ineligible for a period of at least 2 weeks from the date of full recovery of the person
a person who has travelled to another country or region within Australia with exposure to particular epidemiological situations	ineligible for a period of time based on a risk assessment using the most up-to-date epidemiological data
a person with an active infection that would render HCT materials collected from that person unsuitable for use in the manufacture of HCT products	ineligible until such time as the person is demonstrated no longer to be infected
a deceased person who, within 12 months prior to asystole, has been a recipient of allogeneic HCT materials or an allogeneic organ that did not conform with this instrument	permanently ineligible
a deceased person whose cause of death is unknown	ineligible until such time as a post-mortem examination of the person provides sufficient information to conclude that the death of the person was not caused by a transmissible disease
a person who has been vaccinated with a live vaccine that contains attenuated bacteria or viruses, other than a vaccine mentioned in item 24	Ineligible for 4 weeks
a person who has been vaccinated with a live vaccine against smallpox	Ineligible for 8 weeks
a person who has been vaccinated with a live vaccine that contains sera of animal origin	Ineligible for 12 weeks
a person who has been vaccinated with an unknown vaccine	Ineligible for 12 weeks

Table 2		
Medical and social history criteria	TGO guidance	EBAANZ guidance
a person who has a symptomatic infection, fever or infectious illness	Clinical judgement should be used to determine the relevance of the infection, fever or illness to the suitability of the donor. Determination of a disease-free state should be established before a proposed donor can be allowed to donate. This may include an algorithm and testing or specified parameters to demonstrate that an infection has cleared.	Localised non-systemic infections, and infective processes that have clinically resolved may be considered for donation. a) Systemic viraemia b) Systemic fungaemia c) Systemic bacteraemia* d) Septicaemia (includes one or more of the above) e) Active ocular or intraocular inflammation: keratitis, conjunctivitis, retinitis, choroiditis, iritis, uveitis, vitreitis, scleritis, chorioditis. f) Active viral encephalitis of unknown origin or progressive encephalopathy (eg. subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.) g) Active bacterial or viral meningitis* h) Active bacterial or fungal endocarditis* i) Rabies j) Lyssavirus & Hendra virus k) Reye's syndrome l) Rubella m) Tuberculosis n) Typhoid *Systemic bacteraemia is not contraindicated if organ culture storage of corneas is performed. See EBAANZ donor selection guidance document for further information.
a person with an active infection that would render HCT materials collected from that person unsuitable for use in the manufacture of HCT products	A list of infections that are relevant to the product and warrant deferral is to be established. Determination of a disease-free state includes an algorithm and at minimum the essential assays or parameters to demonstrate that an infection has cleared or will render the target cells or tissue unsuitable for manufacture.	
a person who is at risk of prion disease because the person has been, or has potentially been, exposed to the putative causative	Permanent deferral of a donor may need to be considered due to risk of prion disease where:	Should not be accepted for donation if diagnosed or suspected to have the below neurological conditions or are at high risk for neurological conditions:

agent of one of the family of pathogenic transmissible spongiform encephalopathies, including: a) genetic (familial) exposure; b) environmental exposure, including living in or visiting England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time between 1 January 1980 and 31 December 1996; or iatrogenic exposure, including receiving a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man at any time on or after 1 January 1980	▪ patients have symptoms of progressive neurological disease consistent with prion disease AND ▪ activities that could iatrogenically transfer prion disease have occurred.	a) Chronic idiopathic demyelinating polyneuropathy b) Creutzfeldt-Jakob Disease (CJD) or prion disease, any type c) Amyotrophic lateral sclerosis (motor neuron disease) d) Multiple sclerosis e) Guillain–Barre syndrome (exclude for 24 months after resolution) f) Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology g) Blood relatives of persons diagnosed with CJD of any type h) Recipients of human pituitary-derived hormones2 i) Recipients of human-derived dura mater2 *Dementia as a result of cerebrovascular disease, brain tumour or trauma, and metabolic-induced dementia may be acceptable. See EBAANZ donor selection guidance document for further information.

Table 3	
Medical and social history criteria	EBAANZ guidance
Retinoblastoma	permanently ineligible
Malignant tumours of the anterior ocular segment, or adenocarcinoma or melanoma in the eye of primary or metastatic origin.	permanently ineligible
Animal bites of any kind outside of Australia and New Zealand	Ineligible for 12 months since bite
Bitten by bat(s)	Ineligible for 12 months since bite
Haematological malignancies including: o) Hodgkin's Disease p) Leukaemia q) Lymphoma r) Lymphomatoid granulomatosis s) Lymphosarcoma t) Myeloma u) Myeloproliferative diseases v) Polycythaemia vera - primary (secondary polycythaemia is acceptable)	permanently ineligible
Metastatic Melanoma	permanently ineligible

K1.000 Retrieval and Processing of Eye Tissue

K1.100 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.

K1.100 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.

K1.200 Enucleation Procedure

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

K1.300 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.

K1.400 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:
    1. the type of tissue
    2. method of transport
    3. distance from retrieval site

K1.500 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.

L1.000 Examination and Evaluation of Eye Tissue

L1.100 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.

L1.200 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.

L1.300 Laboratory Slit-lamp Examination & Evaluation

- 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, polymegethism, 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.

L1.400 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.

L1.500 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.

M1.000 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.

M1.100 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.

M1.200 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.

M1.300 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.

M1.400 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.

M1.410 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.

M1.420 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.

M1.500 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.

M1.600 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.

N1.000 Serology and Microbiology Testing

N1.100 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.

N1.200 Serologic Testing

- 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:
    1. a post-mortem sample procured within 24 hours post-asystole, or
    2. 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.

N1.300 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:
    1. a pre-transfusion/infusion sample shall be obtained and tested. It is recommended that testing be done on the most recent pre-transfusion/infusion specimen for which identity and quality can be ensured, or
    2. the Eye Bank shall establish an algorithm for calculating the effect of plasma dilution on the donor sample and demonstrate that it is less than the designated limit.

N1.400 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:
    1. Human Immunodeficiency Virus Types 1 and 2: anti -HIV-1 , anti-HIV-2
    2. Hepatitis C Virus (HCV): anti-HCV
    3. Hepatitis B Virus (HBV*): HBsAg

        **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 determine infectivity status more precisely.*
    4. Serology testing for HTLV-I and HTLV-II is not required for eye tissue donors.
    5. Serology testing for syphilis is not required for eye tissue donors.

N1.500 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 considered in determining suitability for eye tissue transplantation. Guidance shall be sought from the Medical Director.

N1.600 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 for infectious diseases, 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.

O1.000 Microbiological Testing

O1.100 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.
    1. Microbiological testing in Eye Banks performing the hypothermic storage method is not mandatory for the release of tissue.
    2. 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.

O1.200 Microbiological Tests

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

O1.210 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.

O1.220 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.

O1.300 Bioburden of Ocular Tissue

O1.310 General

- The product 'Human ocular tissue' is not sterile and cannot be subject to terminal sterilisation.
- Surgical retrieval of ocular tissue starts at the procurement/retrieval site (e.g. mortuary).
- The ocular surface is highly likely to be contaminated by environmental micro-organisms, due to the absence of blinking and tear film production following death (1, 2).
- Microbial/bioburden testing at this stage is unnecessary and will yield no beneficial or interpretive result. This is supported by published evidence showing that preoperative donor corneoscleral rim cultures, are unreliable predictors of endophthalmitis complicating corneal transplantation (3, 4).
- Decontamination of ocular tissue starts at the point of controlled air quality (eg
- biological safety cabinet).
- Immersing the ocular tissue in a disinfectant such as povidone-iodine or chlorhexidine and a sterile saline rinse, has been shown to reduce bioburden (1, 2, 5, 6, 7, 8, 9).
- Bioburden testing of ocular tissue has been shown to be an unnecessary processing step. TGO 109 guidance recognises that 'some starting materials are

not sterile as they have inherent microflora that will not be eradicated by processing or manufacturing steps.'

- The unique nature of ocular tissue renders the results and significance of bioburden testing invalid, and any subsequent decisions based on the results of such testing are unsound (4, 10, 11).
- Table 1 explores in further detail microbial factors for ocular tissue.

O1.320 Ocular Retrieval

- Enucleations are not required to be undertaken in any specialised air-controlled environments, as it will not eliminate or reduce the environmental microbial flora already present on the cornea and sclera (see 12.4.1)
- Strategies to reduce microbial flora may still be employed at this stage including irrigation with sterile saline (12) or betadine swabs/drops. This is a risk reduction strategy and does not replace decontamination procedures in the laboratory (figure 1).

O1.330 Physical Evaluation

- Ocular tissue must undergo slit lamp evaluation of whole eyes, as part of quality control and the physical evaluation process.
- This process must occur prior to decontamination.
- An area with specified air quality is not required (see H1.320 and Figure 1).

O1.340 Processing

- Following post-procurement evaluation, whole eyes must be subjected to a decontamination protocol prior to processing.
- This decontamination protocol must be conducted within an air controlled environment to reduce the bioburden on the ocular surface before processing of the Corneoscleral disc (Figure 2).

O1.350 Microbial Testing

- Aseptic operations during processing (decontamination stage) should have limits set for microbial/environmental testing.
- Monitoring schedules should be selected for sample size, timing and frequency.
- The data should be used to establish trends to demonstrate a continuous level of environmental control.
- Any change in supposed typical microflora found should be monitored and be subjected to further analysis.

Factor	Low		Risk		High
Duration of exposure of procured tissues/cells during procurement	no exposure (closed system)	≤1h	1-2h	2-3 h	≥ 3 h
No. of personnel present while tissues/cells are exposed to the environment	1 person	2-3 persons	4 persons	5 persons	≥ 6 persons
Reduction of bioburden during or after procurement	closed system	validated antibiotic/substances treatment	Only substances intended to reduce microbiological contamination (e.g. glycerol, antibiotics, betadine swabs/drops)	only washing intended to reduce microbiological contamination	no reduction
Route of application	superficial coverage (e.g. corneas, skin, amniotic membrane) or application in intra-uterine cavity	durable implant in a poorly vascularised site	small durable implant in a well-vascularised site	large durable implant in a well-vascularised site	direct application into the bloodstream (infusion)

Figure 1: Risk assessment for ocular tissue bioburden prior to decontamination. Adapted from EDQM 4th edition (13).

Probable risk assessment: It is considered a low-risk procedure and is therefore reasonable to conclude, that it is not considered necessary to procure and physically assess eyes in a location with controlled, defined air quality. However, steps must be taken to reduce the bioburden on the ocular surface before/during procurement and before excision of the corneoscleral disc.

Factor	Low		Risk		High
Duration of exposure of procured tissues/cells during procurement	no exposure (closed system)	≤1h	1-2h	2-3 h	≥ 3 h
No. of personnel present while tissues/cells are exposed to the environment	1 person	2-3 persons	4 persons	5 persons	≥ 6 persons
Reduction of bioburden during or after procurement	closed system	validated antibiotic/substances treatment	Only substances intended to reduce microbiological contamination (e.g. glycerol, antibiotics, betadine swabs/drops)	only washing intended to reduce microbiological contamination	no reduction
Reduction of bioburden during processing	validated sterilisation	substantial microbial reduction	limited microbial reduction (e.g. antibiotics)	only washing intended to reduce microbiological contamination	no reduction
Risk that contaminants will not be detected in the tissue or cell due to the limitations of the sampling method	-Visible contamination indicator - microbiological testing of preservation medium	culture of transport media and/or washing solution	a biopsy of tissue tested from each individual tissue	swabbing	no detection method
Route of application	superficial coverage (e.g. corneas, skin, amniotic membrane) or application in intra-uterine cavity	durable implant in a poorly vascularised site	small durable implant in a well-vascularised site	large durable implant in a well-vascularised site	direct application into the bloodstream (infusion)

Figure 2: Risk assessment for bioburden reduction during ocular tissue decontamination. Adapted from EDQM 4th edition (13).

Probable risk assessment: It is considered a low-risk procedure and is therefore reasonable to conclude, that when aseptic technique and bioburden reduction strategies are used the overall process is low risk.

Table 1: microbial factors for ocular tissue; adapted from EDQM 4th edition (13)	
Criterion	Ocular tissue-specific
Risk of contamination of tissues or cells during processing	• Processing whole eyes in a tissue establishment, allows control of air quality (e.g. biological safety cabinet with HEPA-filtered air). • Decontamination of the eyes before processing is a necessary step. It is reasonable to assume, that bacteria and fungi will be present on the ocular surface due to the absence of blinking and tear film production following death. • Corneas may be removed from their storage medium just prior to surgery. They are therefore re-exposed to the environment and an appropriate controlled air quality system must be applied (e.g. laminar flow cabinet in a room with HEPA- filtered air).
Use of antimicrobials during processing	• Corneoscleral discs may be stored in media containing antibiotics and antimycotics. The medium may also contain a marker (e.g. phenol red) that changes colour with a fall in pH caused by growth of micro-organisms. • Turbidity of the storage medium is also an indication of contamination. • Storage of corneas in organ culture, allows for the testing of medium samples for microbial growth during storage, as well an effective antimicrobial activity in the medium, owing to the higher storage temperature than that used for hypothermic storage.
Risk that contaminants will	• There is typically no microbiological testing of hypothermic corneal storage media.

not be detected in the final tissue or cell product due to limitations of the sampling method	Even if a sample of hypothermic medium is taken, the time available before transplant is limited to just a few days, which reduces the chance of detecting contaminants. • For organ-cultured corneas, there is a greater chance of detecting contamination because of the extended, albeit still limited, storage period. A second sample of storage medium may be taken after transfer of an organ-cultured cornea to medium, to reverse stromal oedema and for transport to the recipient hospital. However, the time before transplantation is only a few days and a negative-to- date release will apply. • There is a known risk that contamination may not be detected until after transplantation.
Risk of transfer of contaminants at transplantation	• Corneal tissue for the great majority of transplant procedures cannot be sterilised because living cells are required for a successful graft outcome. • The most frequently isolated micro-organisms in controlled areas used for aseptic processing are bacteria from the human skin (e.g. Coagulase-negative staphylococci). Such micro- organisms are native human skin flora, or native environmental inhabitants, where most do not cause serious disease (14). Table 1 explores contamination risk under several circumstances. • Post-operative endophthalmitis caused by micro-organisms transferred with the graft is therefore a risk and is defined as a serious adverse reaction (see table 1). It is however extremely rare; out of 39500 registered grafts spanning 35 years, <0.01% had a report of post-operative endophthalmitis (15). Additionally, it has been reported that adverse events following corneal transplantation are more commonly associated with recipient and surgical factors rather than eye banking practices (16). Attributing a cause is not always straightforward owing to the, albeit slight, risk of post-operative infection associated with any intraocular surgical procedure. • Prophylactic medications are prescribed as standard clinical care.

O1.400 References

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P1.000 Unique Identification, labelling and Traceability

P1.100 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.

P1.200 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.

P1.220 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.

P1.230 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.

P1.300 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 o 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

P1.400 Labelling for Distribution and Transport

- 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

Q1.000 Documentation of Donor Eye Tissue

Q1.100 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.

Q1.200 Minimum Information to be Retained

- Eye Bank records shall include the following minimum information:
    1. Name of source Eye Bank (if tissue sourced from another Eye Bank)
    2. Unique donor and tissue identification code(s)
    3. Name of donor
    4. Date of birth of donor (or year of birth where no precise date of birth is known)
    5. Cause of death
    6. Death date and time
    7. Enucleation or in situ excision date and time
    8. Type of preservation medium
    9. Lot numbers of preservation medium (and other reagents if used)
    10. Preservation date and time
    11. Slit lamp report (if performed)
    12. Results of evaluation by microscopy
    13. Names of persons performing donor screening, consent, retrieval, processing, evaluation, and release
    14. Printed results of all required serologic tests
    15. Printed results of microbiological tests (if performed)
    16. Utilisation of tissue i.e. surgical, research, training, quality control etc

- And if tissue was sent for surgical use:

    1. Date, time and method of transportation
    2. Name of surgeon receiving/transplanting tissue
    3. Place and date of transplant
    4. Name of recipient
    5. Date of birth of recipient (or year of birth where no precise date of birth is known)
    6. Adverse reaction reports (if received)
    7. Follow-up reports (if received)

R1.000 Utilisation and Release of Eye Tissue

R1.100 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.

R1.200 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
    1. distributed for transplantation into a recipient
    2. used for research/clinical training/education or other purpose
    3. discarded
- Records should indicate the reason if tissue is not distributed, or ultimately used, for transplantation.

R1.300 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:
    1. Donor screening suitability
    2. Slit-lamp and microscopic evaluation criteria
    3. Non-reactivity for required serological tests
    4. 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 signatures(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.

R1.400 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.

S1.000 Documentation to Accompany Eye Tissue

S1.100 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 discernible; otherwise separate forms are advised

S1.200 Eye Tissue Report

- The Eye Tissue Report shall contain the following minimum information:
    1. Name of distributing Eye Bank
    2. Address and telephone number of Eye Bank
    3. Unique tissue identification code
    4. Type of preservation medium
    5. Age of donor
    6. Death and preservation dates and times , and/or death-to-preservation interval and storage interval
- And in addition for corneal tissue:
    1. Results of microbiological tests (if performed)
    2. Results of endothelial evaluation by microscopy (indicate if not performed)
    3. Type of keratoplasty that tissue is suitable for i.e. penetrating, anterior lamellar, endothelial lamellar etc
    4. 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 lamellar anterior or endothelial keratoplasty:
    5. Estimated thickness of transplant portion
    6. Estimated diameter of cut
    7. Post-cut endothelial microscopy reports for tissue intended for endothelial keratoplasty (if performed)

S1.300 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 regarding 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.
- A statement pertaining to the results of the mandatory serological tests (for example that HIV, HBV and HCV results were non-reactive)
- It must be advised if all or any of the tests performed have not been met or validated.

T1.000 Packaging and Transport

T1.100 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:
    1. the name, address, telephone number of the Eye Bank distributing the tissue
    2. the name, address, telephone number of the Transplant Unit receiving the tissue
    3. the type of tissue
    4. recommended storage conditions
    5. any special handling instructions

T1.200 Transport

- Transport from Eye Bank to Transplant Unit may be performed by:
    1. hand delivery by Eye Bank personnel or,
    2. 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.

U1.000 Distribution of Eye Tissue and Recipient Information

U1.100 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.

U1.200 Recipient Information

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

U1.300 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.

U1.400 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.

V1.000 Adverse Reactions, Return and Recall of Eye Tissue

V1.100 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.

V1.200 Adverse Event 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 orevidence 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 (ifapplicable).

- Adverse reaction reports shall be available for inspection by regulatory agencies and be retained for a minimum period of twenty years.

V1.300 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:
    1. re-distribution for transplantation)
    2. 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. Attention should be paid to:
    1. Integrity of the tamper-evident seal and container for evidence of tampering or contamination
    2. 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.

V1.400 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.

W1.000 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.

W1.100 Types of Non-Surgical Eye Tissues

- Tissues for non-surgical purposes may include (but are not limited to):
    1. those which do not meet donor screening, testing or evaluation criteria and cannot be distributed for transplantation
    2. other structures in the eye that are not able to be transplanted e.g. lens, retina
    3. those which are derived directly from donors screened as not suitable for donation for transplant purposes
    4. 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.

W1.200 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.

Y1.000 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 0oC 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 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 28o – 37oC 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, includi 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.