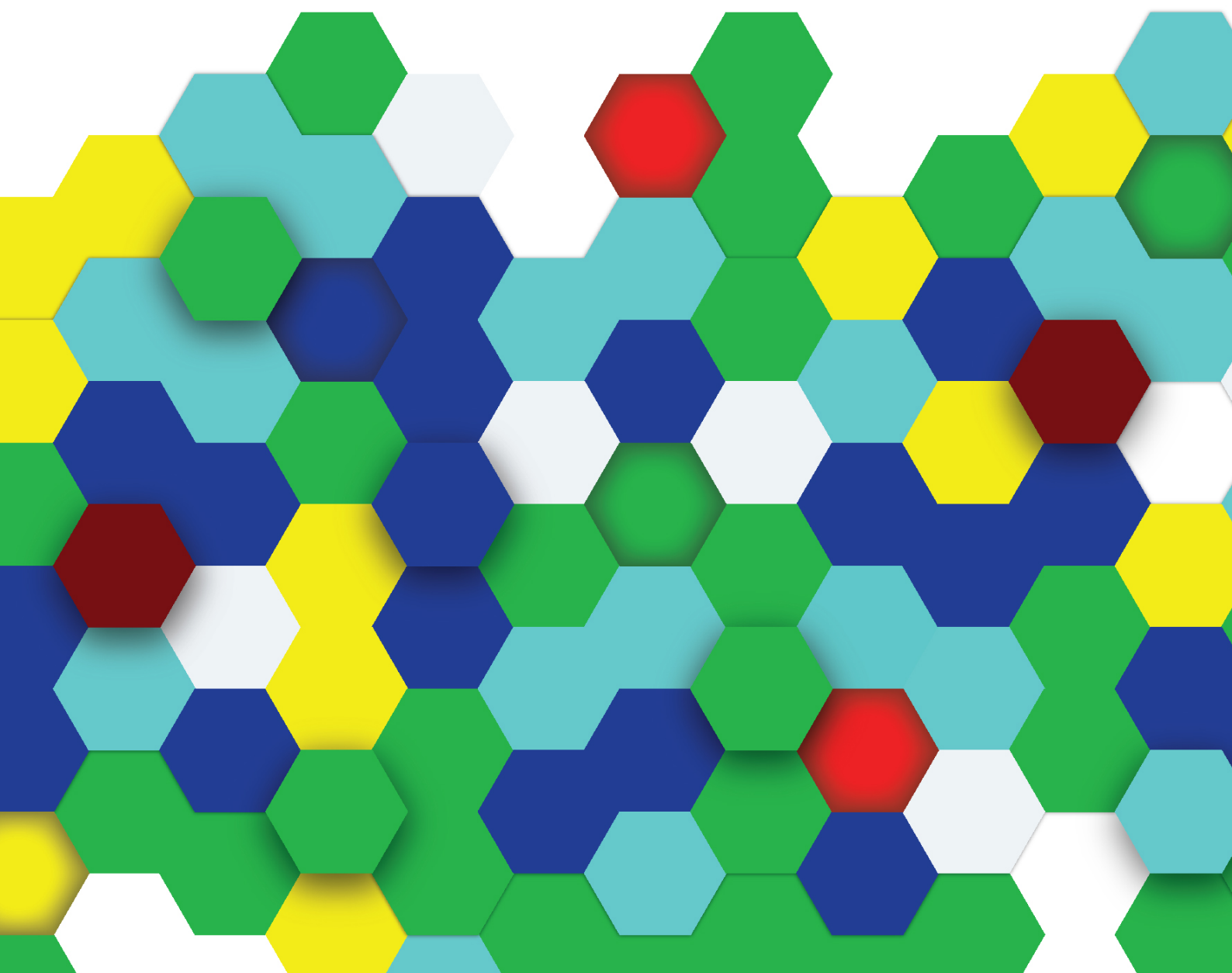




NATIONAL GUIDELINES

A RESOURCE FOR AUSTRALIAN HOSPITALS, OPERATING THEATRES AND DAY SURGERY STAFF REGARDING THE CARE AND HANDLING OF HUMAN TISSUE FOR OCULAR TRANSPLANTATION ©





NATIONAL GUIDELINES © 2016: Eye Bank Association of Australia and New Zealand.

For further information, please contact: info@ebaanz.org or visit www.ebaanz.org

About EBAANZ

The *Eye Bank Association of Australia & New Zealand* (EBAANZ) is a not-for-profit organisation, and the peak body for eye donation and transplantation services in Australia and New Zealand (ANZ).

EBAANZ is dedicated to helping restore sight, provide national and international leadership, develop standards for eye banking, and advocate for the eye banking sector by promoting the unique requirements of eye banks, and facilitating the sharing of information and expertise amongst EBAANZ members.

Special Thanks

EBAANZ would like to thank the Centre for Eye Research Australia, the University of Melbourne, and the Victorian Lions Clubs for their financial and collegial support towards the development of this framework, and our volunteer Steering Committee, Peer Commentators and External Policy Advisors for their invaluable expertise and support.





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Introduction

The National Guidelines: A Resource For Australian Hospitals, Operating Theatre and Day Surgery Staff regarding the Care and Handling of Human Tissue for Ocular Transplantation (here onwards termed the Guidelines) has been developed as a resource tool. Specifically, this is designed for administrators, nurses and operating theatre technicians working within hospitals, day surgeries and clinics around Australia (here onwards termed as the Facility). Tissue for eye transplantation is globally termed Human Tissue for Ocular Application and shall here onwards be termed HTO.

The Guidelines provide information and recommendations, starting from the point of receipt of the HTO by the facility, up until the point of transplantation or return (recall) of the HTO to the Eye Bank/s (EB). They have been inspired by informal dialogue between EBAANZ Member EB and individual facility staff involved in caring for HTO. Through these discussions, staff have expressed uncertainty regarding HTO origins, processes, care, storage and handling. This has prompted EBAANZ to proactively develop this resource to guide practice.

The Guidelines have also been developed to support Australian EB with their own compliance with the Therapeutic Goods Administration (TGA) to ensure, where appropriate and practically possible, information has been communicated to the facilities where HTO is transplanted.

Definitions/Abbreviations

- ANZ – Australia and New Zealand
- AM – Amniotic Membrane
- ANZOD – Australian and New Zealand Organ Donation Authority
- ARTG – Australian Register of Therapeutic Goods
- cGMP – Code of Good Manufacturing Practice
- EB – Eye Bank/s
- EBAANZ – Eye Bank Association of Australia and New Zealand
- HTO – Human Tissue of Ocular Application. This includes cornea, sclera, amnion and stem cells and excludes man-made medical-devices or tissue of non-human origin
- Facility – Is inclusive of hospital, day surgery (ambulatory) and clinic based healthcare facilities
- OT – Operating Theatre
- TGA – Therapeutic Goods Administration of Australia
- The Guidelines – Refers to this document
- WHO – World Health Organization

Note: These Guidelines shall exclude Stem Cells for Transplantation because they are not processed by EB. For information regarding Stem Cells for Transplantation, please contact your local corneal surgeon.



Objectives of the Guidelines

1. Support facility staff with the planning, care and management of HTO;
2. Provide a resource for policy development, staff education, competence and compliance;
3. Provide national evidence to EB and/or facility accreditation and regulatory bodies regarding practice and policy;
4. Provide background information to staff involved in the education and care of pre and post-operative ocular transplant recipients; and
5. Improve care/outcome for patients receiving HTO.

How to use The Guidelines

The Guidelines commence with an overview of EB and an explanation of the types of HTO available in Australia. It is followed by a series of *Guiding Principles* and *Strategies* that facilities are encouraged to implement within their policies and practice.

Introduction to Eye Banking in Australia


There are currently five eye banks (EB) in Australia (and 12 fully licensed tissue banks). The five EB are licensed to provide tissue for eye surgery, which is defined as Human Tissue for Ocular Application (HTO). They do so via the Therapeutic Goods Administration's (TGA) code of Good Manufacturing Practice (cGMP), and in accordance with a jurisdiction-based Human Tissue Act. This is because, within Australia, HTO is licensed as a therapeutic good on the Australian Register of Therapeutic Goods List (ARTG).

All five EB, along with the New Zealand National Eye Bank (located in Auckland), are active members of the sector's peak body, the *Eye Bank Association of Australia and New Zealand* (EBAANZ). Under a Memorandum of Understanding, they are equally involved in the development and management of Australia and New Zealand's (ANZ) Medical Standards for HTO, listed contraindications to donation, education, competency development programs and bioethical management. Through this collaborative process, ANZ's EB community strives to meet the needs of transplant recipients and surgeons, by ensuring that their position, as custodians of HTO, is ethically managed to ensure donor's wishes are respectfully fulfilled.

Within Australia, the EB works one-on-one with corneal surgeons and collectively through the Royal Australian and New Zealand College of Ophthalmologist's Corneal Special Interest Group and associated annual forums. Nationally, they collaborate with the Australian Corneal Graft Registry and provide activity reports to the governing bodies of DonateLife (where they also engage with the peak association for the tissue sector – Biotherapeutics Association of Australia), and the Australian and New Zealand Organ Donation registry (ANZOD).

EBAANZ members participate in global initiatives, as advised by the World Health Organization (WHO), through their foundation partnership involvement with the *Global Alliance of Eye Bank Associations*. EBAANZ Members also comply with the International Declaration of Human Rights, World Health Assembly's WHA63.22 (2010) and the WHO's Aide-Memoire: Access to safe and effective cells and tissue for transplantation (2006). They also collaborate with bioethicists and peer organ-transplant groups such as the Custodian Group of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.

Currently, Australian EB provide corneal and scleral tissue for transplantation, and where needed, tissue for ethically approved research. As Australia currently does not process amniotic tissue, there is a national agreement to allow



processed amniotic tissue, from the National Eye Bank of New Zealand, to be dispatched to Australian Surgeons (via the EB) under the TGA Special Access Scheme.

When a surgeon has scheduled a patient for surgery at a facility, they simultaneously notify their local EB to book the required tissue. From this point, the EB aims to ensure that HTO is ready for their needs. Recipients are informed that while their surgery shall be scheduled at a particular time, this date may change depending on the availability of donated tissue. Additionally, the EB will only release tissue that has been checked and approved as suitable for transplantation.



Background on How HTO is Prepared

These Guidelines relate to tissue obtained from a human eye and tissue obtained from the amniotic membrane layer.

Human eye tissue is obtained after confirmation of consent from the deceased prior to death and/or their family after death. The EB collates information about the deceased person's ocular, medical and social history, allowing the EB to ascertain the suitability for transplantation. Thereafter, the EB Coordinator will recover (remove) the eyes within 24 hours of circulatory standstill (death). Additionally a blood sample will be taken for histology/pathology tests, and screening for diseases of contraindication. The eyes are then transported to the EB where the tissue is separated and prepared. The tissue is tested for its integrity and suitability for transplantation. Tissue that passes all the required testing, and is found suitable for donation, is stored in a preservation (which is termed *storage medium*) until the time of surgery.

The cornea and sclera are the only parts of the human eye that are prepared for transplantation:

Cornea: Corneal tissue is used for all types of corneal surgeries and can be preserved (stored) in several ways. The method of storage, i.e. cold or warm and the length of time the cornea can be safely preserved in its container vary depending upon the type of cornea and the preparation. Also, depending on the requirements of the surgeon and the services of the EB, corneal tissue may be provided to the facility as a whole cornea or pre-cut for lamellar grafts. The two common storage methods of cold and warm will be discussed in the section **How to Store HTO**.

Sclera: Sclera is used to provide 'patch-grafting' to an eye that might have a melanoma/burn or to cover areas of surgical excision - including enucleation surgery, or for a drainage-valve implanted during glaucoma (trabeculectomy) surgery. Sclera can be stored in two ways. It can be provided as a whole or in segments. We will discuss the two common storage methods in detail within the section **How to Store HTO**.

Amniotic Membrane Layer The Human Amniotic Membrane (AM) Layer is the inner most layer of the placental membrane (Kheirkhah et al, as cited in Vajpayee et al 2010). It is a tough and semi-transparent membrane used for ocular surface reconstruction - such as a conjunctival patch-graft for burns, Stevens - Johnson syndrome, and corneal stem cell deficiencies. It can be a permanent or overlaid graft. The AM is obtained from the amniotic layer of the placenta and is divided into smaller pieces, ready for surgical utilisation.

AM is obtained with consent from the mother, for both placental recovery and to confirm a caesarean birth will take place. A caesarean birth means the placenta is delivered under sterile conditions (Dekaris & Gabric as cited in Bredehorn-Mayr et al 2009). This is also coordinated with the attending obstetrician, midwife and/or birthing suite team. The placenta is taken to a separated air-controlled room, where the EB team carefully wash off any remaining blood clots before removing the AM layer. It is dissected from the placenta until a full sheet-layer is separated. It is then cut into pieces and placed flat on a membrane support. This process can often require several team members. A full donor history and blood test (of the mother) is completed and the AM undergoes a full blood and sterility test. The mother is required to undergo a further blood test several months later to re-confirm test results. Once processed and tested, the AM is stored frozen or sometimes freeze-dried (European Eye Bank Association 2014).
Note: The freeze-dried option is presently not available in Australia.



How to Correctly Check-in Eye Bank Tissue

Generally the surgeon's office will order the tissue directly from the EB and ask it to be delivered to the operating theatre (OT) on the day of (or the days before) the scheduled surgery time.

As soon as tissue arrives at the facility it must be checked and immediately logged into the tissue register by a member of the team (i.e. a nurse from the OT who is familiar with these guidelines and the facility's policy on tissue handling). This is to ensure that the correct tissue has been provided for the correct recipient (patient), and to quickly resolve any issues. Checking requires examination of the provided documents, with the labeling on the bottle, and cross-checking against the facility's surgical schedule. You will need the:

- HTO – take the bottle out of the transport container (i.e. esky) but leave it inside its outer transparent packaging sleeve;
- HTO paperwork - will be within the transplant container, sometimes inside an envelope; and the
- Surgeon-patient OT scheduling list.

What to look for on the label and accompanied documents

This information can also be used to assist with completion of the Safe Site Surgery check.

- Integrity of the HTO packaging. Ensure that it has not been tampered with, there are no cracks, and the label is clear and easy to read;
- Temperature of the HTO. Check the HTO has been provided in the appropriate storage temperature for its type of preservation and storage (see section *How to Store Tissue* where we discuss preservation and temperature);
- The label on the HTO container corresponds with the label on the accompanying paperwork. Look specifically to cross-match the:
 - Unique coding number
 - Branding logos
 - Dates of use and/or expiration

The name of the surgeon performing the surgery (this will be outlined on the paperwork provided);

The intended recipient's name. Check that this appears on the documents provided. You may also like to cross-match with your facility's OT scheduling list, and ensure that the tissue is prepared as requested.

For example, some surgeons may ask for (or routinely order) corneal tissue to be prepared as "pre-cut" tissue ready for different types of layered (i.e. DSAEK) surgery. You may need to ask the surgeon's rooms if unsure.

If any issues are identified during the check-in process, the EB and/or surgeon need to be notified immediately so that problems can be resolved prior to the patient's scheduled surgery time. Resolution of issues can include HTO recall, replacement or re-allocation.

How to Store Tissue (until time of surgery)

Each HTO has its own unique storage and temperature requirement to ensure appropriate preservation of the HTO.

Within the paperwork that the EB provides, you will find information on how that particular HTO has been prepared and preserved, along with instructions on how and where to store the tissue and at what temperature. Please see appendix 4 for an example of the paperwork.

Always keep the accompanying paperwork and the HTO together to avoid any confusion.

Cornea

There are two methods of corneal preservation used by Australian EB. They each have very different temperature requirements. Different EB use different methods and these are identified below. These are:

1. Kept cold (hypothermic). Tissue is supplied in Optisol-GS containers where the cornea is free-floating within the container, or a star chamber where the cornea rests in a guarded position and is restricted from movement. Corneas stored via the hypothermic preservation method can be delivered prior to the day of surgery.
 - a. When received, please remove the cornea from the transport container (esky) but keep it inside its plastic sleeve, and place it into a medical-grade fridge that has a regulated temperature range of 0-10 degrees Celsius (ideally 0-4, and never below 0 as this can freeze and damage the tissue).
2. Kept at human body temperature (Organ Culture Medium - Normothermic). Tissue may be supplied in a slightly larger glass bottle or in a star chamber. Normothermically preserved corneas are generally delivered on the day of the scheduled surgery or the afternoon prior to a morning surgical list. The tissue is delivered at room temperature.
 - a. When received, please keep normothermic corneas at body or room temperature. i.e. do not refrigerate. Keep away from extremes of temperature, e.g. not in strong sunlight.

Table 1: Storage and Temperature for Normothermic and Hypothermic stored cornea

WHICH EB	APPEARANCE	TECHNICAL PRESERVATION NAME	WHERE TO STORE IT	HOW TO STORE IT	WHEN TO USE IT BY
NSW, VIC & WA (QLD COMING SOON)	Warm – pink coloured liquid	Organ Culture Medium (Normothermic)	Secure cupboard in normal OT air conditioned environment until the commencement of the surgical list. It can be moved into the OT at commencement of the surgical list	At body temperature (37 degrees) or normal OT room temperature.	As per the expiry date
NSW, QLD, SA, VIC & WA	Cold – pink coloured liquid	Hypothermic	Medical grade Fridge (with temperature and monitoring control) It can be moved into the OT at the commencement of the surgical list	Between 0-10 degrees Celsius	As per the expiry date

Note: It is best to keep the cornea in a routine place/position which is well known to other staff and surgeons. The facility should nominate the place/position.

Sclera

Sclera can be provided in whole or segmented pieces. In Australia, sclera is preserved in alcohol and can be prepared via two methods whereby the use of alcohol is required for both.

Note: The surgeon will be required to rinse-off the alcohol once the tissue is decanted into a bowl/dish on the operating table. Instructions are outlined in the provided documentation.

The two methods are:

1. In 95% alcohol (VIC):
 - a. The tissue will be free-floating in clear alcohol. When you receive this tissue keep it at room temperature until the time of surgery. It will need to be rehydrated by the surgeon and rinsed as per the provided instructions.
2. Saline (NSW, QLD, SA & WA): Sclera is stored in 95% alcohol at the EB and rehydrated prior to distribution. It is distributed in Saline - NaCl (+/- Gentamycin). When the tissue is received by the facility, ensure appropriate quality checks are undertaken and preservation is maintained via refrigeration until use. Please refer to instructions on the documentation included with delivery.

Table2 : Storage and Temperature for Sclera.

WHICH EB	TYPE	APPEARANCE	WHERE TO STORE IT	HOW TO STORE IT	WHEN TO USE IT BY
VIC	95% Alcohol	Clear liquid	Secure cupboard in normal OT air conditioned environment until the commencement of the surgical list. It can be moved into the OT at the commencement of the surgical list	OT Room temperature (within normal temperature range for an OT)	As per the expiry date
NSW, QLD, SA & WA	Saline (+/- gentamycin)	Clear liquid	Medical grade Fridge (with temperature and monitoring control) It can be moved into the OT at the commencement of the surgical list	Between 0-10 degrees Celsius	As per the expiry date

Reminder: Complete a full tissue – documentation – recipient check for sclera.

Please note, that in compliance with global practice and standards, any provided sclera is to serve one recipient only. Facilities and surgeons are not permitted to cut and share sclera between more than one recipient. This is to prevent infection risk to all recipients and ensure tissue-tracking, and billing and ensure long term recipient outcomes can be effectively monitored and reported to governing authorities and regulators. This practice is not permitted under HTO license with the TGA and is reportable to the EB for notification and legally required follow-up.

Amnion

Amnion, which is obtained from the Amniotic Membrane (AM), is not widely used within Australia. It is provided in small squares which, stored frozen at the EB, are delivered to the facility thawed and ready for refrigeration. While the specific time of arrival depends on freight dispatch from New Zealand, ideally it will be available on the morning of an afternoon OT list or the afternoon prior to a morning OT list. AM is dispatched only for specific patients and the tissue needs to be matched to that patient. It is important to outline that AM is not a stock consignment item – it is ordered for a specific recipient only.

When the facility receives the tissue it needs to be refrigerated at a temperature of 0-10 degrees Celsius. There is often essential accompanying information on the care of AM, which might be different from that of sclera and cornea - so ensure you read through accompanying details carefully. Any additional import documents need to go to the surgeon. Routine log and checking systems apply.

Reminder: the tissue must match the patient it was ordered for. This is an Australian regulatory requirement.

Table 3: Storage and Temperature for stored AM.

WHICH EB	APPEARANCE	WHERE TO STORE IT	HOW TO STORE IT	WHEN TO USE IT BY
CAN BE ORDERED FROM YOUR CLOSEST EB (WHO IN TURN ARRANGE THE DISPATCH FROM THE NZ EB)	70ml plastic yellow-topped container	Medical grade Fridge (with temperature and monitoring control) It can be moved into the OT at the commencement of the surgical list	Between 0-10 degrees Celsius	As per the expiry date

How to check HTO ready for surgery (Safe Site Surgery Checking System)


HTO needs to be checked during Sign-In and Time-Out as it is treated as a prosthesis within hospital records. To do this correctly, the checking needs to take place between the recipient and donor tissue's identifiers, surgical schedule, surgeon's notes, donor tissue label and donor tissue documentation. Any discrepancies or issues noted must be immediately addressed and pre-operative preparations must come to a halt until rectified. Please see the Pathway Matrix in appendix 1 .

How to Decant onto the Sterile Field

Tissue must only be opened on the instruction of the surgeon, by the designated OT staff member and must be transferred to the sterile field in a manner that does not compromise sterility.

For corneal and scleral tissue, the seal will need to be opened. Bottles with crimple-metal lids should be opened by following the perforation line to prevent injury to self. The bottle ring should be pulled in a downward direction and then either clockwise or anticlockwise to safely remove the metal seal without causing harm to the staff member.

With out compromising the sterile field and causing cross-contamination, decant the contents of the bottle (fluid and tissue) into a waiting bowl. In some cases, the tissue can float to the bottom of the bottle. Experienced OT nurses suggest that tipping quickly – without spilling or causing a splash, will ensure the tissue exits with the fluid. Another useful method is swirling the fluid and the cornea in a rotating method to allow the cornea to become mobile and then to quickly empty the contents into the sterile operating container. To minimise risk, care must be taken to prevent spillage of preserving solution. Should the tissue not exit the bottle smoothly, the surgeon will need to utilise sterile forceps to retrieve the corneal tissue. Please see the Decanting Photo Guide in Appendix 2 .



Precut tissue in a star chamber may be directly removed by the surgeon with a pair of forceps. The chamber needs to be held as close as possible to the sterile field ensuring appropriate care is undertaken to minimise risk of contamination to the sterile field.

During Surgery

It is important to keep the tissue in one safe spot on the sterile field to reduce the risk of contamination, accidental overturning or damage. The tissue is to be handled minimally and only by the surgeon and the scrub nurse.

The surgeon is responsible for preparing the tissue at all times. This includes:

- For cornea, rinsing it with a sterile saline wash prior to trephination and lamellar dissection
- For scleral tissue, it must be kept hydrated on the punch-block until needed, and then rinsed and/or cut ready for transplantation.

What to do at the completion of the surgery

On completion of the surgery any remaining HTO is to be disposed of in an appropriate and respectful manner, and in accordance with facility policy for the disposal of human waste. *Each facility should check with the supplying EB as to the appropriate disposal method.*

Note: *For facilities in WA, all remaining corneal rims are required to be returned to the EB in the transport bottle and container (i.e. esky) they were supplied in.*

Any provided donor labels may be used for placement on the OT notes (i.e. operative section or prosthesis record) and/or the surgeon's own notes.

All HTO documents provided by the EB, are to be handed to the surgeon. In Australia, the surgeon is responsible for continuous monitoring of long term outcomes of the patient post-transplantation. Additionally, the documents provide vital information (and forms) that the surgeon will need in order to report to the Australian Corneal Graft Registry regarding the outcome of the surgery long term.



What to do with HTO that is not used

If, for some reason, HTO is not used (i.e. patient cancellation) and the assigned surgeon confirms that the tissue is not needed, the facility is required to contact the EB as soon as possible. Depending on the status of the HTO, the tissue may be returned to the EB, reallocated or in exceptional circumstances disposed of. The variance between return, reallocation or disposal can be confusing and is dependent on whether the EB is able to accept returned HTO and if the HTO packaging was opened or tampered with. To assist this process the EB will also ask if the tissue was opened and handled and, for sclera, they will ask if it was rehydrated. As tissue has been accepted by the surgical facility there may still be a payment required from the hospital to the EB for opened and/or un-used tissue. Please ensure that facility managers are notified of unused tissue to facilitate financial follow-up as required.

What to do if HTO is recalled, damaged or defective

Recall: The EB will immediately notify the facility and surgeon of any HTO recall issues and provide a suitable replacement. In these cases, the facility is advised to follow the guidelines from the EB regarding the return of the recalled HTO to the EB.

Other issues: If the facility identifies an issue with HTO they have received (i.e. cracked container, tampered bottle, incorrect recipient details, non-match between donor tissue and recipient, or incorrect tissue type or cut provided) then the facility should contact the EB immediately. The EB, is required to recall the HTO and conduct a follow-up quality investigation with all relevant internal and external parties. Additionally, the EB is required, by law, to notify the TGA of any recall and defect issues as part of the HTO's license on the ARTG.

Finally, the facility is advised to document the event, within their own quality management reporting system.

How to return: Always try and return the tissue inside it's original bottle/container and transport box along with all relevant paperwork. From the facility's perspective, and their internal quality management system, ensure a copy of all receiving documentation is attached to the incident report.


Ensure that the tissue is returned as soon as possible as per the relevant procedure for storing and transferring HTO (i.e. temperature monitored).

Replacement Tissue: The EB will liaise directly with the surgeon and facility to arrange for replacement tissue to be dispatched as soon as possible.

What to do if remnants of HTO are requested for research

From time-to-time, and under pre-agreed ethics approved research projects, a surgeon and/or researcher (sometimes in conjunction with the EB) may request remaining HTO (e.g. the corneal-scleral rim of the donor tissue post-trephination) to be returned for approved research. Facilities are required to confirm with the surgeon and researcher that such ethics approval has been granted with an appropriate scientific ethics committee prior to allowing remaining HTO to be removed from their facility. Approval must be in writing, by the ethics committee (authorised representative) and the HTO removal is to be closed out by the Director of Nursing of the facility.

Staff involved in the provision of HTO remnants to a surgeon or researcher, are advised to do so without cross-contamination by self or others. A notification on the outside of the container – identifying that the tissue may be contaminated – is also advised. The surgeon or researcher will advise on how the HTO is to be prepared for handover as this depends on the research design and associated requirements.



Please note that the scope of this document excludes surgeon and researcher requests for recipient corneal buttons as this is outside of the scope of practice of the EB. Therefore, facilities are advised to review their own policy, agreements and patient-consent processes in this regard.



Guiding Principles

Principle 1. The Facility and staff shall take responsibility for HTO whilst it is in their care.

Guiding Strategy

1. Policy and procedures (Standard Operating Procedures) shall be inclusive and considerate of the care and management of HTO via:
 - a. Development and implementation of a logging system to track incoming and outgoing HTO to/from the facility; and
 - b. Guidelines to assist in the checking and handling.
2. Staff involved in ocular transplantations shall be trained and deemed competent with the handling and management of HTO prior to any handling of HTO.

Principle 2. HTO shall be stored and monitored in accordance with the recommendations of the dispatch EB.


Guiding Strategy

1. Staff shall review the accompanied documentation to confirm the storage method (i.e. temperature);
2. HTO shall be stored – until commencement of the surgical list – within a temperature controlled (monitored) environment as outlined by the dispatching EB for that preservation and tissue type;
 - a. The tissue, depending on the surgeon's request, may require it to be warmed to human body-temperature prior to being transferred to the surgical table. Many OT team members do this by placing the tissue's transport bottle in the ambient OT room environment and/or to body temperature for a few minutes before transfer to the surgical table.
3. The storage location shall be:
 - a. Temperature controlled and monitored;
 - b. Close to the OT where it is needed; and
 - c. Kept away from the general public and patient (pre-operative) waiting areas to ensure compliance with privacy and security.

Principle 3. HTO shall be routinely included in Safe Site Surgery Checking processes.

Guiding Strategy

1. Facility staff shall routinely perform HTO checks during *Sign-In* and *Time-Out*;
2. The *Time Out* shall cross-reference the donor tissue labelling and documentation with the proposed scheduled surgery and the recipient (patient) three key identifiers;
 - a. Tissue shall be matched to the patient it was specifically ordered for.
3. Discrepancies identified shall cease pre-operative recipient preparation until the discrepancy is resolved. Cancellation of surgery may be required;

- 
4. The surgical team, during *Time-Out* shall confirm they have prepared, set-up and checked that any required HTO cutting devices (i.e. trephination equipment) are in good working order and ready for use; and
 5. Facility staff shall confirm approval for remaining HTO to be provided for research if requested.

Principle 4. Facilities and staff shall maintain appropriate record of HTO use.

Guiding Strategy

1. The facility shall ensure that a full copy of relevant medical records are retained and stored in accordance with quality management systems and the National Safety and Quality Health Service (NSQHS) standards.

Principle 5. Facilities and staff shall ensure surgeons receive all required documents to adhere to reporting requirements of the Australian Corneal Graft Registry (ACGR).

Guiding Strategy

1. OT staff shall ensure surgeons are provided the necessary documentation from the ACGR – supplied by the EB with the tissue - during the surgical list, and prior to departure from the facility.

Principle 6. Facilities and staff shall report defective HTO to the EB, report infection issues that potentially resulted from HTO, and support the surgeon to facilitate the return/disposal of HTO not used.

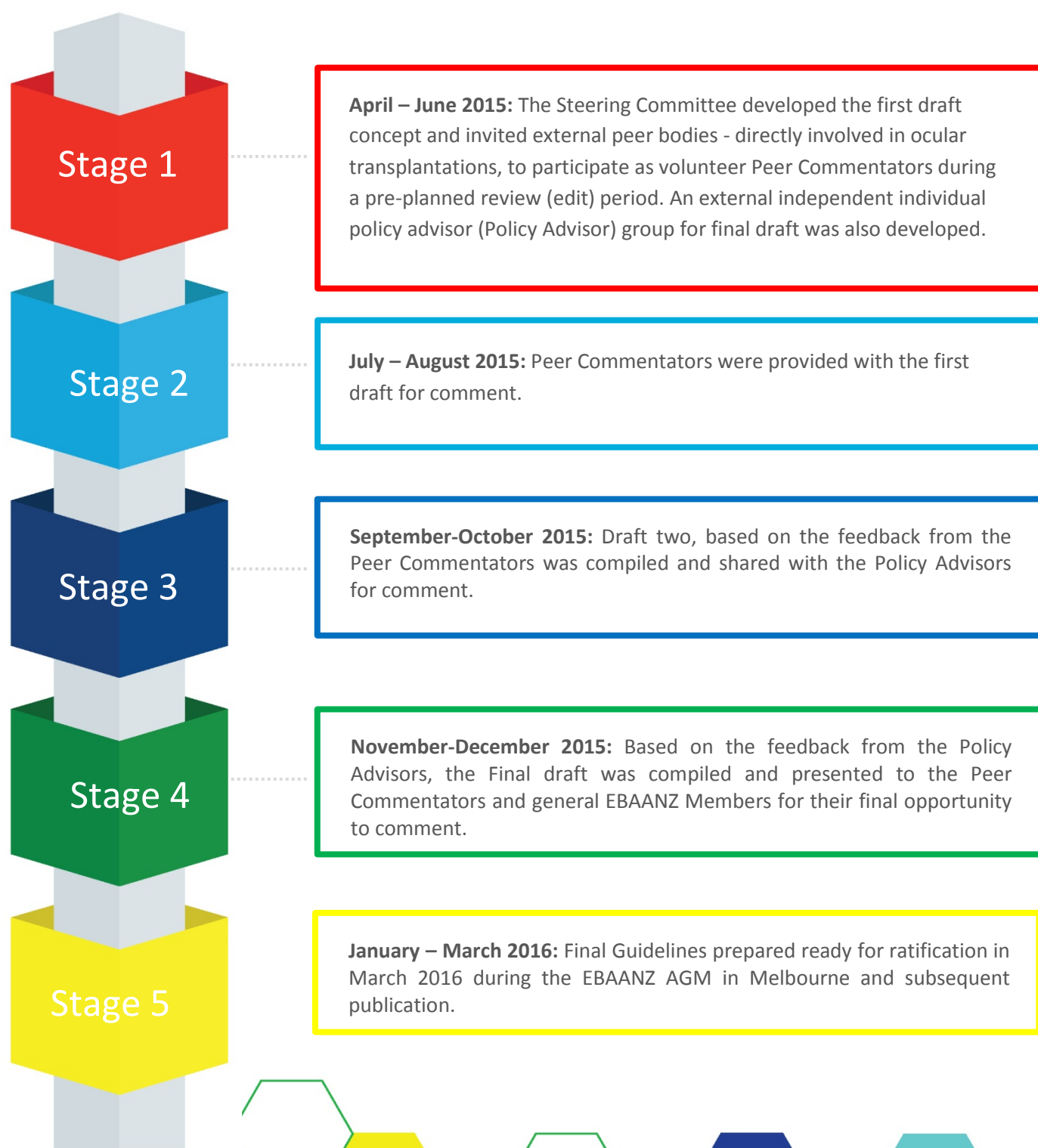
Guiding Strategy

1. Facility staff shall notify the surgeon and EB immediately and follow the prompts advised by the EB regarding the return of the HTO to the EB;
2. The EB shall arrange alternative HTO as quickly as possible to prevent delay for the recipient;
3. HTO not used shall be returned as directed by the assigned surgeon and the EB;
4. HTO not used shall be disposed of as directed by the assigned surgeon and EB and in accordance with facility waste management policies; and
5. Relevant facility staff shall inform their manager (or point of contact), in writing, to follow-up on financial and/or dispatch matters as required (i.e. quality incident reporting tools).

Preparation of the Guidelines

During the EBAANZ AGM on March 4th 2015, held at the Lions Eye Institute, Perth Australia, agreement was made by the Executive of EBAANZ to develop a Guideline to support all clinical and allied health staffs (i.e. operating theatre nurses and technicians) who, indirectly, become the custodians of HTO during the point of receipt at the facility until the time of transplantation.

From this, an agreed EBAANZ Steering Committee was established. It was decided that it shall primarily include EBAANZ members who are also registered nurses. The Steering Committee was to also include one physician (Medical Director) and one external nurse consultant currently involved in scrubbing/circulating for corneal surgeries.





Participants in the development of The Guidelines

The Guidelines Steering Group included 4 Australian EBAANZ representatives and one invited nurse proficient in corneal operating theatre scrubbing and circulating. Additional Peer Commentators were welcomed to participate voluntarily in the draft development. A group of independent individual external policy advisors was also established to provide comment on the final draft (note, these were not all representing their employing organisations). Of those invited, the below confirmed their involvement – and for which EBAANZ would like to extend their thanks.

EBAANZ Steering Committee:

- (Lead) Heather Machin, RN, MBA - Project Officer to EBAANZ and Global Alliance of Eye Bank Associations. Lions Eye Donation Service, Centre for Eye Research Australia, University of Melbourne, VIC
- Hayley Fleay, RN – Donor Coordinator at Lions Eye Bank of Western Australia, Perth, WA
- Dr Con Petsoglou MD – Medical Director, Lions New South Wales Eye Bank, Sydney, NSW
- Helen Scott, RN – Operating Theatre Staff Nurse, Queensland Eye Hospital, Cura Group, Brisbane, QLD
- Jane Treloggen, RN – Manager, Lions New South Wales Eye Bank, Sydney, NSW

Invited Commentators:

Professional Organization Representatives

- Australian Day Hospitals Association
- Australian Ophthalmic Nurses Association – NSW
- Australian Ophthalmic Nurses Association – QLD
- Australian Ophthalmic Nurses Association – VIC (including SA & TAS)
- Australian Ophthalmic Nurses Association – WA
- Australian Collage of Operating Room Nurses
- Royal Australian and New Zealand College of Ophthalmologists

Facility Representatives

- Chatswood Vision Eye Institute- Vision Group, Sydney, NSW
- Flinders Medical Centre, Adelaide, SA
- Fremantle Hospital, Perth, WA
- Queensland Eye Hospital- Cura Group, Brisbane, QLD
- Royal Perth Hospital, Perth, WA
- Royal Victorian Eye and Ear Hospital, Melbourne, VIC
- St. John of God Hospital, Subiaco, Perth, WA

External Independent Policy Advisors:

- Linley Bielby (Manager), Adrienne Harper (Education Coordinator) and Chris Akers (Transfusion Nurse). Blood Matters Program - Australian Red Cross Blood Service, Department of Health and Human Services, Victoria. Sector Performance, Quality & Rural Health Branch.
- Wendy Bomgaars, RN, B.Sc., MBA (p) CF/OrgChg, NSQHSS & ISO Auditor 9001:2015, Strategy /Efficiency Advisory – Health, Director, Practice Management International
- Helen Craig, Manager Strategic Policy & Advocacy, Royal Australasian College of Physicians.



References

1. Dekaris, I. & Gabric, N. (2009), as cited in Bredehorn-Mayr, T., Duncker, G. I. W. & Armitage, W. J. (2009). *Eye Banking. Chapter: Preparation and Preservation of Amniotic Membrane*. Karger. Switzerland
2. European Eye Bank Association (2014). Directory: Twenty-Second Edition. *European Eye Bank Association*. January 2014.
3. Kheirkhuh, A., Sheha, H., Casas, V., Raju, V. K. & Tseng, S. C. G. (2010). As cited in Vajpayee, R. B., Sharma, N., Tabin, G. C. & Taylor, H. R. (2010). *Corneal Transplantation 2nd Ed. Chapter 42: Amniotic Membrane Transplantation*. Jaypee-Highlights Medical Publishers, New Delhi.

Links and other items of interest

Websites:

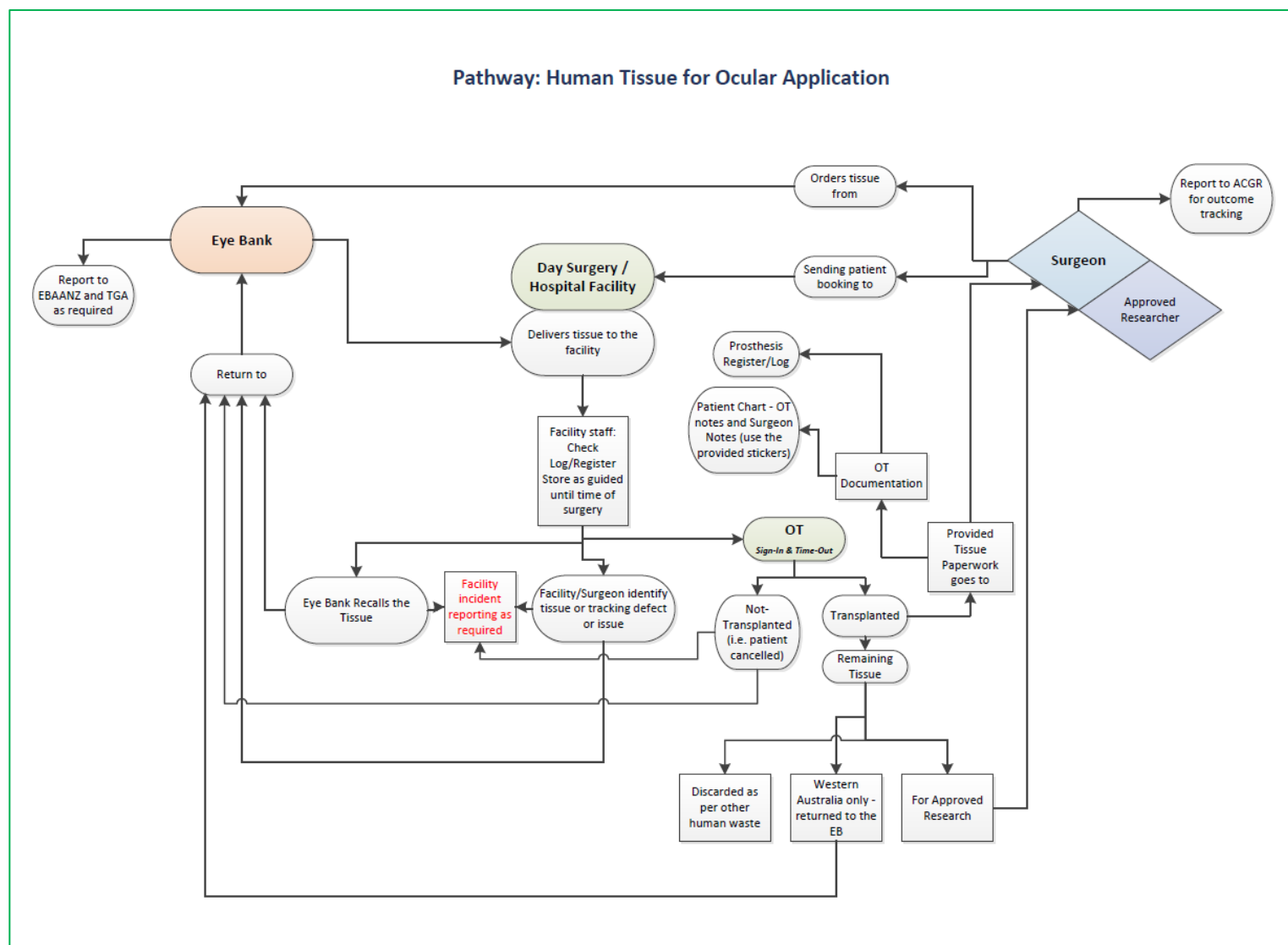
- DonatLife Australia: www.donatelife.gov.au
- Eye Bank Association of Australia and New Zealand: www.ebaanz.org
- Global Alliance of Eye Bank Associations: www.gaeba.org

Documents:

- United Nations. (1948). Universal Declaration of Human Rights. Available at: www.un.org/en/documents/udhr/
- World Health Organization. (2006). Aide-Memoire: Access to safe and effective cells and tissue for transplantation. Available at: <http://www.who.int/transplantation/AM-HCTTServices.pdf>
- World Health Organization. (2010). Guiding principles on human cell, tissue and organ transplantation. Available at: www.who.int/entity/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf?ua=1

APPENDIX

Appendix 1: Tissue Pathway Matrix



Basic bottle top

Step by step guide to open a basic bottle top.

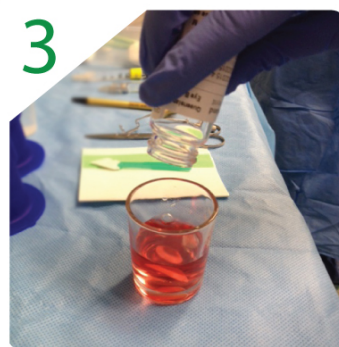
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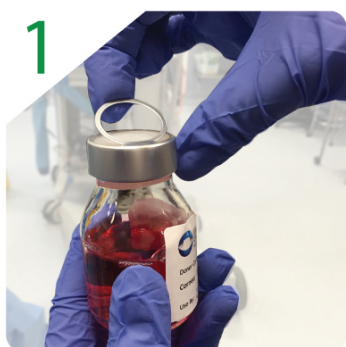
3



Ring-pull bottle top

Step by step guide to open a ring-pull bottle top.

1



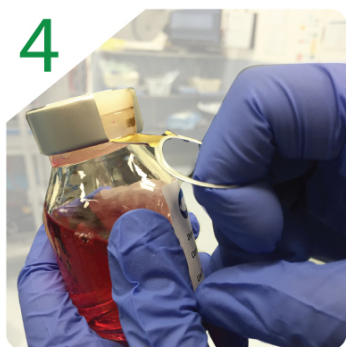
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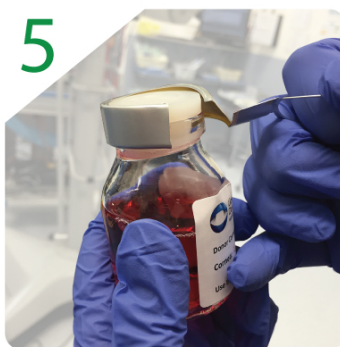
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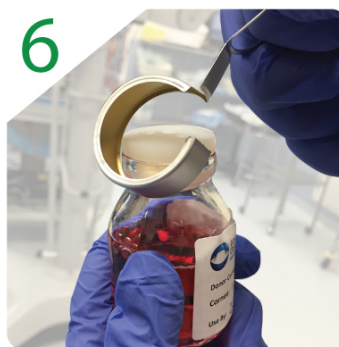
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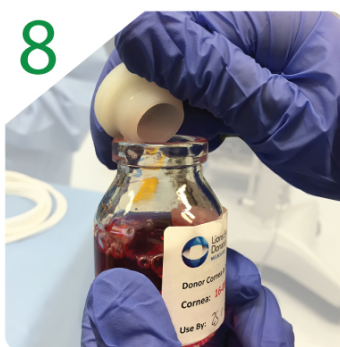
6



7



8



9



Appendix 3: Facility Competency Template

Competency #: Care and Handling of Human Tissue for Ocular Application	
Competency Statement: <i>The employee cares for, handles and manages Human Tissue for Ocular Application (HTO) in accordance with facility policy and EBAANZ Guiding Principles</i>	
Competency Elements	Assessor's Assessment
	0 = Not applicable to the position 1 = High proficiency 2 = Moderate proficiency 3 = Limited proficiency
• Demonstrates knowledge of facility policy and procedure, and EBAANZ Guiding Principles when working with HTO	
• Completes full tissue and recipient check and confirms the integrity of the HTO prior to checking it into the facilities stock and/or presenting to the Operating Theatre	
• Stores according to recommended range – as outlined in accompanied documentation	
• Demonstrates inclusion of HTO checks during Sign-In and Time-Out	
• Decants HTO on to the sterile field without contamination to self, others or HTO	
• Appropriately cares for discarded HTO (i.e. corneo-scleral rim)	
• Understands the procedures for research, recall, damaged or unused HTO and does so in accordance with the facilities quality management reporting system	
<p align="center">Statement of Attainment</p> <p align="center">The Competency Statement has been achieved by this employee to the level of:</p> <p align="center"><input type="checkbox"/> Competent <input type="checkbox"/> Not Competent</p>	
Evidence of achieving Competency Statement:	
Recent practice	
Observation of everyday performance	
Result of discussion/questioning/interviewing	
Result of formal assessment(s)/quizzes	
Continuing Professional Development activities	
Other (please clarify)	


Employee Name _____	Signature _____	Date ____/____/____
Assessor's Name _____	Signature _____	Date ____/____/____

Appendix 4: Tissue Documentation and Labelling (Corneal Example)

Labelling on Bottle

ORGAN CULTURE TRANSPORT MEDIA
BATCH: ZZZZZZZZ
NUMBER 1
MFG: AA/BB/CCCC
EXP: XX/YYYY
Contains MEM, Glutamax, Dextran, Foetal Bovine Serum, Penicillin G, Streptomycin Sulfate, & Amphotericin B
LNEB-L-L-010 Date Effective: 14/09/2015

Provided Documentation

 Eye Bank No:

Release of Cornea for Transplantation

Date of Death	Time of Death
Date of Enucleation	Time of Enucleation
Date of Preservation	Time of Preservation

Blood Samples: (circle)	Pre-mortem	Post-mortem	Results from DonateLife
Serology			
HIV 1/2	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	HTLV/III	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
HbsAg	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	CMV IgG	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
HbC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	CMV IgM	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
HCV	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	EBV IgG	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
Syphilis	<input type="checkbox"/> Reactive <input type="checkbox"/> Non-Reactive	EBV IgM	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
Virology			
HIV-NAT	<input type="checkbox"/> Reactive <input type="checkbox"/> Non-Reactive	HCV-NAT	<input type="checkbox"/> Reactive <input type="checkbox"/> Non-Reactive
HBV-NAT	<input type="checkbox"/> Reactive <input type="checkbox"/> Non-Reactive		

Tissue		
Tissue Side (circle):	Right	Left
Storage Type (circle):	Organ Culture	Optisol
Tissue Cut (circle):	DSAEK	Whole Cornea


Release Checklist		
	Meets Release Criteria	Does <u>NOT</u> meet Criteria
Consent	<input type="checkbox"/>	<input type="checkbox"/>
Medical / Social History	<input type="checkbox"/>	<input type="checkbox"/>
Physical Assessment	<input type="checkbox"/>	<input type="checkbox"/>
Cause of Death / Post Mortem	<input type="checkbox"/>	<input type="checkbox"/>
Blood Collection and Storage	<input type="checkbox"/>	<input type="checkbox"/>
Slit Lamp Examination	<input type="checkbox"/>	<input type="checkbox"/>
Cell Count (> 2,200 cells / mm ²)	<input type="checkbox"/>	<input type="checkbox"/>
Viability* (>80%)	<input type="checkbox"/>	<input type="checkbox"/>
Viability* (>70%, DALK* only)	<input type="checkbox"/>	<input type="checkbox"/>
Serology / Virology	<input type="checkbox"/>	<input type="checkbox"/>
Microbiology	<input type="checkbox"/>	<input type="checkbox"/>
Container Integrity Check	<input type="checkbox"/>	<input type="checkbox"/>

* Viability is only performed on Organ Culture Tissue. * Tissue is deemed for DALK use only.

Release Authority			
Tissue Suitability	Right	Left	Signature
Suitable for Release	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
NOT Suitable for Release	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Please turn over page for Product Information

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 Eye Bank No:

Product Information

This tissue must be inspected prior to use. The tissue should not be used more than 30 days from the date of preservation for normothermic storage (Organ Culture). The tissue should not be used more than 14 days from the date of preservation for hypothermic storage (Optisol).

This tissue is bioburden reduced via using Povidone-iodine, although it has tested negative for microorganisms, no guarantee can be made on its sterility.

Tissue returns cannot be accepted by the Lions NSW Eye Bank.

This product contains an indicator (phenol red) which should appear a light rose colour. A change of colour to either yellow or dark red indicates an unacceptable shift in pH, which could possibly be caused by contamination. IN THE EVENT OF A COLOUR CHANGE OR MEDIA TURBIDITY, THE TISSUE MUST **NOT** BE USED. Contact the Eye Bank immediately in the event of this occurrence.

Instructions for Use:
This tissue is for corneal transplantation only. It is intended to contain viable cells. This tissue is for single use only. Optisol storage comes should be stored at between 2°C - 8°C prior to use. Organ Culture comes should be stored at room temperature prior to use. Tissue marked as '>70% viability' or 'DALK only' should **ONLY** be used for Deep Anterior Lamellar Keratoplasty (DALK) and **NOT** for Penetrating Keratoplasty (PK), Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK), Descemet's Membrane Endothelial Keratoplasty (DMEK), or any other surgery which requires function of the endothelium.

It is recommended that corneal tissue be rinsed in buffered salt solution prior to transplantation to remove residual storage media.

This tissue should be used for clinical use only. All tissue not used in the surgical procedure must be discarded in accordance with local hospital protocols for human tissue.

Disclaimer: There is a minimal but definite risk of transmitting disease with transplant of donor tissue. Although this donor tissue is subject to stringent quality control, no responsibility can be undertaken for its complete safety.

Optisol Stored Tissue
Optisol stored tissue is supplied in a sterile buffered medium which contains dextran, chondroitin sulphate, gentamicin sulphate and a phenol red indicator. This may cause reactions in patients who are allergic to sulphur based drugs or antibiotics.

Organ Culture Stored Tissue
Organ Culture stored tissue is supplied in Organ Culture Transport (OCT) Media which contains Minimal Essential Media, GlutaMax, Penicillin G, Streptomycin Sulfate, Amphotericin B, Dextran and a phenol red indicator. This may cause reactions in patients who are allergic to sulphur based drugs or antibiotics.

Organ Culture stored tissue was cultured in Organ Culture Storage (OCS) Media which contains Bovine Foetal Serum from a negligible risk closed herd of cattle from Australia and New Zealand. However, despite this low risk and that the product used testing negative for prion proteins there is a minimal but definite risk of transmitting Bovine Spongiform Encephalopathies with transplant of donor tissue.

If there are any adverse events or adverse reactions with this tissue, please contact the Lions NSW Eye Bank immediately. All events and reactions will be investigated to improve product safety.

If you have any other concerns regarding this tissue product, please contact the Lions NSW Eye Bank:

Lions NSW Eye Bank
Level 1, North Block
Sydney & Sydney Eye Hospital
8 Macquarie Street
Sydney NSW 2001
Tel. (02) 9382 7855
Fax (02) 9382 7274

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