



Australian Government  
Organ and Tissue Authority



DonateLife

# **Australian Law Reform Commission (ALRC) Review of Human Tissue Laws - Discussion Paper**

**Submission from Organ and Tissue  
Authority (OTA)**

12 February 2026



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## 1. Introduction

The Australian Organ and Tissue Authority (OTA) welcomes the opportunity to make a submission to the Australian Law Reform Commission (ALRC) Review of Human Tissue Laws Discussion Paper.

The OTA supports the need to harmonise and modernise existing state and territory human tissue laws to reduce fragmentation and legal uncertainty across jurisdictions. A nationally consistent framework is important to support equitable, ethical and effective organ and tissue donation and transplantation practices, while remaining adaptable to evolving clinical practice, technological advancements and community expectations.

The OTA's submission has been developed through a structured consultation process drawing on the expertise of its advisory committees, advisory groups, peak professional bodies, international experts and Commonwealth government health portfolio regulators. Feedback received through these forums was carefully considered and incorporated to reflect consensus positions where possible, while transparently acknowledging areas of divergence. The resulting submission therefore represents a comprehensive response informed by broad stakeholder input and grounded in the operational realities of the donation and transplantation sectors. The OTA contributed to and supports the Australian Government Health-portfolio group response and this submission should be read in conjunction with that response. The OTA would also like to acknowledge Associate Professor Helen Opdam's submission to the ALRC discussion paper as a clinical expert in this field.

The OTA considers that contemporary human tissue legislation should focus on establishing clear, high-level objects, principles, obligations and prohibitions. Detailed clinical and operational matters are more appropriately addressed through, policies, protocols, clinical guidelines, standards and codes that can be updated in line with evidence and practice. This approach promotes legal certainty while enabling flexibility across donation, retrieval and transplantation processes.

The OTA supports the inclusion of clear legislative objects aligned with core principles, including equity, dignity, autonomy, public trust and informed consent. These principles provide important guidance for policy development and practical application across the donation and transplantation system.

In making this submission, the OTA would like to acknowledge and thank all organ and tissue donors, who have transformed the lives of people needing a transplant. We also acknowledge the dedication and commitment of DonateLife specialist staff, intensive care and transplantation teams, community advocates and supporters. Transplantation is only possible through the donation of organs and tissues, and its life-changing benefits would not be possible without this shared commitment.

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## 2. A nationally harmonised regulatory framework

The OTA is the Australian Government agency responsible for leading the nationally consistent DonateLife program to increase organ and tissue donation and improve opportunities for transplantation in Australia.

Since the DonateLife program began in 2009, there has been over 7,000 deceased organ donors, resulting in more than 20,000 people receiving a life-transforming transplant.

The key contributor to increasing organ donation and transplantation has been the establishment of the national coordinating agency, OTA, who fund the DonateLife network of donation specialists, embed agreed nationally consistent best clinical practices, and deliver locally coordinated public awareness activities.

There is a clear delineation of responsibilities across governments. The Australian Government sets national policy, provides funding, sets public messaging and administers the Australian Organ Donor Register (AODR), while state and territory governments are responsible for hospital-based donation services and downstream clinical activities, including retrieval and transplantation.

The OTA's work is guided by the OTA Strategy 2022–2027, which sets out a five-year plan focused on building community support, optimising clinical opportunities and strengthening system enablers. This is complemented by the National Strategy for Organ Donation, Retrieval and Transplantation in Australia, released in November 2024, which aims to support nationally consistent best practice across the end-to-end system.

The OTA considers that value has been demonstrated through a framework based on national coordination and collaboration, with national guidelines and protocols, underpinned by transparent data, analytics and reporting rather than prescriptive enforcement. Any proposed reforms should align with and enhance existing legislative, policy and governance arrangements, including the OTA's enabling legislation<sup>(1)</sup>, to avoid duplication and unintended consequences. Modernised legislation should enable, rather than prescribe, policy and program delivery so that clinical practice and community engagement remains current and evidence based.

Collaboration with governments, clinical sector and the community is integral to any successful change in human tissue legislation.

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<sup>1</sup> [Australian Organ and Tissue Donation and Transplantation Authority Act 2008 - Federal Register of Legislation](#)

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### 3. Definitions of ‘Tissue’

Any reforms to legislation should be flexible to adapt to existing public awareness programs and not impede program delivery. Consideration must be given to the varying awareness levels about organ, eye and tissue donation in the community. Additionally, these terms are used separately in public awareness materials and campaigns. For example, ‘DonateLife’ for organ and tissue donation and transplantation.

### 4. Determination of death

Reforms relating to the determination of death should apply universally for all purposes of death determination and not be limited to human tissue or donation-specific contexts. Given the broad application of death determination, nationally uniform provisions enacted through legislation separate from human tissue laws.

The OTA supports a unified brain-based concept of death which is consistent with current medical and scientific understanding of death. However, any legislative formulation must be sufficiently clear, concise and practical to be understood and applied by health professionals across a wide range of settings, as well as by the broader community.

Expert stakeholders have advised the draft proposals are too complex, which could lead to uncertainty regarding the process for the determination of death. The current wording has created uncertainty as to the acceptability of circulatory criteria for the determination of death. The legislation should avoid interpretations that would require neurological assessments when circulatory criteria are appropriate and routinely used.

Any reforms should be accompanied by education, guidance and communication for both health professionals and the community to support confidence in death determination processes. This is essential to maintain confidence in the system and encourage ongoing participation in donation programs.

### 5. Pre-mortem intervention

The OTA notes there is currently no internationally agreed definition of pre-mortem interventions. A broad definition is recommended, as attempts to define pre-mortem interventions too narrowly, risk creating arbitrary distinctions as to what is and what is not a pre-mortem intervention, with likely unintended constraints on clinical practice.

The OTA supports approaches that avoid prescribing specific permissible pre-mortem interventions in primary legislation. International consensus work, including recent work led by the European Society of Transplantation, highlights the importance of flexibility to accommodate evolving clinical practice and ethical guidance.

Any reforms should also account for operational impacts. The proposed requirement for obtaining valid consent from the person’s authorised decision-maker could create barriers when adopting a broad definition for pre-mortem interventions, which could be inclusive of clinical practices that may occur prior to such consent being feasible. This includes the

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preliminary assessment of patients at end of life for donor suitability and the continuation of supportive treatments that preserve the opportunity of organ donation.

Legislation should instead provide a principled framework. Detailed guidance on permissible interventions should be developed and maintained through professional standards, guidelines and codes of practice. This approach enables ethical and clinical considerations to be addressed dynamically while maintaining appropriate safeguards <sup>(2)</sup>.

## **6. Consent and disclosure provisions**

### **6.1 Consent and family communication**

Very few people can be an organ donor, with only around 2% of people who die in Australian hospitals meeting the criteria required to be an organ donor. It comes at an intensely emotional time for families and can be challenging for all involved. The OTA emphasises the importance of clear, compassionate and culturally safe communication, delivered by appropriately trained professionals, to support families through end-of-life care and donation decision-making.

Evidence indicates that the quality of care and communication provided to families influences both their experience and consent outcomes <sup>(3)</sup>. Enabling legislation that is clear, coherent and readily interpretable is essential to support best practice in this context.

The OTA supports contemporary approaches that recognise and respect an individual's expressed decision about donation, while acknowledging the critical role families play in practice. Consent reforms must be developed with careful consideration of these unique nuances and contextual factors that characterise deceased organ donation. Several elements of the current proposals introduce additional complexity and place significant responsibilities on authorised decision-makers. Current legislation recognises an individual's preference of organ and tissue donation for example registration on the Australian Organ Donor Register. Legislation should uphold an individual's expressed preference, established practices and broader community expectations. Legislative frameworks should reflect current social, cultural and family structures and support authorised decision-making models that uphold primacy of an individuals' preference and promote dignity, respect and trust.

### **6.2 Disclosure provisions**

Disclosure and sharing of information are essential to safe and effective organ donation and transplantation practice, including communication between clinical teams and respecting donor families in sharing of their stories.

Legislation should provide clarity on when clinically relevant information may be disclosed, while maintaining robust protections for privacy, confidentiality and anonymity. Harmonisation with privacy and health information legislation is important to avoid uncertainty and support consistent practice.

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<sup>2</sup> [Donations Actions Framework](#)

<sup>3</sup> [Feedback from families | DonateLife](#)

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The OTA recognises the importance for donor families to be able to acknowledge and commemorate their loved one's donation or to freely partake in community awareness activities for organ and tissue donation, whilst also enabling and respecting privacy and anonymity. Maintaining anonymity is essential to uphold ethical principles, protect privacy, and sustain confidence in the donation and transplantation system, and should align with the [All Governments Statement on Privacy and Anonymity in Donation and Transplantation](#)<sup>(4)</sup>.

## **7. Donation of tissue by living persons**

Inconsistent approval processes across jurisdictions can create barriers in what can be time-critical decisions, including participation in the Australian and New Zealand Paired Kidney Exchange (ANZKX) program. Consideration needs to be given to reforms that can streamline the existing approval processes while maintaining safeguards that protect donors and recipients.

## **8. Prohibition of trade and advertisement for donation tissue for transplantation**

Legislative settings for organ and tissue donation should value and safeguard the gift of donation, ensuring voluntary, non-remunerated donation, and the protection of donors and recipients, while supporting equitable access to transplantation. Clear and consistent prohibitions on trade and inappropriate inducement are essential to uphold ethical integrity and public trust.

Reforms that modernise and provide a consistent approach across Australia to any form of public communication regarding the prohibited exchange of organs and tissues are supported. However, any change must not impede existing public communication programs, including the DonateLife national program, that seeks to raise awareness about donation and transplantation. In some current jurisdictional legislation the broad prohibition of advertising creates barriers, that impact national community messaging.

## **9. Closing**

The OTA will continue to engage with the Commissioner and assist the ALRC as the reform progresses, providing technical expertise and policy insight in matters relevant to OTA, supporting the development of a coherent, ethical and future-focused legislative framework that strengthens Australia's organ and tissue donation and transplantation system.

We look forward to the publication of the Review of Human Tissues Laws – Final Report.

For any queries or further information related to this submission, please contact:

[parliamentary@donatelife.gov.au](mailto:parliamentary@donatelife.gov.au)

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<sup>4</sup> [All Governments Statement on Privacy and Anonymity in Donation and Transplantation](#)