Lions Eye Donation Service
MELBOURNE

July 4th 2025

Australian Law Reform Commission: Review of the Human Tissue Laws

LEDS Response to Issue Paper 51 (May 2025).

Dear Review Committee,

Thank you for the opportunity to provide comment on Issue Paper 51 (May, 2025) regarding the review of the Australian Human Tissue Laws. This review is timely and important for donors, donor families, recipients and those working in the sector.

Lions Eye Donation Service (LEDS) at the Centre for Eye Research Australia (located within the Royal Victorian Eye and Ear Hospital) Melbourne, is the primary agency involved in the recovery of consented eye donations from Victorian and Tasmanian donors, and the allocation of their donations towards transplant, training, service validation and research use around Australia and New Zealand. LEDS is licensed to provide ocular human biologicals for therapeutic purposes through the Therapeutic Goods Administration (TGA) and prepares those donations in accordance with the relevant therapeutic goods orders and good manufacturing practice standards.

LEDS wishes to provide the following response to the Commission's Issues Paper.

1. We agree with the Commission's statements regarding the outdated nature of the tissue Acts across Australia and the need to both up-date the Acts and harmonise them across the nation.
2. Such up-dates must align (harmonise) with the NHMRC *Ethical Guidelines for cell, tissue and organ donation and transplantation in Australia*, as well as any WHO, OECD and other guiding documents for the donation recovery and allocation toward transplantation and other non-therapeutic (non-transplant) activities e.g. research, training and eye bank service validation.
3. Such up-dates and harmonisation must be designed to increase access to donation options for Australians and improve the allocation to Australians across urban, rural and remote areas.
4. Donations must be managed and treated as a common good for the collective benefit of all, meaning the laws must restrict for-profitsation.
5. As the sector and biomedical technologies advance, the laws must support the Australian providers (e.g. eye and tissue banks) to be part of the advancements but ensure that their activity and/or the activities of biotechs that seek access to donations with the intent to commodify and/or commercialise from the donation, are accountable, monitored and required to report their activities transparently, at the federal level, with their profitisation from donors restricted.
6. Future donations that are moved through future therapy/biotech pathways must be ethically consented to ensure donor wishes and societal expectations of the management and use of their donations, in those therapies, is upheld and honoured.

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7. The perception of cellular therapies must expand past stem cells to include the full range of potential cellular types and uses in the eye and tissue field (e.g. corneal cells, including autologous cellular therapy use) to ensure a broader range of potential cellular activities are captured and supported within the laws and guidelines.
8. Harmonisation must include the recovery of donations for the purposes of use in training, service validation and research – which are not universally outlined in the current Acts but remain critical to the service and the broader advancements of the healthcare system (e.g. prevention through new treatments developed with research tissue).
9. The use of human donations in animal model research must also be considered, with laws and/or NHMRC research guiding documents (for both human and animal) providing a greater degree of guidance to the sector on management, consent and appropriate allocation in these circumstances.
10. Non-profit eye and tissue banks, which work within societal expectations and those of the NHMRC ethical guidelines and their Act, must be protected and supported to ensure their viability and sustainability.
11. For-profit banks and subsidiaries, and those in the biotech space that access donations – that are mostly sourced from public hospitals and through banks supported by the State/Territory governments, must be required to submit their data and financial statements to the jurisdiction they operate within, as well as federally.
12. Regardless of whether a service or organisation is the recovering agent or a processing agent, or importer, or exporter or a combination of all, their data must be reported federally. This is regardless of non-profit or for-profit status.
13. There needs to be greater transparency from services and organisations that import and/or export tissue across international borders. Such activities must automatically require federal reporting, regardless of the bank's status of non-profit or for-profit.
14. The changing nature of donation needs to be considered, e.g. the anticipated increase in Voluntary Assisted Dying (VAD) programs. Alignment with VAD Acts is therefore necessary.
15. In terms of the review process:
    a. We advocate for a non-profit eye and/or tissue bank representative to be engaged on the Commission's working group, as currently there are no representatives from this group on the panel. As the largest sector group to be impacted by changes to the laws, their input is essential.
    b. It would be prudent to include a sector representative from the sectors professional bodies, the Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand.
    c. We note that the references in Issue Paper 51, and its commentary, refer to organs, which are outside the scope of the review. We would recommend this be altered in the next stage of the review to reflect eye and tissue matters, references and recommendations.

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Commission's Questions:

1. What is your personal experience of how human tissue is obtained or used in Australia?

   LEDS Response

   LEDS is a non-profit eye bank, which is a Custodian of the gift of donation. LEDS works with donors, donor families and affiliated healthcare and eye/tissue services to recover donations and prepare them for allocation to therapeutic and non-therapeutic use. LEDS also manages the CERA Biobank. LEDS works closely with all its end users. LEDS works with the Organ and Tissue Authority as a member of their Eye and Tissue Advisory Committee as well as being a core member of the Eye Bank Association of Australia and New Zealand. LEDS is actively engaged in the local, national, and international sector.

2. What is your personal experience of how human tissue laws work in Australia?

   LEDS Response

   As a service provider and Custodian of the donation, LEDS works within the human tissue laws of Victoria and Tasmania. The laws underpin the service at every point. The laws are not prepared for the emergence of future therapies (cellular, bioengineered) in the field, and the growth of demand for tissue for non-therapeutic purposes.

3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?

   LEDS Response

   LEDS agrees with the proposed points. The laws must ensure the donation remains as a common good for the benefit of all, and in during so, must ensure eye and tissue banks have the space and resources they need to develop and evolve their service to meet changing technologies and demands, and must be supported to do so within the confines of the ethical principles which govern the field.

4. When we think about reforming human tissue laws, what principles should guide reform?

   LEDS Response

   LEDS supports the points raised by the review, with public trust at the forefront. This is because without public trust the sector falls down. Therefore non-ethical providers pose a potential threat to the sustainability of the service. The laws must support the sector to advance and do so by meeting the recommendations of the NHMRC, OECD and WHO.

The principles of fairness should be applied to both the recovery and allocation of the donation and the ability of the sector to flourish. Guiding frameworks, as identified in Issue Paper 51 (e.g. the Barcelona Principles) will help guide the review.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry?

   LEDS Response

   Yes, we agree with the focus points. These could be expanded. Please see our comments throughout this submission to help guide the next review period, as several sub-elements we share are not included in Issue paper 51 but would benefit from being evaluated and considered in the review's discussion round.

6. What, if any, other issues should we be focusing on in this Inquiry?

   LEDS Response

   Please see our overview above which outlines several pinch points that would value exploration.

7. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

   LEDS Response

   Issue paper 51, while comprehensive, provides commentary on organs, and uses organ references, guidelines, and practices. These are valuable but they are, in many instances, outside of the scope of this review – unless discussing a multi organ-eye-tissue donation. As organs are not regulated, but tissues are, then the use and/or focus on those aspects and guidelines will not provide effective coverage of the issues at hand. We, therefore, recommend the inclusion of eye and tissue (and other human biological) specific references and engagement to provide effective reform of this specific field.

8. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

   LEDS Response

   These are all important matters that require review, however we agree that they are outside of the scope of this review and should be examined in detail independently.

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Additional discussion:

1. In terms of imported donations, while the TGA effectively reviews and approves the medical suitability of imports, no governing agency and/or law is checking to ensure that the imports match the Australian laws and ethical expectations of Australian society. For example, Australia has no transparency in terms of ensuring imports are meeting other expectations, e.g. modern slavery – which may present in this field as counterfeit or by labelling the tissue based on its country or production, rather than country of donor origin. As Australia is a UN/WHO Member State it has a responsibility to ensure tissue coming into Australia is not in conflict with the related global principles (e.g. Sustainable Development Goals).
   Additionally, Australia must consider its wider impact when it imports. For example, Australia as a high resource nation, at the top of the human development index, has the resources to develop its own sustainable service and should not be reliant on imports. For every import that Australia takes, it is one import that does not make it to someone else, in a low-middle resource nation who does not have the same access to resources as Australia. For Australia to maintain its position as a responsible regional and global nation, helping to shape international development, then it's allowance of imports into Australia, at the detriment to the growth of the Australian sector and the detriment to low-middle resource nations, needs to stop. Similarly, as a responsible nation, Australian eye banks (and other human biological providers) should be supported to help people in low-middle resource nations through a transparent and ethically managed Australian export program. Such a program must be done without Australian access being compromised and managed in line with international development best practices.
   There are also imports that come in through medical supply companies (e.g. dry amnion that is supplied to optometrists) that do not move through an Australian eye or tissue bank and thus Australia may not be capturing these types of activities when presenting its total data sets. Similarly other tissue coming in through a surgeon initiated 'special access scheme' request, while approved by the TGA, may not be tracked in the human transplant data sets.
2. While outside of this review, it may be valuable to develop frameworks or greater guidance around what recipients of the donations are informed of. For example if their donation is animal or human (e.g. bone for dental work) or imported. As consents tend to occur at the practice level it is difficult to determine what Australian recipients know about the donation they receive and/or if they would object to receiving the donation if they knew its origin.

Thank you for this opportunity to participate in the review. LEDS welcomes the opportunity for further engagement.

Regards

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