



Bioethical Framework for Policy and Procedure 2015

**The Eye Bank Association of Australia and
New Zealand: Bioethical Framework 2015 ©**

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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. EBAANZ is dedicated to helping restore sight, providing national and international leadership and standards for eye banking, and advocating 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.

The EBAANZ bioethical framework for policy and practice

Preamble

Australia and New Zealand (ANZ) enjoy the privilege of well-established eye bank organisations and strong health care systems providing access to high quality ophthalmology services for their populations. ANZ professionals working in eye banking continue to advance their individual and regional practice while contributing to the development of the international eye banking sector, through their involvement in initiatives such as the *Global Alliance of Eye Bank Associations* (GAEBA), professional organisations such as the *Eye Bank Association of Australia & New Zealand* (EBAANZ), and their participation in other professional groups and activities. In the course of these domestic and international interactions, members of the ANZ eye banking community have identified opportunities to enhance their own practices and to contribute further to the development of ethical and effective programs of eye banking internationally. The development of an EBAANZ Bioethical Framework was proposed to provide support and guidance for members with responsibility for procurement, processing, distribution, or use of human ocular tissue within ANZ and internationally.

Policy and practice within ANZ is governed by various national and state legislation, in particular the various state and territory *Human Tissue Acts* in Australia¹ and the *Human Tissue Act* (2008) in New Zealand. Guidelines for ethical practice in procurement of human tissue after death including corneas are provided by Australia's National Health and Medical Research Council's (NHMRC) Guidelines: *Organ and Tissue Donation After Death, For Transplantation – Guidelines for Ethical Practice for Health Professionals* (2007),(4) and in New Zealand, through the Human Tissue Act 2008. These and other resources aim to ensure the protection of deceased donors, and to optimise the safety and quality of transplanted tissue for the benefit of recipients.(8,10)

While the primary responsibility of EBAANZ is towards members of the ANZ community, EBAANZ recognises professional responsibilities to foster the development of eye banking globally, and to reduce the burden of treatable and preventable blindness across the world. This accords with the mission of such international initiatives as the Millennium Development Goals, and *Vision2020 (and Vision2020Australia)* - which is a joint program of the *International Agency for the Prevention of Blindness* and the *World Health Organization (WHO)* who collectively developed the *2014-2019 Global Action Plan: Towards Universal Eye Health*. Furthermore, increasing globalisation has led to considerable growth in the international movement of patients, professionals and human tissue products. In this context, existing guidance for domestic practice may be insufficient for professionals confronting ethical issues in the transnational setting. With occasional export or import of ocular tissue and derived products by members of EBAANZ, a framework for governance of these activities in particular is a necessity. Finally, EBAANZ acknowledges concerns raised by international case reports of trafficking, tampering and counterfeit activities in ocular tissue. EBAANZ seeks to contribute to emerging international efforts by health authorities, professional organisations and others by helping to establish effective systems and tools of global governance that will promote effective implementation of ethical practice and policy in accordance with the highest professional standards.

¹ *Transplantation and Anatomy Act* 1978 (2014) ACT, *Human Tissue Act* 1983 No 164 (2013) NSW, *Transplantation and Anatomy Act* (2014) NT, *Transplantation and Anatomy Act* 1979 (2013) QLD, *Transplantation and Anatomy Act* 1983 (2014) SA, *Human Tissue Act* 1985 (2012) TAS, *Human Tissue Act* 1982 (2014) VIC, *Human Tissue and Transplant Act* 1982 (2010) WA, *Human Tissue Act* 2008 (2013). See p. 10 for a list of the Acts.

This Framework is inspired by the 2008 *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*,⁽⁵⁾ which was developed under the leadership of The Transplantation Society and the International Society of Nephrology, and is informed by the 2010 *WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation*,⁽⁸⁾ the 2007 World Medical Association (WMA) *Statement on Human Tissue for Transplantation*,⁽¹⁰⁾ and the 1948 *Universal Declaration of Human Rights*.⁽⁶⁾ It is intended to contribute to developing work by the WHO towards a global consensus on ethical governance, vigilance and safety, and universal coding for medical products of human origin (MPHO).⁽⁹⁾

The Framework was developed in consultation with representatives from all EBAANZ jurisdictions where eye banks are located, including: Australia (AU): New South Wales (NSW), South Australia (SA), Queensland (QLD), Victoria (VIC), Western Australia (WA), and Auckland, North Island, New Zealand (NZ), and represents the consensus of participants at the EBAANZ AGM held on the 4th March 2015 in Perth, and those involved in the development through the Framework Working Group. It provides a framework to guide and govern professional activities in the procurement, processing, distribution and clinical application of human ocular tissue. The scope of this framework is further intended to include procurement, processing, distribution and clinical application of other medical products of human origin, where this application constitutes delivery of ophthalmological services, such as amniotic membrane transplantation.

Each EBAANZ member is responsible for their individual implementation of the EBAANZ Framework within their organisational policies and standard operating practices and for ensuring staff working for or with an EBAANZ member eye bank within ANZ, or internationally, uphold the principles outlined in this Framework.

Principles

1. The primary objective of EBAANZ activities should be to promote the wellbeing of recipients of human tissue for ocular application (HTO) within ANZ, and to protect the interests of donors and their communities.

Proposed strategies:

- Procurement of HTO should at all times be consistent with recommendations outlined in section 4.3 of the NHMRC (2007) guidelines: *Organ and Tissue Donation After Death, For Transplantation – Guidelines for Ethical Practice for Health Professionals*;(4)
- Guidelines for the ethical procurement of placental tissue and amnion, including requirements for informed consent, should be established in conjunction with relevant obstetric and midwifery experts;
- EBAANZ should support donor advocacy activities and public education in collaboration with individual eye banks and health authorities.

2. BAANZ members will work together and may collaborate with local, national and international agencies, both governmental and nongovernmental, in supporting the development and implementation of eye banking programs and related activities aiming at the promotion of improved ocular health and sight restoration.

3. EBAANZ members shall strive to ensure that their practice and policies are consistent with existing state or national legislation and regulations governing the recovery, processing and release of HTO, and consistent with evidence-based best practice standards and recommendations.

4. During periods of insufficiency in supply, HTO for transplantation should be equitably allocated within ANZ to suitable recipients without regard for gender, ethnicity, and religion, social or financial status. Allocation criteria and policy should be transparent and informed by evidence, consistent with ANZ legislation and national guidelines.

Proposed strategies:

- Members are encouraged to seek support from community and governmental agencies to assist in development and maintenance of resources required for best practice in service delivery, including:
 - (i) programs and educational tools for staff training and professional development;
 - (ii) policies and standard operating practice guidelines;
 - (iii) data collection tools and programs for ongoing evaluation of practice and performance.

5. Where HTO become a source of financial gain or comparable material advantage, this compromises respect for human dignity, autonomy, and the wellbeing of donors, their families, and the recipients of these tissues, and violates the principles of equity, solidarity, and altruism that underpin the public donation of these resources.

Financial gain in HTO is prohibited in ANZ according to the Human Tissue Acts, consistent with the WHO *Guiding Principles on Human Cell, Tissue and Organ Transplantation*.(4)

Proposed strategies:

- (i) Where prospective donors include "vulnerable individuals or groups (such as intellectually or physically disabled, illiterate and impoverished persons, undocumented immigrants, prisoners, displaced persons and political or economic refugees)",(5) additional care should be taken to ensure the absence of exploitation, coercion, or other practices that may constitute human trafficking or illicit trade in HTO;
- (ii) Financial considerations or material gain of any party must not influence the allocation of HTO, nor override primary consideration for the health and wellbeing of donors and recipients;
- (iii) The prohibition of financial gain does not preclude the recovery of costs incurred in the procurement, processing, transfer, preservation, storage, distribution or clinical application of these tissues and their derived products, with the condition that such cost recovery does not exceed standard fees for services which should be transparently declared and subject to independent oversight and review.

6. Trafficking, tampering and counterfeit activities in HTO endanger donors and recipients of these tissues, and violate the principles of this framework.²

Trafficking in human tissue for ocular application includes the following practices:

- (i) illicit removal of HTO, inclusive of removal without the valid consent of a living donor; removal from a deceased donor without family consent other than as authorized under domestic law; removal where a living donor or a third party has been offered or received a financial gain or comparable advantage;
- (ii) use, preparation, preservation, storage, transportation, transfer, receipt, import and export of illicitly removed HTO;
- (iii) solicitation or recruitment of donors of HTO, where carried out for financial gain or comparable advantage;
- (iv) promise, offer, gift, request or receipt of any undue advantage, by healthcare professionals, eye banking professionals, public officials, or persons who direct or work for private institutions, for the illicit removal of ocular tissue or amnion or for the use of such tissues where these have been illicitly removed;
- (v) Forgery, falsification or otherwise tampering with packaging, labeling and documentation which alters, conceals or otherwise misrepresents critical information such as: origin, donor history, authorisation of donation, eye bank identification, tissue quality, processing date and cell count.

Tissue Labeling Recommendations:

- a. Standardisation of labeling, tracking and documentation requirements for procurement, processing, distribution and use of HTO is recommended;
- b. Where concerns are raised about documentation or labelling, especially in the context of international transfer of HTO, further information should be sought from providers and concerns should be promptly communicated to EBAANZ and appropriate authorities where relevant.

² The definition of trafficking used in this Framework is based on the 2014 Council of Europe Convention against Trafficking in Human Organs as described in (3).

7. Transparency of policy and practice is essential for institutional and professional accountability and enables the safe, effective and ethical conduct of activities related to HTO. Information collection and review enables ongoing evaluation to enhance quality and safety in the achievement of best practice goals.

Proposed strategies:

- (i) Maintain open communication within the EBAANZ community regarding HTO procurement, exchange, and utilization, and in particular, concerning:
 - a. Local and national surplus tissue and estimates of future transplant needs;
 - b. Export and import data, inclusive of all partnership activities that may be external to current EBAANZ data groups;
- (ii) Maintain support for the Australian Corneal Graft Register (ACGR);
- (iii) Prompt reporting of all adverse events, effects and potential risks encountered to the EBAANZ data registries, and communicate, where relevant, to the international NOTIFY library - www.notifylibrary.org.

8. Jurisdictions in which EBAANZ members or their regional partners are located should strive to achieve self-sufficiency in donation and transplantation of HTO by providing a sufficient number of tissues for residents in need from within their jurisdiction, or through regional cooperation. Collaboration between jurisdictions is not inconsistent with pursuit of self-sufficiency, as long as the collaboration protects the vulnerable, promotes equity between donor and recipient populations, fosters eye bank sustainability, and does not violate the principles of this Framework. Treatment of patients from outside the jurisdiction is acceptable if it does not undermine a jurisdiction's ability to provide services for its own population.

Proposed strategies:

- (i) Any HTO remaining once local and national ANZ needs have been met may be exported outside of ANZ, within eye bank policy and the legal requirements of export and import locations, and prior to tissue expiration;
- (ii) ANZ eye banks that partner with external eye banks or programs shall seek to ensure they have established an exit strategy and/or the provision of capacity building – strengthening – activities, within their agreement, to promote the long term self-sufficiency of each party;
- (iii) Capacity building activities may include support of local health services, and development and/or implementation of public education and advocacy activities;
- (iv) Where ANZ provides HTO to external partners or for clinical application in foreign patients who travel to ANZ for this purpose, service provision may be provided free of charge (as part of compassionate access or humanitarian programs) or at cost.

9. EBAANZ members recognize their ethical responsibility for procurement, processing, distribution or use of HTO entrusted to them, including where these materials or derived products are imported or exported beyond jurisdictional borders.

Proposed strategies for governance of transnational activities:

- (i) Members are encouraged to inform EBAANZ and seek review of requests for HTO that originate outside of ANZ prior to establishing tissue transfer agreements with non-ANZ institutions or service providers. A mechanism to facilitate reporting and guidelines to assist review of such requests should be developed by EBAANZ;
- (ii) Tissue transfer agreements should be in place between the eye bank and any partners prior to any exchange of HTO. For international partnerships, this may include an agreement with a humanitarian group, ministry of health, and/or local hospital or eye bank. Agreements should address such elements as:
 - a. cost-recovery, if any, and shall exclude profit;
 - b. short term and - where relevant and feasible - long term outcomes of partnerships, and mechanisms for monitoring and reporting the long term follow-up care of the recipients, plans for which must be considered prior to tissue release, with confirmation that care is to be provided by suitably qualified and competent health professionals trained in management and use of these tissues for their intended surgical application;
 - c. prior evidence and/or supportive documentation outlining development of appropriate policies and standard operating practices with the partner organisation/s involved in receiving, storing and distributing HTO that is to be introduced to or released from ANZ.
- (iii) Submit import and export data, outlining international origins and destinations, to the EBAANZ registry;
- (iv) Respect reciprocal laws, and ensure all activities operate in accordance with relevant ANZ legislation;
- (v) Efforts to achieve the best possible standards of practice should be made, and activities should only take place where there is evidence to assure sufficient standards of quality and safety of practice to protect donors and recipients of HTO.

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Key Definitions

Amnion – a membrane sac that protects the human embryo, which is recovered from the placenta at the time of delivery and processed into material suitable for ocular surgery transplantation.

Cost-recovery – the recovery of costs incurred through provision of eye bank services, where payment of costs does not represent a financial gain (profit) deriving from the human body or its parts.(8)

Ocular Tissue - the whole eye or any of its components including the corneo-scleral rim, sclera, optic nerve, and macula.

Preparation of the Framework

During the EBAANZ AGM on March 5th 2014, held at the Queensland Eye Hospital, Brisbane, Queensland, Australia, agreement was made regarding the development of a bioethical framework for governance of eye banking activities and the inclusion of a bioethical statement at the beginning of the existing EBAANZ Medical Standards Document.

Stage 1:

EBAANZ representatives Graeme Pollock and Heather Machin met with bioethicist Dominique Martin in March 2014 to establish a plan for development of the Framework. Subsequently, a draft Framework was prepared for review by EBAANZ members. All EBAANZ members were invited to participate and those who were interested in becoming involved became participants in the Bioethical Framework Working Group.

Stage 2:

June-August 2014: The Working Group participants commenced the development of the framework's principles, in collaboration with the Bioethicist. They also agreed to invite none-EBAANZ professional representatives to participate in order to ensure the framework was considerate of the wider eye care and medical community.

Stage 3:

September-December 2014: Principles and strategies were reviewed, revised and a draft approved by members of the Framework Working Group.

Stage 4:

January – February 2015: Final draft prepared by the steering committee.

Stage 5:

March 4th 2015: Official ratification by EBAANZ Committee and members attending the Perth, Western Australia, EBAANZ Meeting on Wednesday 4th March 2015 (held in conjunction with the 32nd Annual Corneal Conference).

Participants in the Bioethical Framework Working Group

The Bioethical Framework Working Group included representatives from all EBAANZ jurisdictions (AU: NSW, SA, QLD, VIC, WA, and NZ). Members of the group included both directors and staff who collectively represent scientists, ophthalmologists, donor-collectors, nurses and technician perspectives. Their input was supported by invited external key professional representatives.

Steering Committee:

- Machin, RN Heather- Project Officer to EBAANZ and GAEBA. Lions Eye Donation Service, Centre for Eye Research Australia, University of Melbourne
- Martin, Dr Dominique– Bioethicist. Lecturer in Health Ethics, School of Population and Global Health, University of Melbourne. Dr Martin is a member of the Declaration of Istanbul Custodian Group and co-chair of The Transplantation Society Ethics Committee
- Pollock, Dr Graeme– Representative EBAANZ and GAEBA. Director, Lions Eye Donation Service, Centre for Eye Research Australia, University of Melbourne

EBAANZ Members:

Eye Bankers:

- Buckland, Lisa – Manager, Lions Eye Bank of Western Australia, WA
- Fuller, Carla – Donor Coordinator, Queensland Eye and Bone Bank, QLD
- George, Pierre – Team Leader, NSW Lions Eye Bank and Bone Bank, NSW
- Miles, Kendall – Coordinator, NSW Lions Eye Bank and Bone Bank, NSW
- Moffatt, Louise – Manager, New Zealand National Eye Bank, NZ
- Nuttall, Nicholas – Director, Queensland Eye and Bone Bank, QLD
- Philpott, EN Margaret – previous Manager, Eye Bank of South Australia, SA
- Pulbrook, Stephen – Manager, Eye Bank of South Australia, SA
- Treloggen, RN Jane – Manager, NSW Lions Eye Bank and Bone Bank, NSW

Ophthalmologists (Eye Bank Medical Directors and members of RANZCO):

- Mills, Dr Richard – Eye Bank of South Australia, AU
- Pendergrast, Dr David – New Zealand National Eye Bank, NZ
- Sutton, Dr Gerard – NSW Lions Eye Bank and Bone Bank, AU

Invited External Professionals:

- England, Dr Peter: Obstetrician, Fellow, Royal Australian and New Zealand College of Obstetricians, St Vincent’s Hospital, VIC, AU
- Schlenther, Dr Gerhard: General Manager, Policy and Development, Royal Australian and New Zealand College of Ophthalmologists (RANZCO), NSW, AU



**Agreement of the Eye Bank Association of Australia
and New Zealand's Bioethical Framework 2015.**

On behalf of: (Name of eye Bank) _____, I (Name of Representative) _____, agree to endorse the principles of the Bioethical Framework of the *Eye Bank Association of Australia and New Zealand*.

Signature: _____ Date: _____
(Please ensure each page is initialed and dated)

Witness Signature: _____

Witness Name: _____ Date: _____