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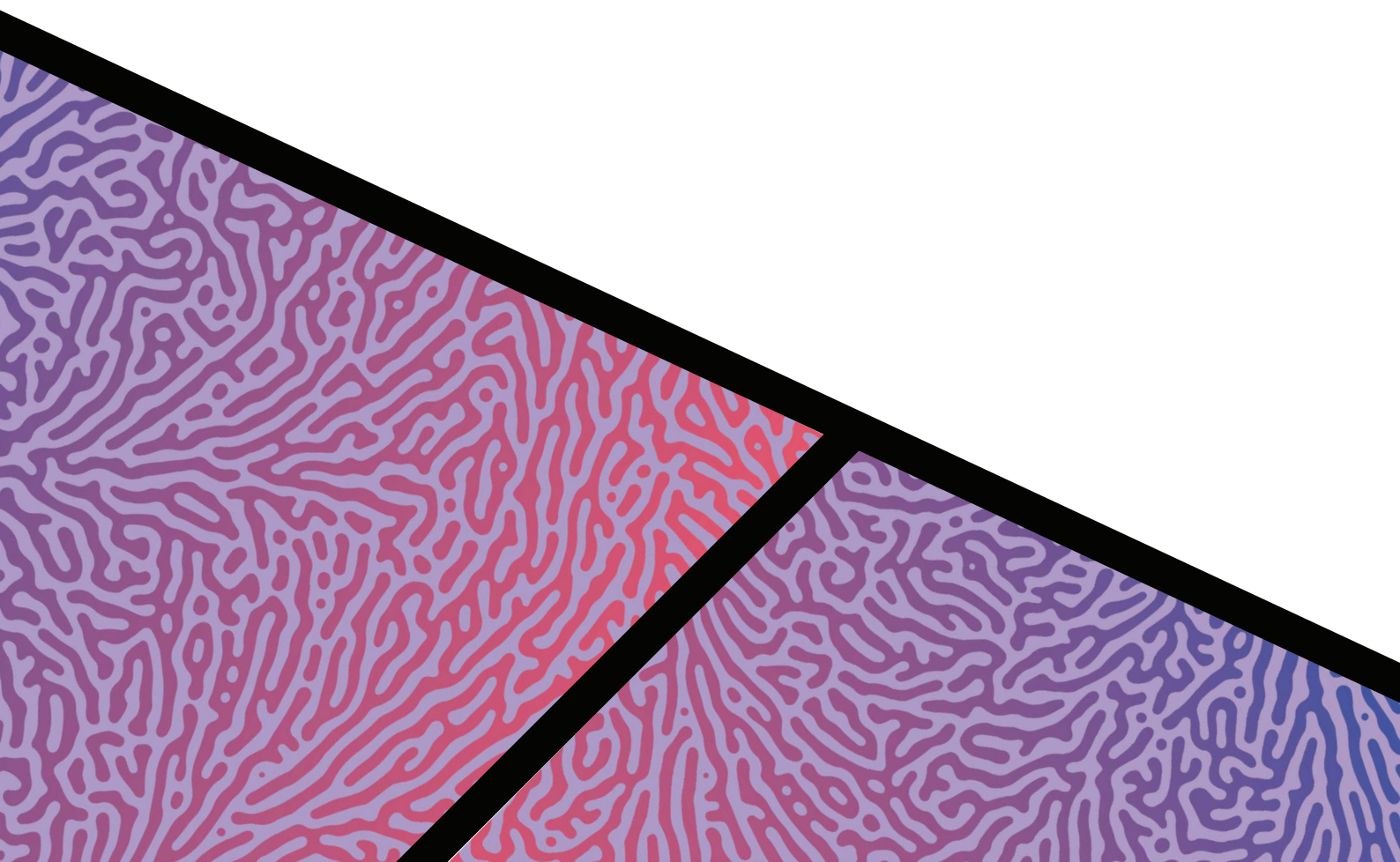
Australian Law Reform Commission

ISSUES PAPER

REVIEW OF HUMAN TISSUE LAWS

Issues Paper 51

May 2025



The Australian Law Reform Commission acknowledges the Traditional Owners and Custodians of Country throughout Australia and their continuing connection to land, sea, and community. We pay our respects to Aboriginal and Torres Strait Islander cultures, and to Elders past and present. In particular, we acknowledge the Traditional Custodians of the lands on which our offices are based: the Wurundjeri people of the Kulin Nation for our Melbourne office; and the Jagera people and Turrbal people for our Brisbane office.

This Issues Paper reflects the law as at 2 May 2025.

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Glossary

ANZICS	Australian and New Zealand Intensive Care Society
Australian Organ Donor Register (Donor Register)	The national register where anyone over 16 years old may register to express their wish to donate human tissue after their death.
Deceased donation	When human tissue is donated after a person has died.
Designated Officer	A medical doctor who provides legal authority for donation. They are appointed to this position by either a Minister or hospital management (depending on the laws of the state or territory).
Human Tissue	Includes solid organs (eg, kidneys, liver, heart, lungs, and pancreas); blood; bone marrow; and other bodily substances (eg, heart valves, bone, tendons, and corneas).
Human Tissue — regenerative	Includes tissue that is replaced in the body of a living person through natural processes after that tissue is removed.
Human Tissue — non-regenerative	Includes tissue that is not regenerative, because it does not replace itself in the body of a living person through natural processes after that tissue is removed.
Human Tissue Acts (HTAs)	A collective term for the state and territory Acts that were adopted in the late 1970s/early 1980s to regulate human tissue in Australia. New South Wales and Tasmania have a <i>Human Tissue Act</i> and an <i>Anatomy Act</i> . Victoria has a <i>Human Tissue Act</i> . The Territories, Queensland, and South Australia have <i>Transplantation and Anatomy Acts</i> . Western Australia has the <i>Human Tissue and Transplant Act</i> and an <i>Anatomy Act</i> .
Living donation	When human tissue is removed from and donated by a living person (donor).
NHMRC	National Health and Medical Research Council: an independent statutory agency that produces health and ethical guidelines.
Organ and Tissue Authority (OTA)	The Australian Organ and Tissue Donation and Transplantation Authority. The OTA ‘works with states and territories, clinicians and the community sector to deliver the Australian Government’s national program to improve organ and tissue donation and transplantation outcomes in Australia.’ ¹
OTA Act	The <i>Australian Organ and Tissue Donation and Transplantation Authority Act 2008</i> (Cth). This Act establishes the Organ and Tissue Authority .

¹ Department of Health and Aged Care, ‘Australian Organ and Tissue Authority’ <<https://www.health.gov.au/contacts/australian-organ-and-tissue-authority-ota>>.

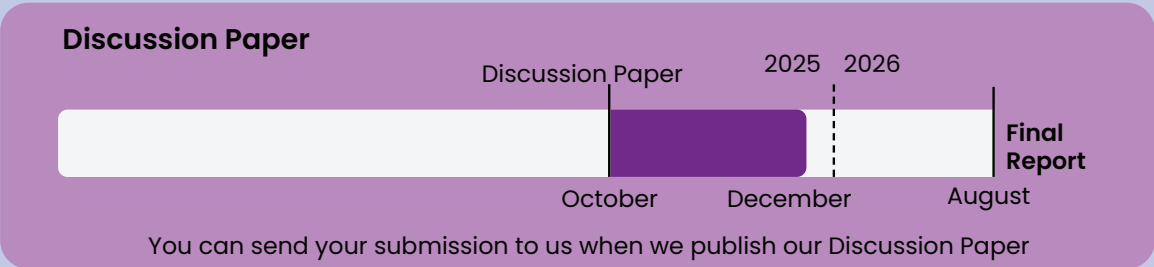
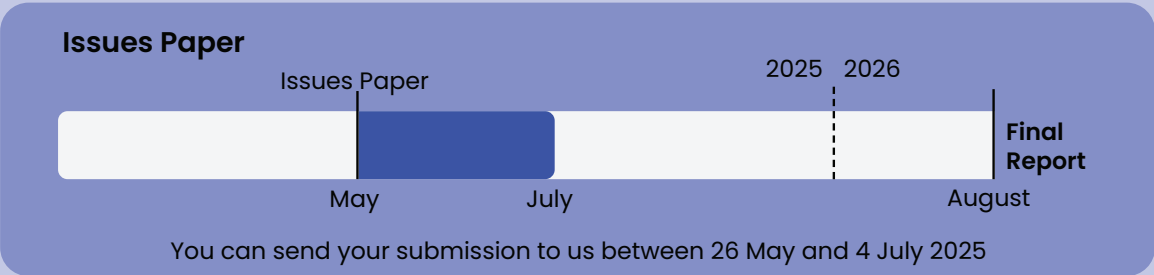
Perfusion technology	Technology that restores circulation to organs after death to preserve the organ for the purpose of transplantation. Perfusion can occur after an organ is removed from a deceased donor using special machines (this is called ex vivo machine perfusion). In some places outside Australia, perfusion can occur inside the deceased donor's body before organs are removed (this is called normothermic regional perfusion).
Post-mortem examination	An examination of the body of a deceased person to obtain information about the cause of the person's death and anything related to disease present in the body. Also known as an autopsy.
Schools of anatomy	Educational institutions that are established by legislation to receive human bodies that have been donated for the purpose of the teaching, study, and practice of anatomy.
Scientific (or 'research') purposes	'Scientific purposes' is an expression used in the HTAs to refer to the use of human tissue in science. Sometimes this is referred to as use for 'research' purposes. Our Terms of Reference note there have been developments in the use of human tissue 'for social, clinical and research purposes'.
TSANZ	Transplantation Society of Australia and New Zealand
UN	United Nations
WHA	World Health Assembly
WHO	World Health Organization

How do I participate?



Make a formal submission

Your submission might respond to either or both of:



Your submission might be



a written document



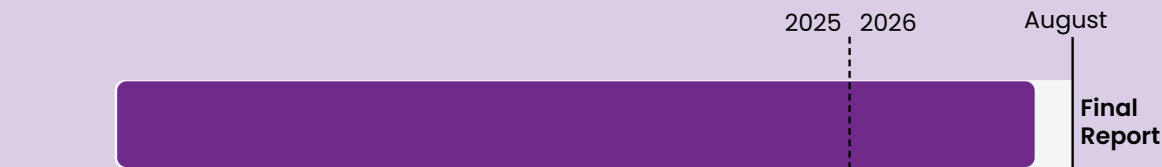
an audio recording



any format that suits you



Get in touch and share your views



You can share your views with us at any time during the Inquiry. You might like to:



email us



send us a letter



give us a call

Starting a conversation

1. This Issues Paper starts a conversation by asking you to let us know your thoughts about our Review of Human Tissue Laws. You can do this by making a submission or in any other way that works for you.
2. Your input is very important and we are committed to listening. At this stage, we are especially interested in hearing about:
 - your personal experience of how human tissue is used in Australia (human tissue use can include many things, for example, organ transplantation or research using tissue samples); and
 - your personal experience of human tissue laws and how they work.
3. We are also interested in hearing from organisations, professional associations, and anyone else with an interest in this area.
4. This Issues Paper sets out eight questions that you may wish to answer. We are asking these questions to help us identify good aims and principles for human tissue laws and law reform, and the issues that we should address when we develop our ideas for reform. You may also want to tell us about your own ideas for reform.
5. You can structure your submission in any way that works for you. You do not have to answer all or any of the questions in our list of questions.
6. The best way to make a written submission is by uploading it through the [ALRC website](#). You can also email your ideas to us, send us an audio or video recording, or contact us to explain how you want to give us your ideas or ask for help to make a submission.
7. We will accept submissions until **4 July 2025**. We will publish submissions on our website, unless you ask for your submission to be confidential (private).
8. We know that making a submission can be time-consuming and sometimes difficult. We also know that people have competing demands on their time and resources.
9. We are asking for submissions now to help us identify good aims and principles for human tissue laws and law reform, and the issues that we should address when we develop our ideas for reform. If you cannot make a submission now, there will be another opportunity to make a submission when we publish our Discussion Paper. The Discussion Paper will contain ideas for reform and ask for feedback on those ideas.
10. You are welcome to make a submission in response to one or both of our papers, whatever you think best.

List of questions

Remember, you only need to answer the questions you want to answer

1. What is your personal experience of how human tissue is obtained or used in Australia?
2. What is your personal experience of how human tissue laws work in Australia?
3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?

You might think about aims such as:

- *increasing the amount of tissue available for transplantation and/or other uses;*
- *creating a transparent and easy to navigate tissue donation system;*
- *making sure tissue donation happens safely;*
- *making sure people have a good understanding of what is involved in donating tissue;*
- *making sure people understand how their tissue will be used;*
- *equity, and removing barriers faced by some individuals or groups to human tissue donation or transplantation;*
- *making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

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

You might consider principles such as:

- *respect for persons and for the human body;*
- *equity;*
- *the importance of public trust in the framework that governs how human tissue is obtained and used in Australia;*
- *the importance of laws that are well designed and effective.*

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

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

You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about:

- *if there are issues caused, or likely to be caused, by current or emerging technology that we haven't identified in this Issues Paper; and*
- *if there is a need to update the HTAs to account for contemporary community values, in ways that we haven't identified elsewhere in this Issues Paper.*

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

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

What we have been asked to do

11. There are many uses of human tissue, including in medicine, research, and education. State and territory legislation — the HTAs — regulate how human tissue is obtained from living or dead people, and how it can be used.²

12. This Inquiry is the first major national review of human tissue laws since we recommended a model law for the regulation of human tissue in 1977.³ The states and territories each adopted legislation based on the model law set out in our 1977 report, although with some variations. Since they were first adopted, the HTAs have been amended in different ways. Medical knowledge and technology have also developed. This means there are inconsistencies in how the states and territories regulate the retrieval and use of human tissue, and some laws may be out of date.

13. A national body — the OTA — was established in 2008 to promote a consistent approach to organ and tissue donation and transplantation, and establish standards and codes of practice.⁴ Its focus is on donation for transplantation rather than other uses of human tissue.

14. After consulting with the Commonwealth and State and Territory Health Ministers, in February 2025 the Commonwealth Attorney-General asked us to conduct an 18-month inquiry into human tissue laws.

15. Our Terms of Reference ask us to consider if any reforms are necessary or desirable to **harmonise** (make consistent) and **modernise** (bring up-to-date) human tissue laws.

The scope of this Inquiry

16. The HTAs are not the only relevant laws in this area. Aside from the HTAs, many laws influence how human tissue is or can be used ([Figure 1](#)).

17. Our Terms of Reference ([Appendix A](#)) are broad and do not say exactly what laws we should consider. We will limit the scope of our Inquiry to make sure we can provide strong reform recommendations that address the most urgent issues relating to the use of human tissue.

18. Our plan, which may change depending on what people tell us in consultations and submissions, is to:

- take a principles-based approach to reform;
- focus on a selection of ‘high priority’ issues where reform is urgent and/or easy to achieve; and
- focus our reform recommendations to
 - improve consistency across the HTAs (in doing so, we will not propose or draft new legislation, and we will not consider other laws, except where they intersect in significant ways with the HTAs); and
 - improve the adaptability of the HTAs so they can respond well to new and emerging technologies, and are consistent with contemporary values.

19. We will continue to consider and refine this plan over the course of the Inquiry.

2 *Transplantation and Anatomy Act 1978 (ACT); Anatomy Act 1977 (NSW); Human Tissue Act 1983 (NSW); Transplantation and Anatomy Act 1979 (NT); Transplantation and Anatomy Act 1979 (Qld); Transplantation and Anatomy Act 1983 (SA); Anatomical Examinations Act 2006 (Tas); Human Tissue Act 1985 (Tas); Human Tissue Act 1982 (Vic); Anatomy Act 1930 (WA); Human Tissue and Transplant Act 1982 (WA).*

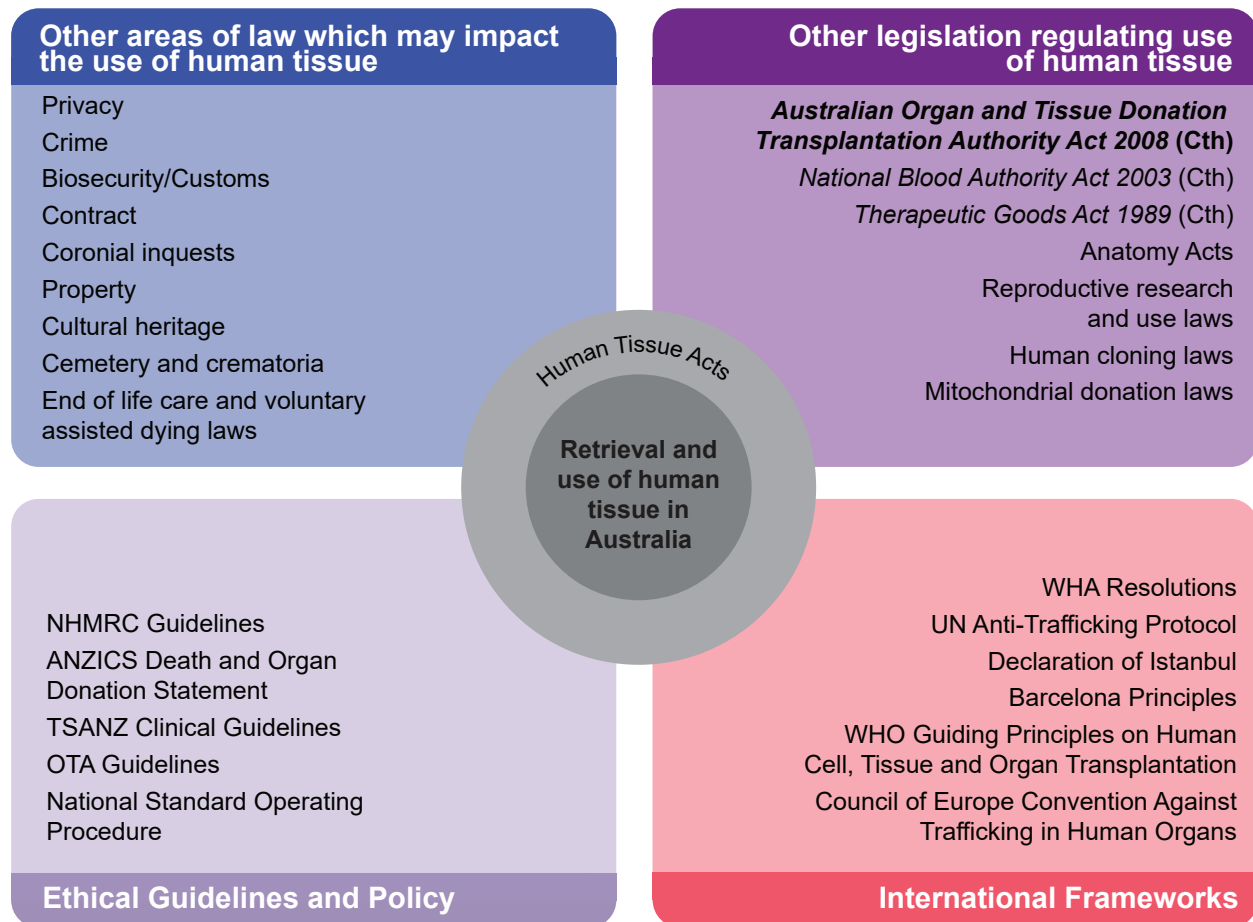
3 This law was included in one of our previous reports: Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977).

4 *Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth)* s 11.

The human tissue landscape

20. In Australia, the retrieval and use of human tissue is governed by a mix of laws, regulations, policies, and ethical guidance. **Figure 1** provides an overview of this landscape.

Figure 1: Regulating the use of human tissue



21. As mentioned earlier, the main laws governing retrieval and use of human tissue are state and territory laws. In **Figure 2**, we highlight some major features of, and differences between, the state and territory HTAs.

Figure 2: Regulating the use of human tissue — state and territory Human Tissue Acts



Aims and principles

22. To reform the law well, we need to think about its aims: what is the law designed to do, and is it working well to achieve its purpose? If it is not working well, how can it be changed to achieve its aims?

23. Good laws do not just achieve their aims, they also work in a way that is principled and just. Our Terms of Reference ask us to take a principles-based approach to this Inquiry.

24. When we consider what reforms are necessary or desirable to harmonise and modernise human tissue laws, as our Terms of Reference ask us to do, we will be guided by:

- the purpose or aims of human tissue laws; and
- the principles that human tissue laws should include or be consistent with.

25. The aims and principles will help us decide:

- when the law in each state and territory should be consistent and when differences are justified; and
- how the law should be updated and respond to new technologies.

26. The HTAs do not currently set out their purposes or identify specific principles to guide how human tissue is obtained and used. But their provisions do reflect broader ethical principles, including the need for informed consent, restrictions on the commodification of tissue, and requirements to respect persons and the human body.

27. When the OTA was first established, the Minister for Health and Ageing explained its purpose was to address ‘the enormous personal costs’ for Australians on organ transplant waiting lists because of a shortage of organs for transplantation.⁵ Aims in the OTA Act include ‘improving access to organ or tissue donation and transplantation services’, and ‘minimising waiting times for ... organ or tissue recipients’.⁶ The OTA Act also includes principles. It requires the OTA to exercise its functions in a way that considers international best practice, safety, effectiveness, privacy, equity, and transparency.⁷

28. Below we set out four principles that are implicit in or could be seen to be fundamental to human tissue laws that are ethical and just. These are not intended to capture all the relevant or appropriate aims and principles of human tissue laws. You may wish to tell us about other aims or principles you consider important.

29. In our discussion, we have considered guidance provided by the WHO,⁸ and other international organisations,⁹ ethical and clinical guidelines that govern tissue retrieval and use in

5 Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 (Cth) 1.

6 Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth) ss 12(a)(ii), (iv).

7 Ibid ss 12(b)–(g).

8 See, eg, World Health Organization, *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, WHA Res 63.22, WHO Doc WHO/HTP/EHT/CPR/2010.01 (2010); World Health Organization, *Principles for Global Consensus on the Donation and Management of Blood, Blood Components and Medical Products of Human Origin*, WHO Doc EB140/18 (29 December 2016); World Health Organization, *Increasing Availability, Ethical Access and Oversight of Transplantation of Human Cells, Tissues and Organs*, WHA Res 77.4, WHO Doc A/77/VR/8 (1 June 2024).

9 See, eg, Global Alliance of Eye Bank Associations, *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies* (2018); Transplantation Society and the International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition).

Australia,¹⁰ and broader understandings of what is required to create good and just laws. In the course of our review, when we are considering what reforms to human tissue laws are necessary or desirable, we will also take into account international best practice.

30. While each of the principles may be important, they may not be equally important in every situation, and each may need to be balanced against the other, as well as against other principles. On the other hand, these principles could help to support and advance each other, as well as the aims that laws are designed to achieve.

Reform should support increased access to human tissue in Australia

31. Currently in Australia, there is not enough human tissue available to meet peoples' need for life-saving interventions. There is also a need for researchers to access tissue for use in research that could produce important public health benefits and enhance peoples' lives.

32. Increasing access to human tissue might include making sure that donation systems operate effectively and are trusted by the public (we discuss public trust below). Donation systems include systems that retrieve and distribute tissue for medical purposes (including transplantation); research; and educational purposes (such as to train medical students).

33. In the transplantation context, the WHO has called for 'high-quality, safe and efficacious procedures ... for donors and recipients alike'.¹¹ For a system to be effective, the benefits achieved must out-weigh the potential risks and burdens and this requires a strong evidence base.¹²

34. Increasing the availability of solid organs for transplantation could improve people's health and wellbeing and save people's lives. It could also help meet international calls for countries to strive for self-sufficiency to address the harms of organ trafficking and transplant tourism.¹³

35. Reforms that promote increased access to human tissue could include:

- facilitating changes that make it easier to identify people who could become donors after they die; and
- removing unnecessary barriers that make it hard for donation systems to operate.

10 See, eg, National Health and Medical Research Council, *Organ and Tissue Donation by Living Donors: Guidelines for Ethical Practice for Health Professionals* (March 2007); National Health and Medical Research Council, *Organ and Tissue Donation after Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals* (March 2007); National Health and Medical Research Council, *Ethical Guidelines for Organ Transplantation from Deceased Donors* (E76, April 2016); National Health and Medical Research Council, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders* (IND2, August 2018); National Health and Medical Research Council, Australian Research Council and Universities Australia, *National Statement on Ethical Conduct in Human Research* (E72C, 2023); Organ and Tissue Authority, DonateLife, *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* (2nd ed, 2021); Transplantation Society of Australia and New Zealand, *Clinical Guidelines for Organ Transplantation from Deceased Donors* (Version 1.13, August 2024).

11 World Health Organization, *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, WHA Res 63.22, WHO Doc WHO/HTP/EHT/CPR/2010.01 (2010) 8.

12 Dale Gardiner et al, 'Baseline Ethical Principles and a Framework for Evaluation of Policies: Recommendations from an International Consensus Forum' (2023) 9(5) *Transplantation Direct* e1471, 5, 7.

13 See, eg, Global Alliance of Eye Bank Associations, *The Barcelona Principles: An Agreement on the Use of Human Donated Tissue for Ocular Transplantation, Research, and Future Technologies* (2018); Transplantation Society and the International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition); World Health Organization, *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, WHA Res 63.22, WHO Doc WHO/HTP/EHT/CPR/2010.01 (2010).

Respect for persons and the human body should be prioritised

36. Respect for persons includes:

- respecting their human rights, dignity, and autonomy;
- honouring their beliefs, customs, and cultural heritage;¹⁴ and
- empowering them to participate in decision-making processes that affect their lives.¹⁵

37. Respect for persons is the foundation of medical ethics frameworks,¹⁶ and fundamental in ethical guidelines governing the use of human tissue.¹⁷ The concept that a person's body and their human remains deserve respect and dignified treatment is widely understood.¹⁸

38. Respect for persons puts an important limit on efforts to increase access to donated tissue. It is important, for example, in the deceased donation context to prioritise the wellbeing of patients receiving end of life care. People should never be seen merely as a means to obtain donated tissue, even where that tissue could help benefit others.

39. Reforms that prioritise respect for persons and the human body could include:

- introducing better protection for the autonomy of donors, recipients, and other participants in donation and transplantation systems, including respecting their rights, beliefs, and cultural heritage;
- updating the HTAs to make sure their consent frameworks facilitate free and informed choice, and self-determination.

Reform should support equitable participation in, and access to, donation and transplantation systems

40. Human rights, such as the right to health, promote equitable participation and access.¹⁹ Recognising that all people have a right to health requires the equitable and non-discriminatory distribution of resources to support good health, particularly for vulnerable or marginalised groups.²⁰

41. Our Terms of Reference ask us to consider 'equity and ethical approaches to improving access to ... transplantation'. Clinical and ethical guidelines governing the use of human tissue highlight the importance of equity when determining eligibility to receive organs and tissues alongside other relevant principles, such as utility.²¹

42. The concept of equity recognises that while all people are equal there may be circumstances where inequalities are unavoidable, necessary, or fair. For example, an 'equitable' allocation of

14 For example, the NHMRC emphasises the need to respect a person's history, culture, and knowledge: National Health and Medical Research Council, Australian Research Council and Universities Australia (n 10).

15 The United Nations' *Convention on the Rights of Persons with Disabilities* requires that people with disabilities have the right to live independently and take part in all aspects of life: *United Nations Convention on the Rights of Persons with Disabilities*, opened for signature 30 March 2007, 2515 UNTS 3 (entered into force 3 May 2008) art 9.

16 See, eg, Tom L Beauchamp, 'The "Four Principles" Approach to Health Care Ethics' in Richard E Ashcroft et al (eds), *Principles of Health Care Ethics* (Wiley, 1st ed, 2006) 37–8.

17 See, eg, National Health and Medical Research Council, 'Ethical Guidelines for Organ Transplantation from Deceased Donors' (n 10) 4–5; National Health and Medical Research Council, Australian Research Council and Universities Australia (n 10) 11.

18 See, eg, The Royal College of Pathologists of Australasia, *Guideline: Ethical and Legal Issues in Relation to the Use of Human Tissue in Australia and New Zealand* (No 4/2003, 2022) 2.

19 The right to health is recognised in the *International Covenant on Economic, Social and Cultural Rights*, to which Australia is a signatory: *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 999 UNTS 3 (entered into force 3 January 1976) art 12(1).

20 Attorney-General's Department, 'Right to Health' <<https://www.ag.gov.au/rights-and-protections/human-rights-and-anti-discrimination/human-rights-scrutiny/public-sector-guidance-sheets/right-health>>.

21 See, eg, National Health and Medical Research Council, 'Ethical Guidelines for Organ Transplantation from Deceased Donors' (n 10); Transplantation Society of Australia and New Zealand (n 10).

tissue might be one that addresses longstanding disadvantage, balanced by the need to achieve the best medical outcome for a donor and/or recipient.

43. Reforms that promote equity could include:

- amending the HTAs to support equitable participation in and access to donation and transplantation systems; and
- updating the HTAs to reduce barriers to accessing organ and tissue programs for some groups.

Reform should promote and uphold public trust

44. Public trust refers to people having confidence that public institutions operate fairly, openly, and to advance the purposes for which the institutions were designed.²²

45. The willingness of people to participate in Australia's organ and tissue donation and transplantation system depends on them having trust and confidence that the system is safe, just, and effective.²³ Similarly, people are unlikely to support the use of human tissue in research unless they trust that the research is ethical and contributes to the public good. The same principle applies to body donation for educational purposes.

46. Public trust is more likely when donation systems have a clear accountability structure, effective governance, transparent operations, and avenues for public participation in decision-making. Any reforms that erode public trust would undermine the health system and the potential for use of human tissue to improve the lives of Australians.

47. Reforms that promote and uphold public trust could include:

- amending the HTAs so that the law is clear and understandable; and
- introducing reporting or information sharing requirements to improve transparency in how donation and transplantation activities are organised and implemented, while ensuring that the privacy of donors and recipients is protected.²⁴

Question 3

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

You might think about aims such as:

- *increasing the amount of tissue available for transplantation and/or other uses;*
- *creating a transparent and easy to navigate tissue donation system;*
- *making sure tissue donation happens safely;*
- *making sure people have a good understanding of what is involved in donating tissue;*
- *making sure people understand how their tissue will be used;*
- *equity, and removing barriers faced by some individuals or groups to human tissue donation or transplantation;*
- *making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

²² Public trust is 'a core component of effective public governance in democratic societies': Organisation for Economic Co-operation and Development, *Building Trust in Public Institutions: Drivers of Trust in Public Institutions in Australia* (2025) 3.

²³ See, eg, Gardiner et al (n 12) 3, 5, 7–8.

²⁴ This is one of the guiding principles endorsed by the WHA: World Health Organization, *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, WHA Res 63.22, WHO Doc WHO/HTP/EHT/CPR/2010.01 (2010).

Question 4

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

You might consider principles such as:

- *respect for persons and for the human body;*
- *equity;*
- *the importance of public trust in the framework that governs how human tissue is obtained and used in Australia;*
- *the importance of laws that are well designed and effective.*

Priority reform areas

48. Below we outline some of the issues we are likely to focus on in our review of human tissue laws.

What should be included in the definition of tissue?

49. The definition of 'tissue' in the HTAs is expansive: it includes organs, body parts, and substances.²⁵ This broad definition raises questions about whether the HTAs cover situations that were not considered possible or socially acceptable when the HTAs were first introduced.

50. The definition of tissue can include sperm and egg cells, which means the HTAs may apply in situations where a person wants permission to remove these cells from the body of their partner after the partner has died.²⁶ It might be more appropriate to regulate this issue using assisted reproductive treatment laws rather than the HTAs.

51. The definition of tissue may include human milk, which can also be defined under other legislation as food or medicine.²⁷ This may create uncertainty, and inconsistency between different states and territories, which would be a problem for human milk banks that distribute milk to babies in need.

52. The definition of tissue may also create problems in research. For example, 'tissue' may include cell lines. Research on cell lines can lead to important medical advances.²⁸ The HTAs prohibit the sale of tissue (see below), but the scope of the prohibition is unclear and may create barriers for researchers to access cell lines in their research. It is also not clear whether the

25 *Transplantation and Anatomy Act 1978* (ACT) Dictionary (definition of 'tissue'), s 6; *Human Tissue Act 1983* (NSW) ss 4 (definition of 'tissue'), 6; *Transplantation and Anatomy Act 1979* (NT) ss 4 (definition of 'tissue'), 6; *Transplantation and Anatomy Act 1979* (Qld) ss 4 (definition of 'tissue'), 8; *Transplantation and Anatomy Act 1983* (SA) ss 5 (definition of 'tissue'), 7; *Human Tissue Act 1985* (Tas) ss 3 (definition of 'tissue'), 5; *Human Tissue Act 1982* (Vic) ss 3 (definition of 'tissue'), 5; *Human Tissue and Transplant Act 1982* (WA) ss 3 (definition of 'tissue'), 6.

26 Rachel Oakeley, 'From Bereaved to Conceived: Creating Life after Death through Posthumous Assisted Reproduction' (2016) 43(4) *Brief* 40, 41–3; Malcolm Smith, 'Recent Australian Legislative Developments in the Regulation of Assisted Reproductive Technology' (2024) 31(2) *Journal of Law and Medicine* 244, 246, 252–3; Alex Polyakov, Jacqueline Piskopos and Genia Rozen, 'Posthumous Conception in Australia: Legal and Ethical Considerations' (2024) 92(2) *Medico-Legal Journal* 86, 87, 89.

27 Neera Bhatia, Julian Koplin and Ainslee Spadaro, 'White Gold on the Black Market: The Need for Regulation of Banking and Donation of Human Milk in Australia' (2022) 48(2) *Australian Feminist Law Journal* 165, 183; Natalie Shenker et al, 'Comparison between the For-Profit Human Milk Industry and Nonprofit Human Milk Banking: Time for Regulation?' (2024) 20(1) *Maternal & Child Nutrition* 1, 9 (figure 1), 11.

28 See generally Peppino Mirabelli, Luigi Coppola and Marco Salvatore, 'Cancer Cell Lines Are Useful Model Systems for Medical Research' (2019) 11(8) *Cancers* 1098.

definition of tissue in the HTAs should extend to emerging fields, such as synthetic biology,²⁹ or bioprinting.³⁰

Issues related to the donation of tissue by living persons

What legal protections are needed for adult living donors?

53. As living donation provides no medical benefit to a donor,³¹ legal and ethical safeguards are important to protect the donor from coercion, respect the donor's autonomy, and minimise risks to the donor's welfare.³²

54. Currently, the HTAs provide fewer safeguards for 'regenerative' tissue (such as bone marrow, which the body replenishes after it is removed) compared to 'non-regenerative' tissue (such as a kidney, which does not grow back after it is removed). For example, there might be a cooling off period to let donors change their mind before having surgery to remove non-regenerative tissue.³³

55. Although the liver is regenerative tissue, partial liver donation has more risks than some non-regenerative tissue donation.³⁴ This means the distinction between 'regenerative' and 'non-regenerative' tissue may be less useful than it once was, and the HTAs may need to be updated.

What tissue should be used in research?

56. Some of the HTAs only allow non-regenerative tissue to be donated for the purpose of transplantation and not for other purposes, such as research.³⁵ These restrictions protect research participants from exploitation, but may get in the way of valid research, where an individual has made a free choice to donate, and the research has been approved by an ethics committee.

57. After tissue has been removed from a living person for a valid clinical purpose such as in surgery, most of the HTAs allow it to be used for an additional purpose.³⁶ The HTAs do not generally require consent to the additional purpose from the donor or impose rules for how the removed tissue can be used. It is important for researchers to be able to access and share tissue for ethically-approved research. But in a previous Inquiry, we identified legal gaps where tissue initially removed for a clinical purpose could later be used in research, transferred overseas, and/or used for genetic testing without the donor's knowledge.³⁷ In this Inquiry, we may consider if the HTAs can or should be used to fill these gaps.

What protections are needed for children?

58. The HTAs are inconsistent in how they regulate donation of tissue from children. Inconsistencies include the type of tissue that can be donated, the purposes for which tissue can be donated, the definition of 'child' or 'parent', and the role and involvement of children and

29 Commonwealth Scientific and Industrial Research Organisation, 'Understanding Synthetic Biology' <<https://research.csiro.au/synthetic-biology-fsp/resources-information/understanding-synthetic-biology/>>.

30 Callum Vidler, David Collins and Michael Halwes, '3D Bioprinting Is Pushing the Boundaries of Human Tissue Engineering', *Pursuit* (31 October 2024) <<https://pursuit.unimelb.edu.au/articles/3d-bioprinting-is-pushing-the-boundaries-of-human-tissue-engineering>>.

31 Maeghan Toews, 'Organ and Tissue Donation and Transplantation' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 836.

32 National Health and Medical Research Council, 'Organ and Tissue Donation by Living Donors: Guidelines for Ethical Practice for Health Professionals' (n 10) 5.

33 For example, s 8 of the *Transplantation and Anatomy Act 1978* (ACT) states that a person may give written consent for the removal of regenerative tissue, while s 9(1) of the *Transplantation and Anatomy Act 1978* (ACT) states that the person may give written consent for the removal of non-regenerative tissue with a 24-hour cooling off period.

34 Organ and Tissue Authority, DonateLife, 'Understanding Living Donation' <<https://www.donatelife.gov.au/all-about-donation/understanding-living-donation>>.

35 See, eg, *Transplantation and Anatomy Act 1983* (SA) s 10.

36 See, eg, *Transplantation and Anatomy Act 1983* (SA) s 37; *Human Tissue and Transplant Act 1982* (WA) s 32.

37 Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Report No 96, 2003) 268–75.

parents in decision-making.³⁸ These inconsistencies may be a problem because they create confusion and may come in conflict with other areas of law.³⁹ How the HTAs limit donation by children may also be out of step with contemporary values and approaches to obtaining consent for medical treatment.

How should people with limited legal capacity to make decisions be supported to donate tissue?

59. The HTAs are largely silent in relation to tissue donation by adults who do not have legal decision-making capacity. Capacity, in the medical context, is assessed based on a person's ability to understand, retain, and apply information relevant to a decision, and to communicate consent.⁴⁰

60. In some cases, a person may have the capacity to make a supported decision about tissue donation or transplantation, in others, they may need a substitute decision-maker. Guardianship legislation allows for another person to be appointed as a substitute decision-maker, to make some decisions on the person's behalf.⁴¹ Whether the HTAs are consistent with other laws governing medical decision-making, and if additional rules are needed, are issues we will consider.

Issues related to the donation of tissue after death

How should 'death' be defined?

61. Under the current law, the death of a person occurs when there is:

- 'irreversible cessation of all function of the brain of the person; or'
- 'irreversible cessation of circulation of blood in the body of the person.'⁴²

62. In most jurisdictions, this definition is in the HTAs but applies whenever a decision needs to be made about when a person has died.⁴³ Because the definition applies more broadly than for tissue and organ donation, it may be better to include it in a separate law.⁴⁴

63. The definition may also need to be updated to:

- include current knowledge about the biological process of death;
- account for and possibly facilitate new technologies, such as normothermic regional perfusion;⁴⁵ and
- ensure consistency with clinical practice, if that practice is justified. Currently in clinical practice, 'irreversible cessation of circulation of blood in the body' is interpreted to mean 'permanent cessation'.⁴⁶

38 Toews (n 31) 839–48.

39 Shih-Ning Then and Gabrielle Appleby, 'Tissue Transplantation from Children: Difficulties in Navigating State and Federal Systems' (2010) 33(2) *UNSW Law Journal* 305.

40 Queensland University of Technology, 'Capacity and Consent to Medical Treatment' <<https://end-of-life.qut.edu.au/capacity>>.

41 Ibid.

42 *Transplantation and Anatomy Act 1978* (ACT) s 45; *Human Tissue Act 1983* (NSW) s 33; *Transplantation and Anatomy Act 1979* (NT) s 23; *Transplantation and Anatomy Act 1979* (Qld) s 45; *Death (Definition) Act 1983* (SA) s 2; *Human Tissue Act 1985* (Tas) s 27A; *Human Tissue Act 1982* (Vic) s 41; *Interpretation Act 1984* (WA) s 13C.

43 Many HTAs use the wording of 'for the law of the [State/Territory]' so that the definition of death applies generally: see, eg, *Transplantation and Anatomy Act 1978* (ACT) s 45; *Human Tissue Act 1983* (NSW) s 33. By comparison, Queensland uses different wording, stating 'for the purposes of this Act': *Transplantation and Anatomy Act 1979* (Qld) s 45.

44 See generally Russell Gordon Smith, 'Refining the Definition of Death for Australian Legislation' (1983) 14(2) *Melbourne University Law Review* 199, 221–2.

45 For a description of normothermic regional perfusion, its benefits to successful donation, and the ethical concerns it raises, see generally Robert D Truog, Andrew Flescher and Keren Ladin, 'Normothermic Regional Perfusion: The Next Frontier in Organ Transplants?' (2023) 329(24) *Journal of the American Medical Association* 2123.

46 National Health and Medical Research Council, *Draft Guidelines for Public Consultation: Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (Version 13, December 2023) 22; Australian and New Zealand Intensive Care Society, *The Statement on Death and Organ Donation* (4.1 ed, 2021) 23.

64. We will consider if the definition of death is consistent with current medical knowledge and fit for purpose.

Who should be able to authorise tissue donation when a person dies?

65. When a person dies in hospital, a Designated Officer, who is a doctor who has been appointed to this special position, must provide authorisation before tissue can be removed from the deceased person's body.⁴⁷ The Designated Officer can provide authorisation for the removal of tissue if it is known that the person wanted to donate their tissue.⁴⁸

66. When an individual's wishes about donation are unknown, the HTAs require the person's 'senior available next of kin' to consent⁴⁹ (or not object, depending on the jurisdiction)⁵⁰ to deceased donation before the Designated Officer can provide authorisation. The definition of 'senior available next of kin' provides a limited and hierarchical list of people who can give consent to donation on behalf of a family member who has died.⁵¹ This definition may need to be updated to reflect contemporary and culturally diverse conceptions of family and kinship.⁵²

67. If an individual expressed a wish to donate before they died, the role of the person's family in providing or withholding consent to donate may be controversial. The current practice in Australia is to seek agreement to donation from a donor's senior available next of kin, even if the person was on the Donor Register or expressed a wish to donate in a different way.⁵³ The practice of deferring to the wishes of the senior available next of kin is not required by the HTAs or other legislation.⁵⁴ There is debate about if it should continue, or if the HTAs should recognise and uphold the donation decisions made by individuals before they died.⁵⁵

68. The involvement of senior available next of kin in donation decisions also raises issues in cases where a person's senior available next of kin is not their appointed substitute decision-maker for other decisions, such as medical treatment decisions. This leads to potential decision-making inconsistencies where one substitute decision-maker is responsible for authorising pre-mortem (before death) interventions to facilitate a successful transplant and withdrawal of life-sustaining therapies, and another person is responsible for deciding about donation.

69. The role of a Designated Officer is also unique. In other countries, such as Canada and the United States of America, legal authority to remove tissue comes from an individual's own decision or the decision of their next of kin rather than a Designated Officer.⁵⁶ We want to know if this system is working well for Designated Officers, donors, donor families, and all of those involved in tissue donation, or if it could be improved.

47 See, eg, *Transplantation and Anatomy Act 1978* (ACT) s 27.

48 Ibid.

49 See, eg, *Human Tissue Act 1983* (NSW) s 23(3).

50 See, eg, *Transplantation and Anatomy Act 1983* (SA) s 21(3).

51 *Transplantation and Anatomy Act 1979* (Qld) s 4 (definition of 'senior available next of kin').

52 See generally Legislative Assembly of Queensland, Parliament of Queensland, *Report of the Review of Organ and Tissue Donation Procedures Select Committee* (2008) rec 4.

53 See, eg, New South Wales Health, *Organ and Tissue Donation, Use and Retention* (Policy Directive No PD2024_022, 26 July 2024) 11.

54 See, eg, National Health and Medical Research Council, 'Organ and Tissue Donation after Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals' (n 10) 33. These guidelines note that 'good practice recognises the important role of relatives': Ibid.

55 Maeghan Toews, 'Increasing Organ Donation Rates: What's Legal and What's Not?' (2017) 39(11) *Bulletin (Law Society of South Australia)* 18; David Shaw et al, 'Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions' (2017) 101(3) *Transplantation* 482.

56 For Canada: Maeghan Toews and Timothy Caulfield, 'Evaluating the "Family Veto" of Consent for Organ Donation' (2016) 188(17–18) *Canadian Medical Association Journal* E436. For the United States of America: Ana S Iltis and Briana Denny, 'First-Person Authorization and Family Objections to Organ Donation' [2025] *The Journal of Medicine and Philosophy* (advance).

Who should be authorised to remove tissue?

70. There is variation between HTAs in relation to who can remove tissue from a deceased person's body. Some HTAs are silent on the issue, some require a medical practitioner to remove tissue,⁵⁷ and, as outlined below, others generally require a medical practitioner but also allow for other authorised people to remove certain types of tissue.

71. In HTAs that allow people other than medical practitioners to remove tissue, there is inconsistency in relation to what types of tissue can be removed. For example, in South Australia, tissue that can be removed includes corneas,⁵⁸ whereas in New South Wales, it can include corneal, musculoskeletal, skin, and cardiovascular tissue.⁵⁹ This raises the question of whether respect for persons and human bodies requires that only appropriately qualified professionals should be able to remove donated tissue. It also highlights a possible need for more consistency to make sure tissue donation can happen effectively.

How should we ensure potential donors are identified in hospital?

72. Successful deceased organ donation programs require potential donors who are receiving end of life care in hospital to be identified so that donation can be considered. Best practice guidelines call for 'routine referral' to encourage health care staff in emergency departments and critical care units to refer all potential donors to DonateLife — the agency that oversees the deceased donation process.⁶⁰ To make sure everyone who can donate is provided an opportunity to do so, some jurisdictions overseas have passed legislation making referral mandatory.⁶¹ We may consider if this approach would help prevent donation opportunities in Australia from being missed.

How should steps and interventions that occur before death be regulated?

73. To determine if a person's organs might be suitable for donation after they die, certain investigative steps need to be taken before they die, such as reviewing medical records and possibly performing screening tests. Sometimes treatments are given to a donor to help the donated organs work well in the recipient. Some of these steps may need to start before donation is raised as a possibility with the person's next of kin. Even when consent to donate is provided by a person's next of kin, the legal authority to undertake these steps is not always clear.

74. Recent attempts to clarify the law surrounding pre-mortem interventions in New South Wales and Victoria have created inconsistencies in relation to:

- who needs to provide consent;
- what counts as a pre-mortem intervention; and
- what facts must be certified in writing by relevant medical practitioners.⁶²

75. Our initial research suggests that clarifying the law surrounding pre-mortem interventions is a high priority for medical practitioners working in deceased donation.

How should donor and recipient information be handled?

76. To safeguard the privacy of donors and recipients, the HTAs have provisions that prohibit the disclosure of information that might lead to the identity of a donor or recipient becoming publicly known. But there are differences between jurisdictions about what amounts to an unauthorised

57 *Transplantation and Anatomy Act 1979* (NT) s 22; *Human Tissue Act 1985* (Tas) s 26.

58 *Transplantation and Anatomy Act 1983* (SA) s 24.

59 *Human Tissue Act 1983* (NSW) s 27(1A).

60 Organ and Tissue Authority, DonateLife (n 10) 6–7.

61 Samara Zavalkoff et al, 'Preventable Harm in the Canadian Organ Donation and Transplantation System: A Descriptive Study of Missed Organ Donor Identification and Referral' (2023) 70(5) *Canadian Journal of Anesthesia* 886, 887.

62 *Human Tissue Act 1983* (NSW) s 27C; *Human Tissue Act 1982* (Vic) ss 24A–24F.

disclosure and what penalties apply. There may also be uncertainty about if the requirements in the HTAs are consistent with other privacy laws.

77. The question of whether the identities of donors or their families and recipients can or should be revealed to one another may be controversial. Some donors, or families of deceased donors, and recipients may want to contact each other, while others may wish to remain unknown. Whether the law should allow or prohibit this type of contact is an issue we may consider.

78. It is not always clear whether a deceased person's next of kin may consent to disclosure of information about their loved one. There are also variations in relation to who is covered by definitions of 'next of kin' in this context. Additionally, there is a lack of clarity and inconsistency between the HTAs about the type of donor health information that can be disclosed:

- by medical professionals to each other when assessing suitability for transplantation; and
- to a potential recipient when they are on an organ transplant waiting list.

Issues related to anatomical and post-mortem examinations

How should consent for body donation be regulated?

79. There are inconsistent provisions across the states and territories for authorising the donation of deceased bodies for dissection (referred to in the legislation as 'anatomical examination') at a 'school of anatomy', such as a medical school.

80. In some jurisdictions, the consent and authorisation framework for this type of donation is included in an HTA, and in other jurisdictions, there are separate Anatomy Acts.⁶³ There are significant differences between jurisdictions about the consent requirements for body donation. In some jurisdictions, bodies can be used for anatomical examination in situations where the individual did not give prior consent and there is no next of kin to provide consent.⁶⁴ These requirements may need to be updated to reflect contemporary values.

81. Sometimes an individual may want to donate their entire deceased body for research. While the HTAs allow tissue to be removed from a deceased body for scientific purposes,⁶⁵ they do not address the donation of the entire deceased body for this use. The New South Wales *Anatomy Act* defines 'anatomical examination' to include 'scientific purposes',⁶⁶ which means research could be included in this type of donation. The legislation in other jurisdictions either does not define 'anatomical examination' at all,⁶⁷ or defines it without referring to scientific purposes.⁶⁸ There is a need for legal clarity about body donation in research.

How should schools of anatomy be regulated?

82. There are 17 body donor programs in Australia with at least one in each jurisdiction except the Northern Territory, and multiple in New South Wales and Queensland.⁶⁹ Our initial research indicates that there may be a benefit to having greater consistency about:

- how long donated bodies can be kept;
- the transfer of bodies between licensed facilities;
- data collection, handling, and reporting;

63 See, eg, *Anatomy Act 1977* (NSW); *Anatomical Examinations Act 2006* (Tas); *Anatomy Act 1930* (WA).

64 See, eg, *Transplantation and Anatomy Act 1978* (ACT) s 37(2); *Human Tissue Act 1982* (Vic) s 32(5); *Anatomy Act 1930* (WA) s 8.

65 See, eg, *Transplantation and Anatomy Act 1978* (ACT) s 27(1)(ii); *Human Tissue Act 1983* (NSW) s 23(1)(a)(ii).

66 *Anatomy Act 1977* (NSW) s 4(1).

67 See, eg, *Anatomy Act 1930* (WA).

68 See, eg, *Anatomical Examinations Act 2006* (Tas) s 3(1) (definition of 'anatomical examination').

69 Rebekah A Jenkin and Kevin A Keay, 'Body Donor Programs in Australia and New Zealand: Current Status and Future Opportunities' (2025) 18(3) *Anatomical Sciences Education* 301, 303.

- ethical oversight and governance; and
- the roles and responsibilities of inspectors of anatomy.⁷⁰

How should tissue removed in post-mortem examinations be used?

83. The HTAs address how tissue removed during post-mortem examinations can be used. The HTAs differ about what can be done with removed tissue and if specific consent is needed for these uses. Some indicate that consent to a post-mortem examination includes consent to other scientific uses of tissue removed during the examination;⁷¹ some indicate that specific consent must be obtained to use tissue removed during a post-mortem examination for scientific purposes;⁷² and others require specific consent but have an exception for ‘small samples’, such as those kept as a tissue slide or block.⁷³

84. The storage and use of tissue removed during post-mortem examinations without specific consent is controversial. In 2001, a public inquiry looked at this issue in New South Wales, and made recommendations that have since been implemented.⁷⁴ Some, but not all, of the other states and territories have adopted similar amendments.⁷⁵ Consent requirements may need to be strengthened in some jurisdictions to maintain public trust and appropriately respect individual autonomy.

Advertising and trade in human tissue

How should trade in human tissue and tissue products be regulated?

85. Paying for or ‘trading’ in human tissue is banned in all the HTAs, but in different ways. In Queensland and Victoria, the HTAs prohibit selling or buying (or agreeing to sell or buy) human tissue.⁷⁶ The prohibition on trade in the other states and territories is broader, banning the offering or provision of any ‘valuable consideration’ in exchange for human tissue.⁷⁷

86. There are some exceptions to these prohibitions in the HTAs, including ministerial exemptions,⁷⁸ reimbursement of necessary costs for donors,⁷⁹ exceptions for processed or treated tissue,⁸⁰ cost recovery for tissue banks⁸¹ and schools of anatomy,⁸² and an exception for certain blood products.⁸³

70 Ibid 321–4; Jonna-Susan Mathiessen and Cameron Stewart, ‘The Anatomy Act 1977 (NSW) Dissected: Review and Reform’ (2024) 31(1) *Journal of Law and Medicine* 24, 38–41.

71 See, eg, *Human Tissue Act 1982* (Vic) s 30(2); *Human Tissue and Transplant Act 1982* (WA) s 28(2).

72 See, eg, *Transplantation and Anatomy Act 1983* (SA) s 27; *Human Tissue Act 1985* (Tas) s 26C.

73 See, eg, *Human Tissue Act 1983* (NSW) ss 31A, 34(1)(b1); *Transplantation and Anatomy Act 1979* (Qld) s 29(2).

74 Bret Walker, *Inquiry into Matters Arising from the Post-Mortem and Anatomical Examination Practices of the Institute of Forensic Medicine* (New South Wales Department of Health, 2001) rec 8.

75 *Human Tissue Act 1983* (NSW) s 31A; *Transplantation and Anatomy Act 1983* (SA) s 27; *Human Tissue Act 1985* (Tas) s 26C.

76 *Transplantation and Anatomy Act 1979* (Qld) ss 40, 42; *Human Tissue Act 1982* (Vic) ss 38, 39.

77 *Transplantation and Anatomy Act 1978* (ACT) s 44(1); *Human Tissue Act 1983* (NSW) s 32(1); *Transplantation and Anatomy Act 1979* (NT) s 22E(1); *Transplantation and Anatomy Act 1983* (SA) s 35(1); *Human Tissue Act 1985* (Tas) s 27(1); *Human Tissue and Transplant Act 1982* (WA) s 29A(2).

78 *Transplantation and Anatomy Act 1978* (ACT) s 44(4); *Human Tissue Act 1983* (NSW) s 32(4); *Transplantation and Anatomy Act 1979* (NT) s 22F; *Transplantation and Anatomy Act 1979* (Qld) s 40(2); *Transplantation and Anatomy Act 1983* (SA) s 35(6); *Human Tissue Act 1985* (Tas) s 27(4); *Human Tissue Act 1982* (Vic) s 39(2); *Human Tissue and Transplant Act 1982* (WA) s 29E (noting that there are some limitations on the Minister’s ability to provide an exemption).

79 *Transplantation and Anatomy Act 1978* (ACT) s 44(3); *Human Tissue Act 1983* (NSW) s 32(3); *Transplantation and Anatomy Act 1979* (NT) s 22E(2)(b); *Transplantation and Anatomy Act 1983* (SA) s 35(4); *Human Tissue Act 1985* (Tas) s 27(3); *Human Tissue and Transplant Act 1982* (WA) s 29A(4)(a).

80 *Transplantation and Anatomy Act 1978* (ACT) s 44(2); *Human Tissue Act 1983* (NSW) s 32(2); *Transplantation and Anatomy Act 1979* (NT) s 22E(3); *Transplantation and Anatomy Act 1979* (Qld) s 42AA; *Transplantation and Anatomy Act 1983* (SA) s 35(3); *Human Tissue Act 1985* (Tas) s 27(2); *Human Tissue and Transplant Act 1982* (WA) s 29D(1) (subject to the Minister making a declaration).

81 *Transplantation and Anatomy Act 1979* (Qld) s 42A; *Human Tissue Act 1982* (Vic) s 39A; *Human Tissue and Transplant Act 1982* (WA) s 29B.

82 *Transplantation and Anatomy Act 1979* (Qld) s 42B; *Human Tissue and Transplant Act 1982* (WA) s 29C.

83 *Human Tissue Act 1983* (NSW) s 37A; *Transplantation and Anatomy Act 1979* (Qld) s 42AB; *Human Tissue and Transplant Act 1982* (WA) s 29A(4)(b)–(c).

87. Not all jurisdictions have all these exceptions, and it is not always clear how the exceptions should be interpreted. We may consider how the law can be clarified, and how it could consistently allow ethical exceptions to the prohibition on trade.

88. For example, broad prohibitions on trade impact the kidney paired exchange program, which matches incompatible donor and recipient ‘pairs’ with each other, providing two or more recipients with organs they otherwise would not have access to.⁸⁴ Despite the success of this program, ministerial exemptions to the prohibition on trade are needed to allow it to function in the jurisdictions that prohibit exchange for valuable consideration for human tissue.⁸⁵ There is also recurring debate about if Australia should financially incentivise plasma donation,⁸⁶ and what legal reforms would be necessary to allow this. The HTAs may need to be updated to support current policy initiatives and enable the future development of policies to support increased provision of human tissue for those that need it.⁸⁷

How should advertisements for trade in human tissue be regulated?

89. Advertising for the purpose of trade in human tissue, or advertising about the right to take tissue from people’s bodies is banned in some jurisdictions.⁸⁸ Broad prohibitions, such as in the Victorian legislation,⁸⁹ may create hurdles for legitimate community donation promotion events and communications.

90. On the other hand, there are commercial markets for human remains operating in Australia, such as for human tissue previously used in medical offices, and cultural or archaeological remains. It is not always clear how the HTAs apply to these markets,⁹⁰ and if ‘loopholes’ in the law are allowing potentially unethical trade in human tissue.⁹¹

Should the law regulate public requests for tissue donation?

91. ‘Public solicitation’ refers to a person requesting a living donor to volunteer from the public. This can happen through traditional media, social media, or other kinds of advertisements. Because these requests do not usually involve direct offers to pay for donation, they may be permitted under the HTAs (except possibly in Victoria, where the prohibition on advertising is broad). Whether the law should regulate or prohibit these kinds of requests is controversial. The requests raise ethical concerns and questions about fairness in the donation system, but there may also be public benefits if the practice increases the overall number of organs available for transplantation.⁹²

84 Organ and Tissue Authority, ‘Australian and New Zealand Paired Kidney Exchange (ANZKX) Program’ <<https://www.donatelifelife.gov.au/for-healthcare-workers/ANZKX>>.

85 Maeghan Toews et al, ‘Kidney Paired Donation and the “Valuable Consideration” Problem: The Experiences of Australia, Canada, and the United States’ (2017) 101(9) *Transplantation* 1996, 1999.

86 Albert Farrugia, Joshua Penrod and Jan Bult, ‘Payment, Compensation and Replacement: The Ethics and Motivation of Blood and Plasma Donation’ (2010) 99(3) *Vox Sanguinis* 202; Robert Slonim, ‘How Australia Can Fix the Market for Plasma and Save Millions’, *The Conversation* (2 September 2018) <<http://theconversation.com/how-australia-can-fix-the-market-for-plasma-and-save-millions-101609>>; Sandor Demeter, ‘Paying for Plasma Is the New Normal: Why Policy Has Changed Decades after Canada’s Tainted Blood Scandal’, *The Conversation* (23 October 2022) <<http://theconversation.com/paying-for-plasma-is-the-new-normal-why-policy-has-changed-decades-after-canadas-tainted-blood-scandal-192746>>.

87 For examples of other living kidney policy ideas, see Stephen J Choi, Mitu Gulati and Eric A Posner, ‘Altruism Exchanges and the Kidney Shortage’ (2014) 77(3) *Law and Contemporary Problems* 289.

88 *Transplantation and Anatomy Act 1979* (Qld) s 41; *Transplantation and Anatomy Act 1983* (SA) s 35(7); *Human Tissue Act 1982* (Vic) s 40; *Human Tissue and Transplant Act 1982* (WA) s 30.

89 *Human Tissue Act 1982* (Vic) s 40.

90 Richards, ‘Calls for Crackdown on “Commodification of the Dead”’, *ABC News* (online, 12 October 2024) <www.abc.net.au/news/2024-10-12/remains-for-sale-commodification-of-the-dead/104463822>.

91 Damien Huffer, ‘Buy One Get One: The Legal and Socio-Cultural Context of “Gifting” Within the Australian Human Remains Trade’ (2024) 7(1) *Journal of Computer Applications in Archaeology* 115.

92 National Health and Medical Research Council, ‘Draft Guidelines for Public Consultation: Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia’ (n 46) 194–6.

Should the HTAs regulate organ trafficking and transplant tourism?

92. Trafficking in persons for their organs is a form of trade in human tissue that is internationally condemned.⁹³ It is prohibited under Australia's Commonwealth *Criminal Code*.⁹⁴ But Australian law does not prohibit Australians from travelling overseas to purchase an organ; a concept known as 'transplant tourism'.⁹⁵ Organ trafficking and transplant tourism are complex legal and policy issues that the Australian Government has focused on in recent years. In 2018, the Federal Joint Standing Committee on Foreign Affairs, Defence and Trade published an inquiry into organ trafficking and transplant tourism,⁹⁶ which the Australian Government has continued to respond to and address in various ways.⁹⁷ We may consider what role, if any, the HTAs can play in the ongoing efforts to address organ trafficking and transplant tourism.

How should donated tissue be allocated?

93. The HTAs regulate how tissue retrieval for transplantation and other purposes can occur, but they are silent about how the donated tissue should be allocated to waitlisted patients. At the national level, the OTA is required to have regard to 'improving access to organ or tissue donation and transplantation services', 'improving the management of waiting lists for potential organ or tissue recipients', and 'improving the management of the allocation of donated organs or tissue'.⁹⁸

94. Allocation processes are set out in the National Standard Operating Procedure.⁹⁹ Allocation practices are audited to ensure that allocation follows these procedures.¹⁰⁰ These guidelines and policies seek to promote equitable outcomes, as much as possible given there is not enough tissue available to meet everyone's needs.¹⁰¹

95. Despite these efforts, there are ongoing concerns about inequities in the waitlisting and allocation systems. For example, concerns about inequities for First Nations people in accessing organ transplants have prompted national reviews and initiatives.¹⁰² We may consider what role, if any, the HTAs can play in assisting current efforts to make waitlisting and allocation more equitable.

What are some other uses for tissue and bodies and how should they be regulated?

96. The HTAs enable donation of tissue for 'scientific purposes', but it is not always clear how far this extends. For example, sometimes quality assurance programs need to use tissue for diagnosis, research, or product development.¹⁰³ The New South Wales, Queensland, and Western

93 Transplantation Society and the International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition).

94 *Criminal Code Act 1995* (Cth) ss 271.7A, 271.7B, 271.7D.

95 Department of Foreign Affairs and Trade, 'Organ Transplant Tourism' <<https://www.smartraveller.gov.au/before-you-go/health/organ-transplant-tourism>>.

96 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia, *Compassion, Not Commerce: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism* (2018).

97 See, eg, Australian Government, *Response to the Senate Foreign Affairs, Defence and Trade Legislation Committee Report: Migration Amendment (Overseas Organ Transplant Disclosure and Other Measures) Bill 2023* (2024).

98 *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) s 12.

99 Australasian Donation & Transplant Coordinators Association, Transplantation Society of Australia and New Zealand and Organ and Tissue Authority, *National Standard Operating Procedure: Organ Allocation, Organ Rotation, Urgent Listing* (Version 4.3, March 2025).

100 Transplantation Society of Australia and New Zealand (n 10) 80–1.

101 *Ibid* 1.

102 Katie Cundale et al, *Final Report: National Indigenous Kidney Transplantation Taskforce* (National Indigenous Kidney Transplantation Taskforce, 2023) 10, 28.

103 The use of tissue for quality assurance in pathology is addressed in clinical guidelines: see, eg, The Royal College of Pathologists of Australasia (n 18) 10.

Australian HTAs have some provisions addressing the use of tissue for quality assurance,¹⁰⁴ but other HTAs do not.

97. The ‘plastination’ of deceased bodies, which allows them to be displayed in public exhibitions, has also raised ethical concerns.¹⁰⁵ The boundary between educational, scientific, and commercial purposes is not always clear. Whether the HTAs should regulate this use is something we may consider.

Question 5

Do you agree that the issues set out in the section ‘Priority reform areas’ should be a focus for our Inquiry? Please tell us why you think these issues should or should not be a focus.

Question 6

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

You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about:

- *if there are issues caused, or likely to be caused, by current or emerging technology that we haven’t identified elsewhere in this Issues Paper; and*
- *if there is a need to update the HTAs to account for contemporary community values, in ways that we haven’t identified elsewhere in this Issues Paper.*

Question 7

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

Issues we are unlikely to focus on in this Inquiry

98. We are unlikely to focus on the issues listed below. In most cases, these issues arise under and are dealt with by frameworks outside the HTAs:

- safety of cells, organs, and tissue (regulated by the Therapeutic Goods Administration);
- coronial inquests, except as they intersect with the HTAs;
- human cloning and embryonic research;
- the regulation of human gametes (sperm and egg cells) and embryos, except as they intersect with the HTAs;
- First Nations ancestral remains, to the extent they are dealt with under cultural heritage laws.

Question 8

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

104 *Human Tissue Act 1983* (NSW) s 34(1)(b3)(i); *Transplantation and Anatomy Act 1979* (Qld) s 42AA(2); *Human Tissue and Transplant Act 1982* (WA) ss 8(1A)(c), 22(1)(c).

105 Paola Bin et al, ‘Plastination: Ethical and Medico-Legal Considerations’ (2016) 11(1) *Open Medicine* 584.

Resources

99. Some of the materials we refer to in this Issues Paper, and other useful resources about the topics discussed here, are available under the [**Further resources**](#) link on the Review of Human Tissue Laws page on our website.

Appendix A — Terms of Reference

1. I, the Hon Mark Dreyfus KC MP, Attorney-General of Australia, following consultation with Health Ministers, and having regard to:

- the role that cell, tissue and organ donation, retrieval and transplantation can play in improving the lives of Australians;
- that Australia has a long standing national approach to cell, tissue and organ donation, retrieval and transplantation operating cross-jurisdictionally;
- that changing community expectations and evolving technology may be affecting how relevant laws should consider cell, tissue and organ donation, retrieval and transplantation;
- significant developments in human tissue donation, retrieval and use for social, clinical and research purposes, including co-modification and potential trafficking;
- the complex ethical issues that may arise in matters relating to donation, retrieval and use of human cell, tissue and organ donation, including ethical sourcing;
- current inconsistencies in legislative arrangements across Australian jurisdictions.

REFER to the Australian Law Reform Commission (ALRC) for inquiry and report under the *Australian Law Reform Commission Act 1996*, consideration of whether, and if so what, reforms are necessary or desirable to harmonise and modernise human tissue laws and across Australian jurisdictions.

- In particular, the ALRC should conduct a principles-based review of the following matters:
 - authorisation to donate, retrieve, and transplant human tissue across Australia;
 - inconsistencies across existing laws relating to cell, tissue and organ donation and retrieval arrangements from living and deceased persons;
 - definition/s of death;
 - post-mortem examinations (whole cadavers and body parts);
 - definitions of tissue;
 - disclosure of information provisions;
 - consent arrangements (including for minors) and delegation functions of next of kin;
 - definitions of minors, adults and next of kin;
 - the regulation of ‘schools of anatomy’ and donation for education purposes;
 - frameworks across all Australian jurisdictions pertaining to the donation and retrieval of cells, tissues and organs from a living and deceased person;
 - the advertising of, and trade in, cells, tissues and organs;
 - cost recovery, financial and infrastructural considerations related to the manufacture and provision of tissue;
 - any other relevant matter.

The ALRC should consider whether, and if so how, implementation of any reforms that the ALRC recommends should be staged or prioritised.

2. Scope of the reference

In undertaking its review, the ALRC should consider:

- equity and ethical approaches to improving access to cell, tissue and organ transplantation;
- contemporary research, emerging technologies and clinical practices for cell, tissue and organ donation, retrieval and transplantation, including antemortem interventions and perfusion technologies;
- any other relevant matter, including international experience and approaches.

3. Consultation

In performing its functions in relation to this reference the ALRC shall ensure widespread public consultation, and identify and consult with key stakeholders, including relevant government agencies, the research community, the health and medical sector, the biotechnology sector, industry bodies and lived experience cohorts, including the families of deceased donors and recipients of cell, tissue and organ transplantation.

4. The Commission is to report to the Attorney-General by 16 August 2026.