Bayside Health

Submission to the Australian Law Reform Commission (ALRC)

Discussion Paper 90: Review of Human Tissue Laws (2025)

Date: 3 February 2026

Contact: Dr Dashiell Gantner, Medical Donation Specialist — The Alfred

Submitted by: The Alfred (Alfred Care Group, Bayside Health), Victoria

Submission to the Australian Law Reform Commission (ALRC)

Discussion Paper 90: Review of Human Tissue Laws (2025)

February 2026

Executive Summary

The Alfred Hospital is a quaternary referral centre for trauma, neurocritical care and transplantation, including the Australia's largest thoracic organ transplant program. As a high-volume donor and transplant service, reforms to human tissue laws, particularly those relating to death determination, consent and authorisation, donation pathways, and emerging technologies, will have significant clinical and operational implications for our organisation.

We strongly support the development of a single, nationally uniform legislative framework for organ and tissue donation and transplantation. National consistency is essential to enable interstate donation, support visiting retrieval teams, reduce legal ambiguity, and maintain efficiency in time-critical clinical environments.

We also support an equity-focused framework where this genuinely enhances opportunities and outcomes. However, equity should not be operationalised through rigid or prescriptive legislative requirements that inadvertently reduce organ utilisation, compromise clinical judgement, or increase waiting-list mortality - particularly within Australia's low-volume, geographically dispersed transplant system.

This submission highlights areas where aspects of the proposed reforms may create unintended consequences, including:

- A delay to highly time sensitive pathways, could be caused by the proposed statutory approvals or committee-based oversight, especially in paediatric and cardiothoracic transplantation.
- There is a risk of clinical rigidity or obsolescence due to proposed legislated requirements that prescribe clinical practice in areas of rapidly evolving technology or evidence.
- Constraints that reduce the flexibility necessary to maximise organ utilisation or respond to unforeseen clinical circumstances.

In areas where significant clinical, ethical, or technological uncertainty remains, we recommend a principles-based legislative framework. This could be supported by nationally consistent guidelines and professional standards that can evolved with practice, rather than codifying requirements that may become outdated or create barriers to future innovation.

The Alfred strongly believes that reform of human tissue laws should preserve the operational flexibility required for Australia's donation and transplantation systems to continue to evolve safely, ethically, and effectively, while maintaining public confidence in the integrity of the system.

Acronyms

ALRC – Australian Law Reform Commission

ANZICS – Australian and New Zealand Intensive Care Society

DCDD – Donation after Circulatory Determination of Death

DNDD – Donation after Neurological Determination of Death

ECMO – Extracorporeal Membrane Oxygenation

NRP – Normothermic Regional Perfusion

OTA – Organ and Tissue Authority

VAD – Voluntary Assisted Dying

Preface

For ease of review Alfred Care Groups response has been structured to reference the relevant sections withing the Human Tissue Laws Discussion Paper: noting that no comments are made on sections 13 to 16.

Summary of Recommendations

1. A nationally harmonized regulatory framework (Proposals 1-4)

- Adopt a nationally uniform legislative framework with a single national regulator, separate from the OTA to avoid conflicts of interest.

2. The Objects of Human Tissue Laws (Proposals 5-6)

- Frame equity to increase opportunity and outcomes without rigid mandates that lower utilisation or increase waiting-list mortality
- Avoid legislating detailed clinical practice in areas of evolving evidence; use principles-based legislation supported by adaptive national guidelines.

3. Removing Barriers and Promoting Equitable Access

- No additional comment.

4. Reforms Relating to the Definition of Tissue (Proposals 7–9)

- No comment.

5. Determination of Death (including Proposals 10 and 13)

- Proposal 10: Amend (Section Y (3)) to avoid requiring clinical brain function testing after valid death determination when artificial support exists solely for post-mortem organ preservation (e.g., NRP).
- Proposal 13: Modify to permit a certifying intensivist to participate in recipient care where roles are clearly separated and documented, consistent with ANZICS standards.

6. Reforms Related to Donation by Living Persons (Proposals 14-22)

- Explicitly preserve rare but life-saving 'domino' heart donation within living donation provisions.

7. Reforms Relating to Deceased Donation (Proposals 23–28)

- Address structural inequity between VAD and non-VAD end-of-life patients by enabling ethically governed pre-mortem interventions to support donation
- Proposal 23: Maintain a clear, uniform national hierarchy for consent/authorisation and provide clinician protections when honouring a deceased's documented wishes despite family objection.
- Retain the Designated Officer role and consider mechanisms for out-of-hospital deaths.
  Proposal 24: Develop nationally consistent VAD-donation guidance
- Proposals 26–27: Permit proportionate, reversible treatments in unexpected death solely to preserve donation opportunities, with safeguards.
- Proposal 29: Support national consistency on workforce and role delineation, ensuring accountability for any non-AHPRA participants

8. Reforms Relating to Tissue Donation for Research (Proposals 32–37)

- Ensure research provisions clarify scope (tissue vs solid organs) and remain proportionate, with HREC oversight to avoid unnecessary barriers

9. Reforms Relating to Donation and Use of Deceased Bodies (Proposals 38–39)

- No specific comment
- **10. Reforms Relating to Stored Tissue Collections**
- Frameworks should stay practical and proportionate, enabling ethical research without undue barriers while maintaining strong oversight for unforeseeable future uses of stored tissue.

11. Reforms Relating to the Prohibition of Trade (Proposals 40–45)

- The law should preserve the prohibition on organ trading while allowing support that reduces donor burdens and protecting clinicians who help patients access overseas transplants in good faith.

12. Reforms Relating to Information Disclosure and Sharing (Proposals 46–48)

- Preserve donor/recipient anonymity while enabling timely, secure inter-agency information flow; protect clinicians and recipients regarding confidentiality

1. A Nationally Harmonised Regulatory Framework (Proposals 1–4)

(See ALRC DP90 Ch.1, Proposals 1–4.)

We support Commonwealth legislation establishing uniform laws and regulations across Australia. Interstate movement of donor teams and organs remains essential to maximise heart and lung utilisation, both for jurisdictions without local programs and between transplanting states.

The development of donation after circulatory determination of death (DCDD) has highlighted jurisdictional variations that create challenges for visiting teams and, at worst, risk inadvertent breaches of local law. A single national framework, administered by a single national regulator, would resolve these issues.

Regulation should be undertaken by a single National Regulator that is independent of the OTA to avoid perceived conflicts and duplication. The OTA's core functions—coordination, promotion, education and system improvement—should be preserved without the additional burden of regulatory enforcement and/or creating the perception of conflict of interest.

We support referred legislation as the superior option to promote national uniformity, to and facilitate timely updates as practice evolves, improving efficiency and outcomes across the sector.

2. Objects of Human Tissue Laws (Proposals 5–6)

(See ALRC DP90 Ch.2.)

We consider that the objects of human tissue laws should be to support the maximum beneficial use of all suitable donor organs and tissues where ethical, clinical and regulatory standards are met.

We note repeated surveys indicate Australians broadly support donation and transplantation. The objects of the legislation should therefore strike a careful balance between respect for individual autonomy and the need for proportionate, ethically justified and time-critical interventions that preserve or optimise donation potential, including in the pre- and post-mortem setting (scenarios are described below and in later sections of this submission). An overly stringent legislative emphasis on individual autonomy, particularly if it implies prospective authorisation for each intervention, risks unintended consequences. In practice, this may preclude necessary action in time-critical circumstances, including in cases of unexpected deaths where there has not yet been opportunity to explore deceased donation wishes, thereby reducing organ utilisation and undermining the objectives of the donation system.

Pre-mortem donor evaluation and optimisation interventions may include tests, imaging, corticosteroids, and antibiotics; post-mortem organ optimisation may include in situ and ex situ regional perfusion.

Equity of access is fundamental; however, transplant biology can impose unavoidable constraints on organ allocation. For example, in cardiothoracic transplantation, matching for blood group, size and immunologic compatibility means that some patients will, despite equivalent disease severity, wait longer for transplant and have a higher risk of dying on the waiting list. The focus should remain on increasing the donor pool, optimising donor organ function, and ensuring flexible allocation that supports utilisation and minimises waiting-list mortality, rather than rigid requirements that unintentionally reduce transplants.

Australia's transplantation system is notable for extended transport requirements for donated organs. Preservation technology is helping to reduce disparities in organ quality and inter-jurisdictional utilisation. A nationally uniform legal framework should support interstate transfer supported by ex vivo perfusion, with allocation driven primarily by patient need. Algorithmic allocation may improve transparency in some contexts but, in Australia's small, geographically dispersed system, rigid algorithms risk reducing thoracic organ utilisation by limiting the flexibility needed to manage logistics (e.g., weather, transport) and to use 'extended-criteria' organs for deteriorating

recipients who may not survive to await an 'ideal' donor. Australia's current flexible approach underpins our world-leading lung utilisation and low waiting-list mortality; reforms should maintain this flexibility.

We support uniform national laws with related regulations and clinical practice guidelines capable of timely update as evidence and technology evolve.

3. Removing Barriers and Promoting Equitable Access

(See ALRC DP90 Ch.3.)

No additional comments beyond Sections 1–2 above.

4. Reforms Relating to the Definition of Tissue (Proposals 7–9)

(See ALRC DP90 Ch.4.)

No comment.

5. Determination of Death (including Proposals 10 and 13)

(See ALRC DP90 Ch.5, esp. pp.47–60.)

We support a unified brain-based definition of death and the associated determination amendments, while noting issues with Proposal 10 and Proposal 13. With a unified definition, historical legislative definitions of 'brain death' and 'circulatory death' will retire; however, key differences will remain in practice of determination of death by clinicians, and in pathways to donation.

Proposal 10 (Section Y (3)) – Application to deceased donors receiving post-mortem artificial supports.

This proposal allows for organ donation from people who have lost critical brain function but still have blood circulation, by proposing that "…where the person's *respiration* is maintained by artificial means…", two registered medical practitioners must certify by clinical examination that there has been a "permanent cessation of the critical functions of the person's brain." Clarification is sought that such testing is not indicated *after* prior determination of death, with the follow rationale.

Respiration is generally understood as the act of breathing (with or without assistance of a mechanical ventilator), which enables the vital processes of oxygen uptake and carbon dioxide removal. We draw attention to the fact that the equipment used in normothermic regional perfusion (NRP) achieves these vital processes without breathing; aadditionally, the process of lung retrieval surgery involves lung re-inflation/ventilation to distribute the preservation solution. Therefore, without clarification that brain function testing need not be done after prior declaration of death, the Proposal wording could be read to require formal neurological death testing for any person on NRP or ventilated, even after death has already been validly certified.

Under the proposed provisions, a person who has had suffered a circulatory arrest leading to "permanent cessation of critical brain functions", will already be declared deceased according to accepted medical practice, prior to commencement of NRP or lung re-inflation. Under the permanence principle, a person cannot die twice; therefore, once death has been determined, no further mode of death certification is necessary or meaningful.

The Discussion Paper notes that empirical studies show auto-resuscitation does not occur following a 5-minute observation period, nor is there restoration of cerebral perfusion during NRP when brain circulation is excluded. Mandating brain function testing in such scenario's conflicts with this evidence.

Alfred Health recommends amending Section Y (3) to avoid any interpretation requiring clinical brain function determination of death when artificial support is in place solely due to a permitted post-mortem intervention. We suggest either:

1) Removing Section Y (3), such that determination of death is made according to "accepted medical practice" (consistent with the ANZICS recommendation), OR

2) Clarifying that brain function testing applies only where circulatory arrest has not occurred, and not where circulation and respiration is artificially provided for organ preservation after death.

Proposal 13 – Role Separation:

Proposal 13 requires that neither medical practitioner who certifies neurological death may be involved in tissue removal or in the care of a transplant recipient. This has potential negative consequences for high-volume transplant centres, such as the Alfred ICU, where intensivists routinely manage both donors and transplant recipients.

There is no evidence indicating that the current Australian system, with rigorous ANZICS frameworks, and documented separation of death certification from organ allocation roles, has produced ethical conflicts. A categorical prohibition would significantly reduce specialist availability and increase pressure on already limited workforce resources. Such a strict prohibition risks undermining the operational viability of transplant care, without improving ethical standards.

Alfred Health recommends modifying Proposal 13(b) to permit participation of a certifying intensivist in the care of recipients where a separation of roles exists, supported by documentation and adherence to ANZICS standards.

This separation requirement could be met by the intensivist being unaware of potential organ allocation, as currently occurs.

6. Reforms Related to Donation by Living Persons (Proposals 14–22)

(See ALRC DP90 Ch.6.)

Paediatric Donation and Time-Critical Pathways

Paediatric cardiothoracic donation represents an informative test case for the proposed framework, given the very narrow clinical windows and low event volumes. From a paediatric transplant perspective, several elements of the proposed legislative framework may unintentionally impede organ donation for children and young people.

Paediatric cardiothoracic donation occurs at extremely low volumes and relies on national processes that allow time-critical decisions to occur without delay. Proposals introducing expanded consent requirements, more prescriptive information obligations, and additional statutory authorisation steps have the potential to slow donation pathways. The composition, scope and availability of oversight committees mentioned in the Discussion Paper (Proposal 17) are unclear. It is not specified whether they would include clinicians with relevant expertise, now whether they could provide the immediate turnaround required to avoid jeopardising organ viability and threatening opportunities for children awaiting life-saving transplantation. We recommend ensuring that legislative reform strengthens the robust systems that currently support paediatric organ donation in Australia.

In relation to Question 10 of the Discussion Paper, we draw the Commission's attention to rare but lifesaving living heart donation, so-called 'domino' donation-transplantation, wherein a person with end-stage lung disease (but a healthy heart) receives a heart-lung transplant, allowing for their native heart to be donated on. This represents a time-critical intersection of living and deceased donation pathways. It occurs particularly in paediatric populations, may not be readily apparent to non-clinical drafters and should be explicitly preserved within any revised framework governing living donation.

7. Reforms Relating to Deceased Donation

(See ALRC DP90 Ch.7.)

We draw attention to a substantive and unintended inequity in access to organ donation pathways at the end of life. Patients receiving palliative care who are approved for Voluntary Assisted Dying (VAD) may access pre-mortem interventions and controlled donation processes, while clinically comparable patients who are not eligible for, or who do not choose VAD face additional barriers to donation, despite sometimes having decision making capacity and/or a clearly expressed intent to donate.

This disparity does not arise from biological unsuitability for donation. Rather, it reflects the fact that VAD provides a lawful mechanism for death to occur at a known time and place, enabling coordinated consent processes, pre-mortem assessment and optimisation, determination of death, and organ retrieval. In contrast, for non-VAD patients care following withdrawal of life-sustaining treatment is exclusively focused on comfort, and death is therefore temporally uncertain. In the absence of legal protection for clinicians to coordinate the timing of death for the limited purpose of facilitating donation, this uncertainty frequently results in loss of donation opportunity – approximately 30% of potential DCDD donors do not die within the timeframes necessary to allow for successful donation.

A clinical scenario illustrates this inequity. A patient with catastrophic neurological injury is receiving life-sustaining treatment which is determined to be futile or contrary to their health-related values. They have an end-of-life wish to donate organs, identified either through the Australian Organ Donor Registry or in discussion with family. Following a consensus decision to withdraw life-sustaining treatment, death may occur within minutes, hours or days, and cannot reliably be predicted. Currently clinicians cannot lawfully take steps to coordinate death; therefore, the opportunity to achieve their end-of-life wishes is often lost. Where lawful mechanism exists to allow death to occur in a planned and foreseeable manner, donation has a higher chance of success.

The result is a two-tier system of access to deceased donation that privileges predictability over patient values. Eligibility for a separate legal regime, rather than consent, capacity, or clinical suitability, becomes a determinant of access to donation pathways. This disparity reflects an inadvertent design choice within legal frameworks rather than an unavoidable clinical reality, and risks entrenching inequity for end-of-life patients and families who wish to donate.

This structural inequity is further reinforced in time critical situations where death occurs unexpectedly, and the patient's donation related wishes cannot yet be explored or confirmed ante-mortem. In the absence of clear legal authority, clinicians currently may be unable or unwilling to undertake interventions to preserve the possibility of donation during this narrow window, even where death is imminent or has just occurred and where subsequent consent may reasonably be anticipated. As a result, patients who die following sudden or uncontrolled deterioration, including in emergency departments or the community, are excluded from donation pathways.

The majority of Australians support organ and tissue donation, and many have expressed a clear willingness to donate after death. A legal framework that forecloses donation opportunities based on procedural timing or the predictability of death risks frustrating those preferences and undermining respect for patient autonomy and is arguably not aligned with community expectations.

Law reform should explicitly address this interaction, with consideration given to mechanisms that enable patients receiving palliative care, irrespective of voluntary assisted dying status, to access equivalent, ethically robust pre-mortem interventions and donation pathways, where appropriate consent and clinical criteria are met.

Proposal 23 - Consent and authorisation:

We support uniform national legislation defining who can consent and authorise donation, when this can occur, and how consent may be withdrawn. The law should give effect to a competent adult's enduring directive regarding

donation wherever possible. Donation staff may still be faced with the situation of family member objection despite a stated wish (including by registration on the Australian Organ Donor Registry). To support patient autonomy, laws should protect clinicians from liability if they give effect to the wishes of a deceased person or the authorised decision maker, despite objections from others.

We support revision and continuation of the Designated Officer role. This provides a final check prior to proceeding with donation and plays an important role in ensuring compliance with hospitals' clinical governance processes. Under current Victorian legislation, the Designated Officer role is also empowered to authorise pre-mortem interventions and organ donation where no other authorised decision-maker is available.

However, the current proposal does not appear to contemplate circumstances in which a potential donor dies outside a hospital setting. Deaths occurring in the community or other healthcare settings, for example as a result of sudden cardiac arrest or Voluntary Assisted Dying, represent a large proportion of deaths and may involve individuals with clearly expressed wishes to donate. Internationally there is growing experience in donation after Voluntary Assisted Dying at home (Canada), or in the commencement of NRP for the purposes of donation after declaration of death at the scene of an out-of-hospital cardiac arrest (Spain, USA).

The revised legislative framework should allow for emergency interventions that preserve the donation opportunity for out-of-hospital deaths, including mechanisms that allow timely verification of death, preservation measures (such as at-the-scene NRP), and transfer to appropriate facilities where ethical and clinical criteria are met, while maintaining robust safeguards and public trust.

Proposal 24 – Designated Officer:

We support consistent national guidelines to organ donation following Voluntary Assisted Dying. We reiterate that there is international experience (in Canada and the Netherlands) in enabling organ donation as a part of medically assisted dying at home. The revised legislative framework should allow for this highly patient-centred innovation, which combines respect both for their dignity and generosity.

Proposal 25 – Authorised decision maker

We support a nationally consistent approach to defining the authorised decision-maker nationally. This ideally is consistent for both pre- and post-mortem (post-mortem this may require clarification as to the role of authorised decision-maker versus executor of the estate).

Proposal 26 and 27 – Pre-mortem interventions

We support legislation permitting guideline- or otherwise ethically approved pre-mortem interventions in time critical circumstances even *prior* to confirmation of donation related consent, for the purpose of preserving the opportunity for donation.

In the roughly 2% of hospital deaths which occur in ICU and are anticipated there is opportunity to explore donation wishes (this reflects the practice of donation after neurological determination of death [DNDD] and *controlled* DCDD). Much more common are unexpected deaths, in which delay to intervention will result in irreversible loss of donation potential. In these cases, the law could allow proportionate, reversible interventions, while steps are taken to ascertain the patient's wishes or those of an authorised decision maker (this reflects the practice of uncontrolled DCDD).

This approach reflects well established community support for donation and recognises that failure to act during this narrow window may permanently impede patient preferences once known. Such interventions would function as temporary holding measures only and would not authorise or imply presumed consent for organ donation. Any framework should require strict safeguards, including cessation if ongoing consent is refused or cannot be obtained.

We support an approach that embeds safeguards through reference to established clinical guidelines, such as those developed by ANZICS, rather than prescribing allowable pre-mortem interventions in legislation. A guideline-based

framework would promote nationally consistent, ethically robust practice across all Australian jurisdictions while remaining responsive to evolving clinical evidence.

Proposal 28 – Respect for donor body:

We support the sentiment while noting the drafting challenge of articulating standards for inherently intrusive procedures. Practice-level guidance should complement legislative statements of principle.

Proposal 29

We support a consistency of approach nationally. The use of non-AHPRA registered staff in donation should only occur if a clearly demonstrated need is present and responsibility for the non-AHPRA participant remains with an AHPRA registered practitioner.

Question 24

Coroners should consider the preferences of donors and the benefits of their organ donation when deciding whether to consent to donation, in addition to considering the community benefit of examining causes of death.

8. Reforms Relating to Tissue Donation for Research (Proposals 32–37)

(See ALRC DP90 Ch.8.)

Clarification is needed on whether these provisions apply solely to tissues or also to solid organs. Research and transplantation may occur simultaneously in relation to the same tissue/organ (e.g., observational data, testing, optimisation strategies). Overlapping pathways for organs, cells and tissues require clear scope to avoid gaps or duplication.

We support a uniform national approach which is consistent with the Australian Code of Responsible Conduct of Human Research. Issues may arise when tissue is held in tissue banks and later used in a new or unforeseen line of enquiry. The consent requirement should not be so onerous as to prevent ethically sound research (particularly where re-contacting families to obtain further consent may be impractical and potentially distressing) provided that appropriate human research ethics committee oversight is in place. This proportional, principles-based approach is consistent with established and emerging international guidance, including the International Ethical Guidance for Research Involving Deceased Donation and Transplantation Activity (INTEGRITY) Guidelines currently released for public consultation by Deakin University, which emphasise system-level governance, transparency, equity, and respect for donors.

9. Reforms Relating to Donation and Use of Deceased Bodies (Proposals 38–39)

(See ALRC DP90 Ch.9.)

No specific comment.

10. Reforms Relating to Stored Tissue Collections

(See ALRC DP90 Ch.10.)

Future techniques or uses of stored tissue cannot be fully anticipated. Frameworks should remain practical and proportionate so as not to unduly impede ethically sound research while ensuring strong oversight.

11. Reforms Relating to the Prohibition of Trade (Proposals 40–45)

(See ALRC DP90 Ch.11.)

While the prohibition on trade in human organs must be preserved, the legal framework should clearly distinguish impermissible financial inducement from legitimate measures that remove disincentives to living organ donation. This includes reimbursement of direct expenses, protection against loss of income, and employment protections during donor assessment, surgery, and recovery. Failure to address donor disincentives risks entrenching inequity, as living donation becomes feasible primarily for those with sufficient financial and social security.

Additionally, there should be no legal impediment in providing care to patients who have had transplants performed overseas, and clinicians who in good faith refer patients to or otherwise support overseas transplant programs (e.g. through training or research collaboration) should not be considered to be contravening Australian law. The circumstances of donation and the financial arrangements in overseas transplant programs may be opaque to providers acting in good faith.

12. Reforms Relating to Information Disclosure and Sharing (Proposals 46–48)

(See ALRC DP90 Ch.12.)

We support retention of anonymous donation. Given heightened risks of identification through social media and rapid news cycles, anonymity is increasingly important. reforms must preserve rapid, secure, unambiguous clinical information flow among transplant teams, donor hospitals and DonateLife.

We support continued confidentiality of identifiable donor information beyond the health-care teams involved. An exemption should allow a treating clinician to discuss specific results necessary for additional informed consent (e.g., higher-than-normal risk donor) without breaching donor confidentiality, while recipients remain bound by confidentiality norms regarding donor identity.

Conclusion

Alfred Health supports nationally consistent, principles-based reform that strengthens ethical safeguards while preserving the flexibility needed to maximise organ utilisation and patient outcomes. We welcome further engagement with the ALRC to refine proposals and to ensure timely, safe and effective donation and transplantation pathways across Australia.