Australian Law Reform Commission (ALRC) Review of Human Tissue Laws Stakeholder Submission

Submission by: Australian Centre for Transplantation Excellence and Research (ACTER), Austin Health, 145 Studley Road, HEIDELBERG VIC 3084

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Introduction

The Australian Centre for Transplantation Excellence and Research (ACTER) at Austin Health welcomes the opportunity to provide input to the Review of Human Tissue Laws. We commend the Commissioner and her team for their consultative approach and engagement with the transplantation community, including through forums such as the TSANZ Annual Scientific Meeting.

Austin Health delivers comprehensive transplantation programs encompassing haematopoietic stem cell transplantation, kidney, liver, and intestinal/multi-visceral transplantation. We host the Victorian and Tasmanian Organ Retrieval Service, providing abdominal organ retrieval across Australia's largest jurisdiction by volume. Our centre has conducted over 200 clinical abdominal organ *ex situ* machine perfusions to date as part of a program of clinical innovation and research in this field.

We also host the Australian Donation and Transplantation Biobank (ADTB), a collaborative national program that facilitates ethically approved research use of donated organs and tissues, underpinned by informed consent from donors or their families and a strong governance framework to ensure alignment with ethical standards and donor wishes.

Clinical, research, policy, innovation, and advocacy activities in transplantation at Austin Health are integrated under the Australian Centre for Transplantation Excellence and Research (ACTER) at Austin Health.

This submission responds to the ALRC Issues Paper, particularly Questions 3 and 4 on aims and principles, and Questions 5 and 6 on priority reform areas. It draws on our operational, clinical, and research experience in transplantation.

While our comments are based on the Victorian *Human Tissue Act 1982*, we support efforts to achieve national consistency across all jurisdictions to support operational consistency (especially for multi-jurisdictional transplant and retrieval services like ours), equity of access, and implementation of national best practice standards.

We recognise that human tissue laws must uphold equity, respect for persons, and public trust, to ensure that all Australians benefit from donation and transplantation practices that are safe, effective, ethically grounded, and culturally respectful.

Living Donation

Adult Living Kidney Donation

The provisions of the Act regulating adult living kidney donation are appropriate and align with safe, ethical practice. The 24-hour cooling-off period does not pose operational barriers in our program, as sufficient time is generally available to meet this requirement even in paired exchange or desensitisation pathways.

However, the wording of consent and certification requirements is legalistic and not clinician-friendly, creating risks of misinterpretation. While we are compliant at Austin Health, we note that there may be variability in certification processes nationally. Clarifying statutory wording to ensure consistent implementation nationally would strengthen adherence to the requirements.

Adult Living Liver Donation

In relation to adult living liver donation, the Act does not explicitly classify the liver as regenerative or non-regenerative tissue. While the liver has regenerative capacity, living liver donation carries risks comparable to non-regenerative tissue donation. Our program applies non-regenerative tissue consent safeguards to liver donors for consistency and safety. In emergent, life-saving scenarios, the 24-hour cooling-off period can create logistical challenges. Legislative flexibility to permit a reduced cooling-off period (e.g. minimum 12 hours) in such circumstances could balance donor protection with clinical urgency. This flexibility should be implemented consistently across jurisdictions to ensure equitable and timely access to life-saving transplantation.

Regenerative Tissue Donation and Cellular Therapies

For regenerative tissue donation, such as bone marrow and peripheral blood stem cells, the current consent and certification processes function effectively. However, as emerging cellular therapies develop, including the use of donated samples to create induced pluripotent stem cells (iPSCs) for therapeutic purposes, it will be important for the Act to provide clear consent pathways. In particular, donors should be able to give informed consent that distinguishes between use for research, therapeutic treatment, and potential commercial applications.

Future technologies such as xenotransplantation, bioengineered organs, and organoid-derived transplantation products may further blur existing legal definitions of tissue and organ, and anticipatory legal and ethical frameworks could be considered by the Inquiry.

Tissue Donation by Children

We have no direct role in tissue donation by children and do not propose a position on these provisions.

Blood donations

Whole Blood Retrieved from Deceased Donors

We do not propose a position on provisions relating to blood donations and transfusions outside the context of transplantation. However, we note that whole blood retrieved from deceased donors is increasingly sought to support transplantation activities, such as

serving as perfusate in *ex situ* machine perfusion. This practice is distinct from standard blood banking, as the blood is used primarily for organ perfusion, preservation, and viability assessment rather than transfusion into recipients. To better reflect this practice, we recommend that the Act explicitly include the retrieval and use of blood from deceased donors within the definition of tissue retrieval, providing clarity for its use in organ preservation and assessment.

Donations after death

Ante-Mortem Procedures

The transplant programs at Austin Health rely on ante-mortem procedures to determine donor and organ suitability and ensure recipient safety.

Noting the emergence of normothermic regional perfusion as a standard of care in organ retrieval, along with the need to manage donor cancer risk, ante-mortem biopsies (e.g., biopsies of skin lesions) or vascular access placement (for normothermic regional perfusion), while not blocked by the Act, are not explicitly included in Section 24A definitions, creating interpretative ambiguity. Permitting such procedures, where clinically appropriate and supported by national or state policies, would support optimal outcomes.

Access to Donor Medical Records

Access to donor medical records, including My Health Record, are increasingly relevant as part of the donor suitability assessment. Current Commonwealth legislation may restrict DonateLife staff from accessing My Health Record where donors are unknown to the health service or have not provided prior consent. The Inquiry should consider legal pathways to support timely access to medical information stored within the My Health Record.

Designated Officer Authorisation

We do not propose a position on designated officer authorisation, next of kin consent, or coroner processes, which are operationally managed by DonateLife and donor teams. We would be pleased to facilitate access to hospital designated officers should the Inquiry wish to engage directly with them.

Post-mortem examinations

Ex Situ Organ Perfusion

Ex situ organ perfusion assessments and pre-implantation biopsies (biopsies performed after the organ has been retrieved to inform decisions regarding viability for transplantation) are important elements of contemporary transplantation practice. These should be clearly permitted under the Act as part of the organ retrieval and assessment process.

Austin Health has a large, comprehensive and contemporaneous experience in *ex situ* abdominal organ machine perfusion for clinical care. Assessments performed on perfused organs, including functional, biochemical, imaging, and histopathological evaluations, are essential to inform suitability and should be legislatively recognised as part of the retrieval and assessment continuum.

Emerging *Ex Situ* Therapies

Emerging *ex situ* interventions, such as defatting, immunomodulatory therapies, other drug treatments, and enzymatic blood group conversion, will increasingly be performed at transplant centres or dedicated perfusion facilities. In future, these interventions may extend to include gene therapy delivered via perfusion, including scenarios involving autologous transplantation where a living donor is also the recipient of the treated organ.

Currently, the Act does not specify responsibility or ownership of organs after donation, creating ambiguity in decision-making for such interventions. We propose that, once procurement is complete (i.e., donation has occurred), ownership of the organ transfers from the donor to the Organ and Tissue Authority, which can then assign responsibility to retrieval or transplant services for these activities.

Ethical frameworks for consent to *ex situ* therapies are being developed. We propose that consent for these interventions be provided by recipients rather than donors or donor families, as the delivery of these therapies is often temporally and geographically separate from the donation event, and their impact is primarily relevant to the recipient.

Donor DNA for Post-Donation Diagnostics

Donor DNA is obtained and stored as part of tissue typing procedures by Lifeblood and other tissue typing laboratories. Access to stored donor DNA is going to be increasingly important for emerging diagnostics such as cell-free DNA chimerism testing, which quantifies donor and recipient DNA in blood to monitor graft health, rejection, and function following transplantation. Stored donor DNA may also support assessment of donor-derived cancers or other pathology relevant to recipient care. Austin Health research groups have expertise on these diagnostics. The Act should not preclude access to DNA for these post-donation diagnostic purposes within ethical and policy frameworks.

Research Use of Donated Organs and Tissues

Finally, while the Act permits the removal of tissue for 'medical or scientific purposes' with appropriate consent, it does not explicitly define research use of donated organs and tissues or establish a dedicated framework for such use. This creates interpretative uncertainty regarding the permissibility, scope, and governance requirements for research activities using donated tissues that are not intended for transplantation. We recommend that the Act clearly permit research use of donated tissue where there is no transplantation purpose, supported by explicit donor or family consent and ethical governance frameworks.

Schools of anatomy

The transplant programs at Austin Health do not operate a school of anatomy and we do not propose a position on these provisions.

Trade in tissue

Kidney Exchange Programs

We support legislative clarification to explicitly exempt kidney exchange programs from trade prohibitions, avoiding reliance on ministerial exemptions and ensuring legal certainty for this practice.

Cost Recovery Models

Similarly, cost recovery models for research use of organs and tissues, such as those employed by the ADTB, should be clearly permitted under the Act, recognising that charging reasonable costs for procurement, processing, administration, and transport does not constitute prohibited trade. We propose the addition of "evaluation" to the list of cost recoverable activities.

Reimbursement of Living Donor Expenses

We strongly support the Act's retention of provisions permitting reimbursement of living donor expenses, ensuring donors are not financially disadvantaged. This should explicitly include evaluation and assessment costs incurred in determining donor suitability, organ suitability and tissue compatibility.

Definition of death

We note that the current statutory definition of circulatory death as 'irreversible cessation' differs from clinical practice, which uses 'permanent cessation'. This discrepancy makes existing clinical application of donation after circulatory death legally ambiguous and prohibits implementation of normothermic regional perfusion under current definitions.

We agree with the ALRC's identification of the definition of death as a priority reform area and support amendments that align with clinical practice, ethical standards, and international norms.

There is compelling emerging evidence that normothermic regional perfusion improves the quality and viability of organs donated after circulatory death, enabling donors and their families to realise their altruistic intent while supporting improved outcomes for recipients and delivering broader health system benefits. Legislative clarification is therefore a high priority for transplant services who are involved in abdominal organ retrieval.

Miscellaneous provisions

We do not identify operational barriers relating to disclosure provisions or the offence and penalty framework. We support a clear and enforceable legal framework to protect donors, recipients, and public confidence.

Conclusion

We support a legislative framework that enables innovation, provides operational clarity, and maintains public trust, recognising these as essential foundations for ethical, effective, and sustainable transplantation in Australia.

We commend the Inquiry for its thorough and consultative approach. We remain willing to engage further to share our expertise in:

- Organ retrieval
- Donor suitability assessment
- *Ex situ* machine perfusion and emerging interventions
- Procurement and use of organs for research
- Multi-organ transplantation

We note the importance of aligning reforms with international best practice, WHO principles, and ethical frameworks to maintain Australia's standing in global transplantation and donation standards. This will also ensure that laws remain responsive to emerging technologies and future clinical innovations.