



Law Council
OF AUSTRALIA

Review of Human Tissue Laws: Issues Paper

Australian Law Reform Commission

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About the Law Council of Australia

The Law Council of Australia represents the legal profession at the national level; speaks on behalf of its Constituent Bodies on federal, national, and international issues; promotes and defends the rule of law; and promotes the administration of justice, access to justice and general improvement of the law.

The Law Council advises governments, courts, and federal agencies on ways in which the law and the justice system can be improved for the benefit of the community. The Law Council also represents the Australian legal profession overseas, and maintains close relationships with legal professional bodies throughout the world. The Law Council was established in 1933, and represents its Constituent Bodies: 16 Australian State and Territory law societies and bar associations, and Law Firms Australia. The Law Council's Constituent Bodies are:

- Australian Capital Territory Bar Association
- Law Society of the Australian Capital Territory
- New South Wales Bar Association
- Law Society of New South Wales
- Northern Territory Bar Association
- Law Society Northern Territory
- Bar Association of Queensland
- Queensland Law Society
- South Australian Bar Association
- Law Society of South Australia
- Tasmanian Bar
- Law Society of Tasmania
- The Victorian Bar Incorporated
- Law Institute of Victoria
- Western Australian Bar Association
- Law Society of Western Australia
- Law Firms Australia

Through this representation, the Law Council acts on behalf of more than 107,000 Australian lawyers.

The Law Council is governed by a Board of 23 Directors: one from each of the Constituent Bodies, and six elected Executive members. The Directors meet quarterly to set objectives, policy, and priorities for the Law Council. Between Directors' meetings, responsibility for the policies and governance of the Law Council is exercised by the Executive members, led by the President who normally serves a one-year term. The Board of Directors elects the Executive members.

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The Chief Executive Officer of the Law Council is Dr James Popple. The Secretariat serves the Law Council nationally and is based in Canberra.

The Law Council's website is www.lawcouncil.au.

Acknowledgements

The Law Council acknowledges the contributions of the following Constituent Bodies in the preparation of this submission:

- Law Institute of Victoria; and
- Law Society of Western Australia.

Introduction

1. The Law Council of Australia welcomes the opportunity to contribute to the Australian Law Reform Commission's (**ALRC**) Issues Paper as part of its review of human tissue laws.
2. In February 2025, the then Attorney-General requested (after consultations with Commonwealth and State and Territory Health Ministers) that the ALRC review Australia's laws relating to cell, tissue and organ donation, as well as retrieval and transplantation. We note that responses to this preliminary consultation will inform a Discussion Paper that will contain ideas for reform and provide further opportunity to comment.
3. We broadly support the principles-based approach to the review as set out in the Terms of Reference, with a focus on giving consideration to whether, and if so what, reforms are necessary or desirable to harmonise and modernise the various Human Tissue Acts (**HTA**) and related laws around the country.
4. In this context, our submission focuses on questions 3 to 8 of the Issues Paper and seeks to provide:
 - recommended objectives of a national framework for the regulation of human tissue;
 - a suggested approach to the different uses of human tissue (e.g., clinical, research, educational, artistic or cultural);
 - perspectives on consent requirements and views on a national approach;
 - recommendations for reform regarding organ trafficking and organ transplant tourism;
 - insights into the need for clarity concerning the interaction with state-based voluntary assisted dying legislation; and
 - the importance of considering coronial jurisdiction and timely access to human tissue donation.
5. We trust our submission is of assistance and we look forward to continuing to engage further, particularly when the Discussion Paper is released.

Question 3: Objectives of a national framework for the regulation of human tissue

6. The Law Council submits that any national framework for the regulation of human tissue should be guided by a clear, principled set of objectives that balance individual rights, ethical standards, public health interests, and legal certainty. The framework should ensure that the collection, donation, use, and disposal of human tissue occurs in a manner that is respectful, lawful, and ethically sustainable.
7. We agree that the objectives set out in the Issues Paper provide sound aims for laws governing how human tissue is obtained and used. While we are supportive of increased access, we also consider transparency, safety; equity and compliance with the law as core aims to be pursued in any reform. Further consideration of recommended objectives is set out below.

Recommended objectives

8. The Law Council considers that the following objectives should underpin any future national framework:

Respect for human dignity and bodily integrity

The framework should enshrine the inherent dignity of the human body and the right of every person to control what happens to their body during life and after death. This includes the protection of bodily autonomy through robust consent requirements and limitations on coercion or exploitation.¹

Free, prior and informed consent

Consent should be the foundation of any lawful donation or use of human tissue. The framework should ensure that consent is voluntary, specific, informed, prior to donation and revocable where appropriate. Where consent cannot be obtained, clear statutory authorisation mechanisms should apply, with appropriate safeguards and transparency.²

Equity and non-commercialisation

Donation and access to human tissue should be based on principles of equity and solidarity. The framework should prohibit financial gain from the donation or use of human tissue, in accordance with established international ethical norms³, and should ensure equitable access to donated tissue, particularly for disadvantaged and marginalised populations.⁴

Public benefit and ethical use

Human tissue should only be used for purposes that are lawful, ethical, and in the public interest—such as medical treatment, transplantation, scientific research, public health, or education. Use for these purposes should be subject to oversight, ethical review, and compliance with regulatory requirements.⁵

¹ See National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapter 1 (Ethical conduct), which recognises respect for human dignity, autonomy, and the right to make informed decisions about participation in research; see also World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principles 3 and 5, which affirm the need for voluntary and informed consent and prohibit coercion and exploitation. These principles are also reflected in Australia's international human rights obligations, including articles 7, 9, 17 and 23 of the *International Covenant on Civil and Political Rights* (ICCPR), 16 December 1966, 999 UNTS 171, entered into force 23 March 1976; as well as articles 3, 15, 16 and 25 of the *Convention on the Rights of Persons with Disabilities* (CRPD), 24 January 2007, 2515 UNTS 3, entered into force 3 May 2008.

² See National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapter 2.2, which outlines the essential elements of valid consent, including that it must be voluntary, informed, and based on adequate understanding; see also World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principles 1 and 5; and *Privacy Act 1988* (Cth), s 16B(2), which recognises permitted health information use under statutory authorisation with safeguards.

³ World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principle 5; see also [Declaration of Istanbul on Organ Trafficking and Transplant Tourism](#) (2018 Edition).

⁴ See World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principles 6 and 9, which prohibit financial gain from human tissue donation and call for equitable access to transplantation services; see also Council of Europe, [Convention on Human Rights and Biomedicine](#) (Oviedo Convention, 1997), Article 21; and Therapeutic Goods Administration (TGA), [Australian Regulatory Guidelines for Biologicals](#) (ARGB), Australian Government (2023), which affirms non-commercial principles in the Australian regulatory framework.

⁵ See National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapters 1 and 2.3, which set out ethical and governance requirements for the use of human tissue in research and education; see also World Health Organization, [Guiding Principles on Human](#)

Transparency, accountability and oversight

The framework should support public trust through transparent governance structures, data integrity, audit processes, and independent oversight. Institutions involved in tissue handling or regulation should be accountable for their decisions and subject to consistent reporting obligations.⁶

Legal clarity, national consistency and interoperability

To reduce legal uncertainty and regulatory fragmentation, the framework should promote consistency across jurisdictions, including alignment of key definitions, consent rules, authorisation pathways, and ethical standards.⁷ This may be achieved through nationally-agreed principles, model laws, or cooperative legislative schemes consistent with the Constitution.⁸

Adaptability and future-focused regulation

The framework should be sufficiently flexible to respond to future developments in medical science, biotechnology, and data-driven health research. This includes establishing clear rules for the use of stored tissue, emerging therapeutic applications, and the intersection of tissue with genomic and digital information.⁹

9. We have received feedback that the following aims are also important from a legal perspective, beyond the list provided in the Issues Paper:
- ensuring that an organ donor's wishes are respected, even if others object;
 - removing practical barriers that make it difficult for donation systems to operate effectively; and
 - ensuring that the privacy of organ donors and their families is maintained.

[Cell, Tissue and Organ Transplantation](#) (2010), Principles 1 and 10, which require ethical use, regulatory oversight and alignment with public interest purposes; and Therapeutic Goods Administration (TGA), [Australian Regulatory Guidelines for Biologicals](#) (ARGB), Australian Government (2023), which outlines regulatory oversight for therapeutic use of human tissue in Australia.

⁶ See Australian Commission on Safety and Quality in Health Care, [National Safety and Quality Health Service Standards](#) (2nd ed, 2021), particularly Standards 1 and 6, which emphasise clinical governance, safety, and the importance of data integrity and accountability; see also World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principle 10, which calls for transparency, traceability, and oversight in all stages of tissue handling; and National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapter 5.1 on institutional responsibilities.

⁷ See Australian Law Reform Commission, [Principled Regulation: Federal Civil and Administrative Penalties in Australia](#) (Report No 95, 2002), which discusses benefits of regulatory consistency and model laws; Council of Australian Governments, [Intergovernmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety](#) (3 July 2008).

⁸ The Law Council notes the cooperative legislative models previously adopted in areas such as corporations law and the national registration of health practitioners. These may serve as precedents for a harmonised approach.

⁹ See National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapter 3.2, which addresses the use of stored human tissue and biobanking; Department of Health, Disability and Ageing, [Australia's Genomics Health Futures Mission](#) (Australian Government initiative from 2018-19), highlighting the integration of genomic data in health research; and Therapeutic Goods Administration (TGA), [Regulation of advanced therapies](#) (Australian Government website, last updated 10 January 2022), which outlines regulatory approaches to emerging biotechnologies.

National and international alignment

10. Australia's approach should also reflect relevant international instruments and guidelines, including:
 - the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation;¹⁰
 - the Council of Europe Convention on Human Rights and Biomedicine and its Additional Protocols;¹¹
 - the UNESCO Universal Declaration on Bioethics and Human Rights;¹²
 - the Declaration of Istanbul on Organ Trafficking and Transplant Tourism;¹³ and
 - international human rights treaties to which Australia is a party.
11. In particular, the following rights may be relevant to points raised in the Issues Paper:
 - the right to privacy in article 17 of the International Covenant on Civil and Political Rights (**ICCPR**) will be important to safeguard the privacy of donors and recipients;¹⁴
 - the right to privacy in article 17, right to bodily integrity in article 9 and right to be free from medical experimentation without consent in article 7 of the ICCPR are all relevant to respect for bodily autonomy;¹⁵
 - article 16 of the Convention on the Rights of the Child and article 12 of the Convention on the Rights of Persons with Disabilities may be relevant to medical decision-making under any proposed reformed legal framework;¹⁶ and
 - the right to health under article 12 of the International Covenant on Economic, Social and Cultural Rights (**ICESCR**), and non-discrimination guarantees in, for example, articles 2 and 24 of the ICCPR and article 2 of the ICESCR, may be relevant to access and participation in donation programs/systems,¹⁷ as well as allocation of donated tissue for waitlisted patients.¹⁸
12. Aligning with these obligations reinforces Australia's commitment to ethical medical practices, prevents exploitative conduct, and ensures continued eligibility for international research collaboration and data-sharing frameworks.
13. The Law Council submits that any future national framework should be grounded in principled objectives that uphold the rights of individuals whose tissue is being used, promote ethical use, ensure legal certainty, and foster public trust. These objectives will serve not only to guide legislative reform, but also to ensure the long-term sustainability, legitimacy and social acceptance of Australia's human tissue regulatory system.

¹⁰ World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010).

¹¹ Council of Europe, [Convention on Human Rights and Biomedicine](#) (Oviedo Convention, 1997).

¹² UNESCO, [Universal Declaration on Bioethics and Human Rights](#) (adopted 19 October 2005).

¹³ See [Declaration of Istanbul on Organ Trafficking and Transplant Tourism](#) (2018 Edition).

¹⁴ Australian Law Reform Commission, [Review of Human Tissue Laws](#) (Issues Paper, May 2025) [76]-[78].

¹⁵ *Ibid.*, [36]-[39].

¹⁶ *Ibid.* The Law Council acknowledges that Australia has a reservation to article 12 of the CRPD allowing for substituted decision-making in certain circumstances, but only subject to appropriate safeguards.

¹⁷ *Ibid.*, [40]-[43].

¹⁸ *Ibid.*, [93]-[95].

Recommendations

- **Any future national framework for the regulation of human tissue should be underpinned by objectives that uphold the rights of individuals whose tissue is being used, promote ethical use, ensure legal certainty, and foster public trust.**
- **Australia's approach to human tissue laws should reflect relevant international instruments and guidelines, including those listed in paragraphs 10 and 11 of this submission.**

Question 4: Principles that should guide reform to human tissue laws

14. The Law Council agrees that the principles set out in the Issues Paper are appropriate to guide reforms to Australia's human tissue laws. To avoid doubt, in our view, the principle of autonomy should be a core principle underlying any reform, as should transparency.
15. The Issues Paper notes the importance of public trust in the framework that governs how human tissue is obtained and used in Australia. The Law Council agrees that this is an important principle to underpin reform and makes further observations on this point below.

Public trust, rule of law, and access to human tissue in Australia

16. The Law Council supports the objective of the ALRC's focus on modernising legal frameworks to reflect contemporary ethical standards, scientific practices, and community expectations. A key consideration in this reform process is the central role of public trust and the rule of law in ensuring that any system facilitating access to human tissue operates ethically, lawfully and with social legitimacy.

The centrality of public trust to voluntary donation systems

17. Australia's current framework for the donation of human tissue is founded upon the principles of informed consent and altruism. The Law Council considers that public confidence in donation systems is essential to their continued operation and effectiveness. Such confidence depends, in turn, upon a perception that:
 - donation processes are transparent and consistently administered;
 - the use of human tissue is appropriately regulated, with clear safeguards against misuse or commercial exploitation; and
 - decisions concerning the allocation and use of donated material are made fairly and ethically.
18. The Law Council notes that, where public trust in these systems is compromised, rates of participation may be affected, and compliance with legislative requirements may diminish. In this regard, fostering and maintaining public trust is not merely a desirable outcome—it is fundamental to the system's viability.

The rule of law and the legal framework governing tissue access

19. The Law Council considers that any framework governing the collection, use and distribution of human tissue must be grounded in the rule of law. This includes ensuring that the relevant legislative provisions are:
 - clear, accessible, and capable of consistent interpretation and application;
 - administered by institutions that are independent and accountable; and
 - subject to appropriate mechanisms for review and oversight.
20. The integrity of these systems must be both substantive and procedural. Individuals engaging with donation systems—whether as donors, family members, or professionals—should be able to rely on the certainty, fairness and lawfulness of the processes involved.¹⁹

Institutional responsibilities and legal coherence

21. Institutions such as the Organ and Tissue Authority, Human Research Ethics Committees, and State and Territory health authorities play a critical role in giving effect to legislative principles and maintaining the community's confidence in the donation system. In the Law Council's view, these institutions must be appropriately supported, both legislatively and operationally, to discharge their responsibilities consistently with the rule of law and community expectations.
22. To this end, the Law Council recommends that the ALRC review give consideration to:
 - where it may be possible to enhance the transparency of institutional processes—including in relation to the use and allocation of donated tissue;
 - ensuring that any reforms to the framework promote respect for, compliance with, and effective enforcement of legislative provisions in practice;
 - strengthening consent provisions to ensure consent is respected in practice;
 - ensuring consistency in consent requirements and other procedural standards across jurisdictions;
 - maintaining strong protections against the commercialisation of human tissue; and
 - providing clear statutory guidance on the use of tissue for secondary purposes, including research.²⁰
23. These measures would serve to reinforce the legitimacy of donation systems and support sustained public confidence.
24. The Law Council submits that any reforms to the legislative framework governing access to human tissue must be guided by the principles of transparency, accountability, and legality, and must reflect the foundational importance of public trust to voluntary donation systems. Ensuring that regulatory structures are consistent with the rule of law will support the continued ethical operation of tissue donation and use and will help to maintain community confidence in the legitimacy of the legal system as a whole.

¹⁹ Law Council of Australia, [Policy Statement on Rule of Law Principles](#) (March 2011) 1–2.

²⁰ See, for example, *Human Tissue Act 1982* (Vic) ss 26–27; *Human Tissue and Transplant Act 1982* (WA) s 22; and National Health and Medical Research Council, [Guidelines under Section 95 of the Privacy Act 1988 \(Cth\)](#), particularly in relation to secondary use of tissue in research.

Recommendations

- **Any reforms to the legislative framework governing access to human tissue must ensure that relevant legislative provisions are:**
 - **clear, accessible, and capable of consistent interpretation and application;**
 - **administered by institutions that are independent and accountable; and**
 - **subject to appropriate mechanisms for review and oversight.**
- **The ALRC review of human tissue laws should give consideration to:**
 - **where it may be possible to enhance the transparency of institutional processes, including in relation to the use and allocation of donated tissue;**
 - **ensuring that any reforms to the framework promote respect for, compliance with, and effective enforcement of legislative provisions in practice;**
 - **strengthening consent provisions to ensure consent is respected in practice;**
 - **ensuring consistency in consent requirements and other procedural standards across jurisdictions;**
 - **maintaining strong protections against the commercialisation of human tissue; and**
 - **providing clear statutory guidance on the use of tissue for secondary purposes, including research.**

Questions 5 and 6: Issues that should be a focus of the ALRC inquiry

25. Broadly, the Law Council agrees that the issues set out as ‘Priority reform areas’ in the Issues Paper should be a focus of the ALRC’s inquiry. The Law Council also welcomes the ALRC’s indication that the definition of ‘death’ will be specifically considered in its review. We note that the Law Institute of Victoria (**LIV**) has previously advocated for the definition of ‘death’ used by the medical profession in the United Kingdom based on the absence of brain function or the cessation of blood circulation to the brain.²¹ Ultimately, we support reform that is consistent with clinical practice and medical knowledge.

Different uses of human tissue and consent

26. The Law Council acknowledges that human tissue is used in a wide range of contexts and that the regulation of such use primarily falls within the jurisdiction of state and territory legislatures, resulting in variation across Australia. While not seeking to prescribe uniform rules for all circumstances, the Law Council submits that any future framework—whether through national reform or harmonisation—should clearly distinguish between different types of use, while upholding consistent underlying principles, including respect for human dignity, bodily autonomy, and informed consent. Making these distinctions is important for establishing

²¹ Stuart Webb (President, Law Institute of Victoria), [Referral of the Human Tissue Act 1982 to the Victorian Law Reform Commission](#) (Letter to the Hon Jill Hennessy MP, 6 September 2019).

appropriate consent requirements, oversight mechanisms, and safeguards that are proportionate to the purpose and context of each use.

27. The Law Council supports a regulatory approach that takes into account the different ways human tissue is used, guided by the idea that stronger oversight should apply where the use involves greater risks or more sensitive purposes. Further comments on specific uses are set out below.

Clinical use (e.g., transplantation and therapy)

28. Uses involving therapeutic intervention for the benefit of recipients (e.g. organ transplantation, blood transfusion, cell therapies) should remain subject to high standards of donor consent, clinical governance, and regulatory oversight. These uses involve direct implications for patient safety and supply chain integrity and need to be tightly regulated under therapeutic goods and human tissue legislation.²²

Research use

29. Use of human tissue for research—particularly where tissue is linked to identifiable personal or genetic information—engages significant ethical and privacy considerations. Research uses should be subject to prior informed consent (unless lawfully waived), review by Human Research Ethics Committees (HRECs), and ongoing governance in accordance with the National Statement on Ethical Conduct in Human Research and relevant privacy legislation.²³
30. It may also be necessary to distinguish between research that involves the collection of new tissue and research that makes use of existing or leftover tissue, such as surgical by-products or archived samples. In such cases, waivers or opt-out models may be considered where risks are minimal and individual rights are not unduly affected, subject to HREC approval.²⁴

Educational use

31. Use of human tissue for education or training (e.g. medical student dissection, surgical simulation) may be lawful under specific statutory authorisation and institutional protocols. It is important to maintain clear statutory grounds for such use, provided that consent was originally obtained or the use is consistent with a recognised exception (e.g. for unclaimed bodies under prescribed conditions).²⁵

²² See Therapeutic Goods Administration (TGA), [Biologicals regulation](#) (Department of Health, Disability and Ageing webpage, last updated 29 August 2022); National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023); and applicable state and territory human tissue legislation, such as the *Human Tissue Act 1983* (NSW), *Human Tissue Act 1982* (Vic) and *Human Tissue and Transplant Act 1982* (WA).

²³ National Health and Medical Research Council, [National Statement on Ethical Conduct in Human Research](#) (2023), Chapters 2.2; see also *Privacy Act 1988* (Cth) and National Health and Medical Research Council, [Guidelines under Section 95 of the Privacy Act 1988](#).

²⁴ National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapters 2.2 and 2.3; see also National Health and Medical Research Council, [Guidelines under Section 95 of the Privacy Act 1988](#).

²⁵ See, for example, *Anatomy Act 1977* (NSW) ss 6–9; *Human Tissue Act 1982* (Vic) ss 32–37. These Acts provide statutory authority for the donation and use of human bodies for educational and scientific purposes, including conditions for the use of unclaimed bodies. See also National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023).

Artistic or cultural use

32. Use of human tissue for artistic or cultural purposes (e.g. anatomical exhibitions or installations) raises unique ethical sensitivities. Consequently, such uses should be expressly addressed in legislation and should, as a minimum, require prior informed consent from the donor or the donor's lawful representative. Any commercialisation of such use should be subject to prohibition or strict scrutiny to ensure alignment with public expectations and ethical standards.²⁶

Consent: the authorisation of tissue donation

33. The Issues Paper says that the ALRC intends to consider '[w]ho should be able to authorise tissue donation when a person dies'.²⁷ The Law Council is supportive of this focus area and considers that free, prior and informed consent should be the central legal mechanism by which individuals exercise control over the use of their tissue. The framework should recognise different modalities of consent depending on context, but should maintain a consistent legal baseline across all jurisdictions.²⁸
34. In this context, the ALRC review may wish to further explore the following concepts in relation to consent:
- **voluntary**: given without coercion or undue influence;
 - **informed**: based on sufficient and understandable information regarding the nature and purpose of the use;
 - **specific**: clearly identifying the uses to which the tissue may be put;
 - **time-limited or enduring**: depending on the context (e.g. research vs immediate therapeutic use); and
 - **revocable**, where practicable, prior to use.²⁹
35. The ALRC review may also wish to look at statutory provisions for consent to be recorded in writing or by other verifiable means, including via digital registers, provided that appropriate safeguards are in place.³⁰
36. We note that, in Western Australia, the *Human Tissue and Transplant Act 1982* (WA) was substantially amended by the *Human Tissue and Transplant Amendment Act 2022* (WA). The main amendments commenced on 19 February 2024 and the changes to the Act and Regulations addressed some of the matters raised by the ALRC's Issues Paper, including the expansion of consent provisions in relation to donation of tissue from living persons and after the death of a person for the

²⁶ See National Health and Medical Research Council, *Ethical guidelines for cell, tissue and organ donation and transplantation in Australia* (2025) which, amongst other things, highlights the ethical considerations of non-clinical uses of human tissue; see also World Health Organization, [Guiding Principles on Human Cell, Tissue and Organ Transplantation](#) (2010), Principle 5 regarding respect for human dignity and prohibition on commercialisation; and Australian Medical Association, [Code of Ethics 2004](#) (Editorially Revised 2006. Revised 2016), which underscores informed consent and ethical use of human biological materials.

²⁷ Australian Law Reform Commission, [Review of Human Tissue Laws](#) (Issues Paper, May 2025) 13.

²⁸ National Health and Medical Research Council (NHMRC), [National Statement on Ethical Conduct in Human Research](#) (2023), Chapter 2.2.

²⁹ *Ibid.*

³⁰ Australian Organ and Tissue Authority, *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* (Edition 2, April 2021). Also see National Health and Medical Research Council, [Guidelines under Section 95 of the Privacy Act 1988](#).

purposes of training, education and quality assurance.³¹ This may serve as a point of reference for the ALRC's review.³²

Role of substitute decision makers

37. Where the individual is deceased, lacks decision-making capacity, or is a child, consent may be obtained from a substitute decision-maker (e.g. next of kin, legal guardian) in accordance with a clearly defined statutory hierarchy.³³ The Law Council supports greater harmonisation of these provisions across jurisdictions.
38. The Law Council notes that, with consent to organ donation being refused by family in almost half of all cases,³⁴ this is a crucial question that should be addressed in the ALRC's review. There needs to be clarification to the law on who has the final say on organ donation. In this context, the review should consider whether express recognition of prior recorded consent—such as that provided through the Australian Organ Donor Register—is given sufficient legal weight where available.³⁵ The approach needs to be consistent with principles of good regulatory practice, including respect for individual autonomy, clarity and certainty in decision-making, and alignment with national infrastructure that facilitates voluntary, informed consent.³⁶
39. Further, based on feedback received from the LIV, consideration should be given in the review to the consent processes for ante mortem procedures performed on potential donors, and the concept of implied consent.³⁷ In the state of Victoria, this is particularly in light of the inclusion of Division 1 of Part IV in the *Human Tissues Act* (Vic). The LIV also flagged the need to examine the interactions of human tissue laws with any relevant state- and territory-based guardianship and other substitute decision-making legislation.³⁸ We would welcome the inclusion of these issues as priority reform areas.

³¹ Other changes include: providing a new regulatory framework in relation to tissue supply arrangements; expanding authority for non-medical practitioners with particular training to remove certain categories of tissue to assist in the timely removal of tissue; aligning with the provisions of the *Therapeutic Goods Act 1989* (Cth) in addressing costs recovery for authorised anatomy schools and for suppliers of human tissue products; and increasing the penalties for unlawful trading in tissue and advertising of tissue trading.

³² For example, in relation to s 22 of the *Human Tissue and Transplant Act 1982* (WA), see: *Ex parte CH* [2023] 487; *Ex parte P* [2022] WASC 477; *Ex parte A* [2022] WASC 52; *Ex parte H* [2020] WASC 99; *Ex parte C* [2013] WASC 3; *Ex parte M* [2008] WASC 276; *S v Minister for Health (WA)* [2008] WASC 262. Two other cases of note: *GLS v Russell-Weisz* [2018] WASC 79 and *Minister for Health v AS & Anor* [2004] WASC 286.

³³ Australian Law Reform Commission (ALRC), [Equality, Capacity and Disability in Commonwealth Laws](#) (Report 124, 2014).

³⁴ See, for example, Rachel Carbonell, Loretta Florance and Jackson Worthington, [Organ donors on the rise, but fewer Australians receiving life-saving transplants](#) (ABC News online, 25 February 2025).

³⁵ Australian Organ and Tissue Authority, *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* (Edition 2, April 2021).

³⁶ Services Australia, [Australian Organ Donor Register](#) (webpage, last updated 10 December 2021). Also see Department of Prime Minister and Cabinet, [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies](#) (June 2023), pp 30–1, which identifies consistency, transparency, and respect for individual rights as key elements of good regulation. Further, see Uniform Law Commission (US), [Revised Uniform Anatomical Gift Act](#) (2006), s 8, which provides for first-person authorisation of donation decisions as legally binding on others, reflecting international best practice on autonomy and certainty.

³⁷ Stuart Webb (President, Law Institute of Victoria), [Referral of the Human Tissue Act 1982 to the Victorian Law Reform Commission](#) (Letter to the Hon Jill Hennessy MP, 6 September 2019).

³⁸ *Ibid.* In Victoria, for example, these would include the *Medical Treatment Planning and Decisions Act 2016* (Vic), and the *Guardianship and Administration Act 2019* (Vic).

Recording and management of consent

40. The framework should enable the secure and consistent recording, storage and transmission of consent information across healthcare, research and regulatory settings.³⁹ The Law Council supports shared access to information and digitally integrated health systems (e.g. My Health Record), subject to strong privacy and data protection standards.⁴⁰
41. The Law Council submits that the future framework should draw principled distinctions between uses of human tissue based on their purpose, risk profile, and ethical significance, while maintaining a coherent and consistent approach to consent. A unified legislative approach across jurisdictions, supported by ethical guidance, is necessary to ensure clarity, public trust and legal integrity in all contexts of tissue use.

Recommendations

- **The ALRC review may wish to further explore the following concepts in relation to consent for human tissue donation: voluntary, informed, specific, time-limited or enduring (depending on context) and revocable (where practicable).**
- **Priority reform areas of the ALRC review should include:**
 - **the consent processes for ante mortem procedures performed on potential donors, and the concept of implied consent; and**
 - **the interactions of human tissue laws with any relevant state- and territory-based guardianship and other substitute decision-making legislation.**
- **The framework for HTAs should enable the secure and consistent recording, storage and transmission of consent information across healthcare, research and regulatory settings.**

Organ trafficking and organ transplant tourism

42. The issue of organ trafficking is relevant across the ALRC review—but especially under Questions 5 and 6—to ensure Australia’s human tissue laws are:
- ethically defensible;
 - internationally aligned; and
 - capable of deterring and responding to serious misconduct.
43. The Issues Paper notes that the ALRC may consider what role, if any, HTAs can play in the ongoing efforts to address organ trafficking and transplant tourism. The Law Council supports this proposal.
44. The Law Council continues to be deeply concerned about trafficking in persons for the purposes of organ removal, organ trafficking, itself, and organ transplant

³⁹ Australian Government, *Privacy Act 1988* (Cth), Part 3, Division 2 (Australian Privacy Principles). Also see National Health and Medical Research Council, [Guidelines under Section 95 of the Privacy Act 1988](#).

⁴⁰ Law Council of Australia, [My Health Record system](#) (24 September 2018); see also Law Council of Australia, [Phase 3 of Australia’s Digital Identity legislation](#) (28 October 2021).

tourism. Such practices have the potential to result in detrimental and fatal consequences for victims.

Extraterritorial application of organ trafficking laws

45. The Law Council notes that one of the recommendations in the Joint Standing Committee on Foreign Affairs, Defence and Trade's (**Joint Standing Committee**) report to Parliament in relation to an inquiry into organ trafficking and transplant tourism is to extend Australia's organ trafficking laws' extraterritorially to capture Australians who travel overseas to receive organs obtained through coercion or exploitation.⁴¹ The Law Council supported the extension of extraterritorial application of the organ trafficking offences⁴² in its submission to the Joint Standing Committee's inquiry.⁴³
46. In its official response, the Australian Government acknowledged the concern, but declined to implement the recommendation. It pointed instead to existing offences under the Criminal Code, which prohibit facilitating travel for the purpose of illegal organ removal, but confirmed that these provisions do not extend to Australians who engage in transplant tourism abroad without involving Australian territory.⁴⁴ Thus, a significant gap in the extraterritorial application of the law remains unaddressed.
47. In 2024, the Parliament passed the *Migration Amendment (Overseas Organ Transplant Disclosure and Other Measures) Bill 2023*. While the legislation introduces a requirement for arriving travellers to disclose any overseas organ transplants undertaken within the past five years and allows for visa cancellation on the basis of involvement in organ trafficking, it does not criminalise transplant tourism or otherwise extend Australia's criminal jurisdiction extraterritorially.⁴⁵
48. The Law Council therefore recommends that the ALRC review consider options for extending the geographical jurisdiction for the organ trafficking offences under the Criminal Code. We acknowledge that this would entail reform of Commonwealth legislation (not only state and territory HTAs), but the Law Council sees value in the offence provisions applying to anyone anywhere regardless of citizenship or residence. Our previous submission provides further details on how this may be achieved.⁴⁶

Council of Europe Convention against Trafficking in Human Organs

49. Australia has not signed or ratified the *Council of Europe Convention against Trafficking in Human Organs* (2014), despite the Joint Standing Committee recommending accession as a mechanism for international cooperation and the

⁴¹ Joint Standing Committee on Foreign Affairs, Defence and Trade, [Compassion, Not Commerce: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism](#) (Report, tabled in Parliament 3 December 2018) Recommendation 5.

⁴² *Criminal Code Act 1995* (Cth) ss 271.7B, 271.7C, 271.7D, 271.7E.

⁴³ Law Council of Australia, [Organ Trafficking and Organ Transplant Tourism](#) (Submission, 14 August 2017).

⁴⁴ Australian Government, [Australian Government Response to the Joint Standing Committee on Foreign Affairs, Defence and Trade Report: Compassion, Not Commerce](#) (February 2021).

⁴⁵ Australian Parliament, [Migration Amendment \(Overseas Organ Transplant Disclosure and Other Measures\) Bill 2024 \(Cth\)](#) (Explanatory Memorandum) 2.

⁴⁶ Law Council of Australia, [Organ Trafficking and Organ Transplant Tourism](#) (Submission, 14 August 2017) 15.

alignment of domestic law with global norms.⁴⁷ As of June 2025, Australia is not listed among the parties to the Convention.⁴⁸

50. The Law Council continues to support the accession to the Council to Europe Convention for the same reasons as listed above.⁴⁹ Accession to the Convention could assist in addressing a gap in Australian domestic legislation regarding the offence of organ trafficking. Subdivision BA of Division 271 in the Criminal Code criminalises only the act of organising or facilitating the movement of another person where the movement could result in the removal of an organ in a manner contrary to State or Territory law, or contrary to the consent or medical needs of the other person. The Subdivision does not criminalise transplant commercialism or transplant tourism.⁵⁰
51. Therefore, it is not organ trafficking per se that is an offence but, rather, the movement of people for the purposes of facilitating the unlawful removal of organs. Trafficking in organs, and trafficking in people for the purpose of organ removal, are two distinct matters.⁵¹ A clear distinction is required to better prevent and prosecute such acts.
52. If Australia accedes to the Council of Europe Convention, there will need to be an assessment of the consistency of its provisions with the Criminal Code. For example, the Convention requires states parties to take the necessary legislative and other measures to:
 - (a) ensure that legal persons can be held liable for offences established in accordance with this Convention when committed for their benefit by any natural person in the circumstances specified;⁵² and
 - (b) ensure that a number of specific circumstances may be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences.⁵³

Recommendations

- **The ALRC review should consider options for extending geographical jurisdiction for the organ trafficking offences under the Criminal Code.**
- **The ALRC review should consider Australia's accession to the 2014 Council of Europe Convention against Trafficking in Human Organs and give due consideration to necessary amendments to the Criminal Code to implement the required international obligations into domestic law.**

⁴⁷ Joint Standing Committee on Foreign Affairs, Defence and Trade, [Compassion, Not Commerce: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism](#) (Report, tabled in Parliament 3 December 2018) Recommendation 6.

⁴⁸ Council of Europe, [Chart of Signatures and Ratifications of Treaty 216: Council of Europe Convention against Trafficking in Human Organs](#) (status as of 26 June 2025).

⁴⁹ As previously recommended in Law Council of Australia, [Organ Trafficking and Organ Transplant Tourism](#) (Submission, 14 August 2017).

⁵⁰ Australian Parliament, [Migration Amendment \(Overseas Organ Transplant Disclosure and Other Measures\) Bill 2024 \(Cth\)](#) (Explanatory Memorandum) 3.

⁵¹ Arthur Caplan et al, [Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organs](#) (Joint Council of Europe/United Nations Study, 2009) 55.

⁵² Council of Europe, [Convention against Trafficking in Human Organs](#) (Treaty Series No. 216) Article 11.

⁵³ Ibid, Article 13.

Other issues that the ALRC inquiry should focus on

53. The Issues Paper highlights that, currently in Australia, there is not enough human tissue available to meet people's need for life-saving interventions.⁵⁴ The Law Council supports the consideration of measures that will help to overcome the current low conversion rate of organ donations in Australia.
54. In this context, we suggest that the ALRC consider whether the framework in Australia should be an 'opt-in' or an 'opt-out' system. The consideration of this threshold question would align with initiatives by a number of overseas governments to increase the rate of organ donation.⁵⁵
55. Another aspect that could be considered in this context is the role of *DonateLife*⁵⁶ to assess whether its current approach to organ donation is optimal to maximise the organ donation conversion rate. Considering donation numbers could be improved, this review is an opportunity to make such an evaluation.⁵⁷
56. Further, the ALRC should consider whether there is a need to give registered health practitioners statutory immunity from civil and criminal proceedings if they follow a donor's wishes and act on lawful and valid consent, despite objections from family members or other persons. This may be akin to the immunity provided in section 52 of the *Medical Treatment Planning and Decisions Act 2016* (Vic).

The interaction with state-based voluntary assisted dying legislation

57. It is important that human tissue laws work cooperatively with state- and territory-based voluntary assisted dying (VAD) legislation. For example, a person choosing to use the provisions of VAD legislation may also want to be an organ donor. The DonateLife 2024–25 Corporate Plan notes that Australia has become the fifth country in the world to facilitate organ donation after VAD, and that as of June 2024 this change has resulted in six people donating their organs in Australia.⁵⁸ Given the volume of people accessing VAD laws across Australia,⁵⁹ it is important to ensure that a reasonable and appropriate approach is taken towards the interaction between human tissue laws and VAD laws and we recommend that the ALRC review examines and clarifies their interaction.

⁵⁴ Australian Law Reform Commission, [Review of Human Tissue Laws](#) (Issues Paper, May 2025) 7 [31].

⁵⁵ See, for example, *Human Tissue Act 2024* (Ireland). Also see: Organ Donation Transplant Ireland, [Human Tissue Act 2024 and the Opt-Out Register](#) (Frequently Asked Questions, 2024).

⁵⁶ The Australian Government Organ and Tissue Authority leads the national *DonateLife* program to increase organ and tissue donation and transplantation.

⁵⁷ See, for example, data in Loretta Florance and Jackson Worthington, [Organ donors on the rise, but fewer Australians receiving life-saving transplants](#) (ABC News Online, 25 February 2025).

⁵⁸ Australian Organ and Tissue Donation and Transplantation Authority, [Corporate Plan 2024-25](#) (2024) 9.

⁵⁹ The 2024 State of VAD Report by GoGentle Australia notes that there are variations in uptake and administration methods among states, but there is a growing utilisation of VAD services across Australia and since 2019, 5,338 Australians have sought VAD and there have been 2467 VAD deaths. See Go Gentle Australia, [State of VAD Report 2024: Voluntary Assisted Dying in Australia and New Zealand](#) (August 2024).

Recommendations

- **The ALRC review should consider:**
 - **whether the framework in Australia for organ donation should be an ‘opt-in’ or an ‘opt-out’ system to increase the rate of organ donation;**
 - **the role of DonateLife to assess whether its current approach to organ donation is optimal to maximise the organ donation conversion rate;**
 - **whether registered health practitioners should have statutory immunity from civil and criminal proceedings if they follow a donor’s wishes and act on lawful and valid consent, despite objections from family members or other persons; and**
 - **the interaction between human tissue laws and state- and territory-based voluntary assisted dying legislation to ensure they work cooperatively.**

Question 8: Issues the ALRC review is unlikely to focus on

Coronial jurisdiction and timely access to human tissue donation

58. The ALRC has indicated that it is unlikely to consider certain issues that arise under, and are dealt with by, frameworks outside of human tissue laws. In particular, the ALRC has noted that the review is unlikely to consider coronial inquests, except as they intersect with human tissue laws.
59. It is important to note that there is a complex interaction between coronial responsibilities and time-critical human tissue donation processes, particularly in circumstances where death is imminent and the Coroner may ultimately assume jurisdiction. These situations raise important legal, ethical and procedural considerations that warrant clarification to ensure the lawful and timely facilitation of donation, while upholding the integrity of coronial investigations.
60. In many Australian jurisdictions, the Coroner’s statutory jurisdiction is generally understood to commence only upon death.⁶⁰ However, clinical protocols for donation—especially for viable organ transplantation—often necessitate preparatory steps before death occurs or before death is formally declared. In cases involving sudden or unexpected deaths, donation opportunities may be lost due to uncertainty about whether pre-mortem interventions (such as the administration of medications to preserve organs) are permissible without prior coronial authorisation.⁶¹ This is further complicated by variations in statutory definitions of ‘reportable deaths’ and procedural differences across states and territories.⁶²
61. Last year, during the Victorian Parliament’s Inquiry into Increasing the Number of Registered Organ and Tissue Donors, a submission from Alfred Health and ANZICS expressed that because of *“the absence of express guidance from the Parliament, Coroners are seemingly declining to authorise organ donation if there is even the*

⁶⁰ See e.g. *Coroners Act 2008* (Vic) s 4(1); *Coroners Act 2009* (NSW) s 6; *Coroners Act 2003* (Qld) s 7. In general, coronial jurisdiction begins after death when certain conditions are met.

⁶¹ See Organ and Tissue Authority, [Best Practice Guideline for Donation after Circulatory Determination of Death \(DCDD\) in Australia](#) (Edition 1.0, October 2021), 9.

⁶² *Ibid.* See also, Parliament of Victoria, [Inquiry into increasing the number of registered organ and tissue donors](#) (Final Report, March 2024).

most remote possibility that the deceased's donatable organs might be relevant to an investigation".⁶³ In practice, this results in donatable organs being discarded and potential transplant recipients missing out.⁶⁴

62. The Law Council submits that greater legislative and procedural clarity would assist to streamline donation processes in this context. We recommend the development of national guidance on:

- the time and manner in which Coroners are to be notified of potential reportable deaths in a donation context;⁶⁵
- the lawful limits of clinical intervention prior to death where a reportable death is likely;⁶⁶
- the responsibilities and authority of designated officers in liaising with coronial staff;⁶⁷
- the balancing of evidentiary and investigative needs against the urgency of donor management;⁶⁸ and
- reasonable response timeframes to enable effective donation without compromising coronial functions.⁶⁹

63. The Law Council considers that a nationally consistent framework would assist in ensuring that coronial oversight is preserved without unnecessarily impeding lawful donation in urgent clinical contexts. Such a framework should be developed in close consultation with coronial authorities, donation agencies, health departments, and the transplant clinical community.

Recommendation

- **The ALRC review should consider the development of a nationally consistent framework to provide greater legislative and procedural clarity on:**
 - **the timing and manner in which Coroners are to be notified of potential reportable deaths in a donation context;**
 - **the lawful limits of clinical intervention prior to death where a reportable death is likely;**
 - **the responsibilities and authority of designated officers in liaising with coronial staff;**
 - **the balancing of evidentiary and investigative needs against the urgency of donor management; and**
 - **reasonable response timeframes to enable effective donation without compromising coronial functions.**

⁶³ Parliament of Victoria, [Inquiry into increasing the number of registered organ and tissue donors](#) (Final Report, March 2024) 197-8, quoting Alfred Health and ANZICS Death and Organ Donation Committee, Submission 47, page 3.

⁶⁴ *Ibid*, 197 [7.3.4].

⁶⁵ This should be done in close consultation with coronial authorities, donation agencies, health departments, and the transplant clinical community.

⁶⁶ See Organ and Tissue Authority, [Best Practice Guideline for Donation after Circulatory Determination of Death \(DCDD\) in Australia](#) (Edition 1.0, October 2021).

⁶⁷ *Ibid*, 9 (regarding the role of Designated Officers).

⁶⁸ Parliament of Victoria, [Inquiry into increasing the number of registered organ and tissue donors](#) (Final Report, March 2024) 178-181, which discusses opportunities for improvements to the tension between donation timeframes and coronial processes.

⁶⁹ Organ and Tissue Authority, [Best Practice Guideline for Offering Organ and Tissue Donation in Australia](#) (Edition 2, April 2021) 7-11.