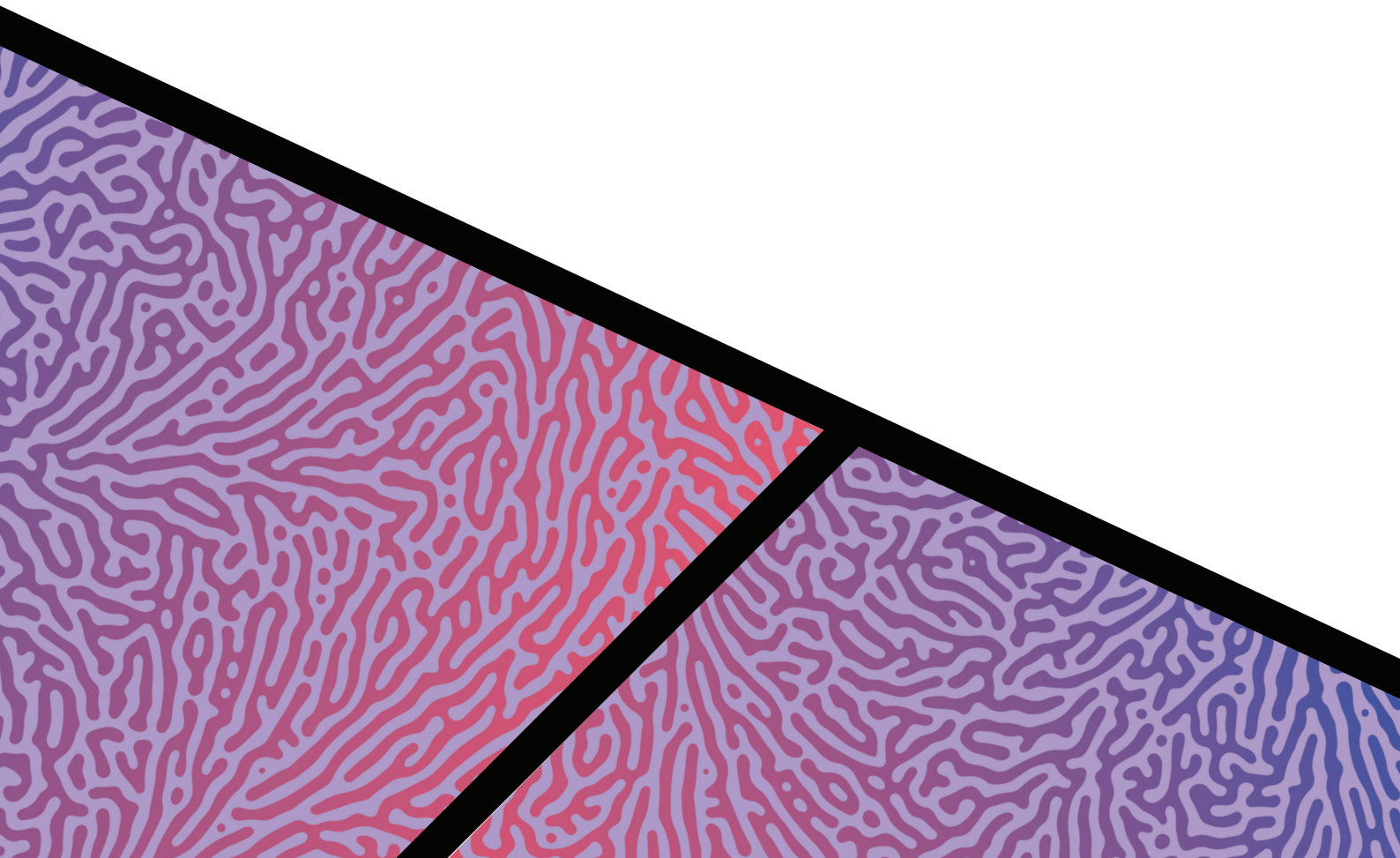
Australian Government
Australian Law Reform Commission

DISCUSSION PAPER

REVIEW OF HUMAN TISSUE LAWS

Discussion Paper 90
November 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 *Discussuion Paper* reflects the law as at 24 October 2025.

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CONTENTS

Glossary

Advance care directive	A document created when a person has decision-making capacity, which can be used if they do not have decision-making capacity in the future, to: • appoint an authorised decision-maker to make health care decisions on their behalf; and/or • explain their preferences in relation to health care. Labels vary in different jurisdictions. Other labels include 'advance personal plan' (Northern Territory).
ANZICS	Australian and New Zealand Intensive Care Society.
Australian Organ Donor Register (Donor Register)	The national register recording organ and tissue donation decisions of people over the age of 16 years.
Authorised decision-maker	A person who is authorised to make decisions on their own behalf, or on behalf of another person. Where a person is an authorised decision-maker for another person, they may sometimes be referred to as a 'substitute decision-maker'.
Biobank	A collection of biological materials (also known as biospecimens).
Deceased donation	When human tissue is donated after a person has died.
Decision-making capacity	A prospective donor's ability to understand the nature and extent of the risk to their health and wellbeing of donating a particular organ or other specific human tissue.[1]
Designated Officer	A person who is appointed by a government minister or hospital management, depending on the laws of the state or territory where they work, to provide legal authority for tissue donation.
Ex vivo machine perfusion	See perfusion technology.
Human Tissue	In the HTAs, '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). In this paper, we use the term 'human tissue' to refer to a broad range of bodily substances, and to deceased bodies. When we want to refer to particular bodily substances, like organs or blood, we use these terms specifically.
Human Tissue —Regenerative	Tissue that is replaced in the body of a living person through natural processes after that tissue is removed.

1 See generally Bernadette Richards, 'General Principles of Consent to Medical Treatment' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 144–54; National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 68–71. Note that a person who does not have decision-making capacity in some contexts — for example, a person with a cognitive impairment who may be legally prevented from entering a contract or running a business — may have decision-making capacity in medical contexts, depending on their level of understanding.

Human Tissue — Non-regenerative	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 legislation enacted in the late 1970s/early 1980s to regulate human tissue in Australia. New South Wales and Tasmania each have a *Human Tissue Act* and an *Anatomy Act*. Victoria has a *Human Tissue Act*. The Territories, Queensland, and South Australia have *Transplantation and Anatomy Acts*. Western Australia has the *Human Tissue and Transplant Act* and an *Anatomy Act*.
Living donation	When human tissue is removed from and donated by a living person (donor).
Medical, educational or scientific purposes	See **Chapter 8**.
National Regulator	The national human tissue regulator that we propose (**Proposal 3**).
Next of kin	An expression used in the HTAs and in other legislation to refer to a person's family members and sometimes other people who have significant relationships with them, such as guardians. In the HTAs, next of kin are ranked in a decision-making hierarchy that gives the most senior available next of kin power to consent to tissue donation on behalf of a person in some circumstances.
NHMRC	The National Health and Medical Research Council. An independent statutory agency that produces health and ethical guidelines; funds health and medical research; supports researchers; encourages the translation of research into better health outcomes; and promotes ethical standards for health and medical research.
Normothermic regional perfusion	See perfusion technology.
Organ and Tissue Authority (OTA)	The Australian Organ and Tissue Donation and Transplantation Authority. 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'.[2]

2 Department of Health and Aged Care (Cth), 'Australian Organ and Tissue Authority' (2023) <www.health.gov.au/contacts/australian-organ-and-tissue-authority-ota>.

OTA Act	The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth). This Act establishes OTA.
Perfusion technology	Technology that restores circulation to organs after a person has died, to preserve the organs 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, machine 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 a deceased person by a pathologist to obtain information related to any disease present and the cause of death.
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.
Senior available next of kin	See next of kin.
TGA	Therapeutic Goods Administration. The federal authority responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods. The TGA regulates medicines, medical devices, and biologicals.
Tissue banks	Facilities that remove, store, process, and/or distribute human tissue to be used by clinicians in medical treatment.
TSANZ	Transplantation Society of Australia and New Zealand
UN	United Nations
Voluntary assisted dying	Voluntary assisted dying occurs when a person has a terminal illness and is given medical assistance to die. It is supported by legislation in most jurisdictions in Australia. The legislation imposes strict criteria for when and how voluntary assisted dying can occur.[3]
WHA	World Health Assembly
WHO	World Health Organization

3 *Voluntary Assisted Dying Act 2024* (ACT) s 1; *Voluntary Assisted Dying Act 2022* (NSW) s 16; *Voluntary Assisted Dying Act 2021* (Qld) s 10; *Voluntary Assisted Dying Act 2021* (SA) s 26; *End-of-Life Choices (Voluntary Assisted Dying) Act 2021* (Tas) s 10; *Voluntary Assisted Dying Act 2017* (Vic) s 9; *Voluntary Assisted Dying Act 2019* (WA) s 16.

Introduction

State and territory legislation — the Human Tissue Acts (HTAs) — regulate how human tissue is removed from living people and from the bodies of people who have died, and how it can be used.[1] The provisions in the different HTAs vary and some provisions are out of date.

We have been asked in our Terms of Reference to suggest reforms to harmonise (make consistent) and modernise (bring up-to-date) human tissue laws.

We published an *Issues Paper* in May 2025. The *Issues Paper* briefly describes:

- what we have been asked to do as part of our review of human tissue laws;
- how different laws and guidelines regulate human tissue donation, transplantation and other uses;
- the content of the HTAs;
- the aims and principles we are using to guide our review. Our aims and principles are to:
    - improve access to human tissue in Australia;
    - provide respect for persons and the human body;
    - ensure equitable participation in and access to donation and transplantation systems; and
    - promote and uphold public trust.

This *Discussion Paper* sets out some reform proposals (options) and asks for your views about them. We also ask some questions and invite your answers.

Making a submission

You can tell us what you think by making a submission or in another way that works for you. You do not have to provide your views on all the reform proposals contained in this *Discussion Paper* or answer all the questions. You can structure your submission in any way that works for you. You may also wish to tell us about your own proposal or proposals for reform.

We will use your views about our reform proposals, your answers to our questions, and any reform proposals you provide us, to consider how best to harmonise and modernise the law, while also promoting important aims and principles (including those set out in our *Issues Paper*). This will help us develop recommendations for our Final Report.

We will accept submissions until **23 January 2026**.

We will publish submissions on our website, unless:

- you ask for your submission to be confidential (private); or
- we have a legal obligation that prevents us from publishing the submission.

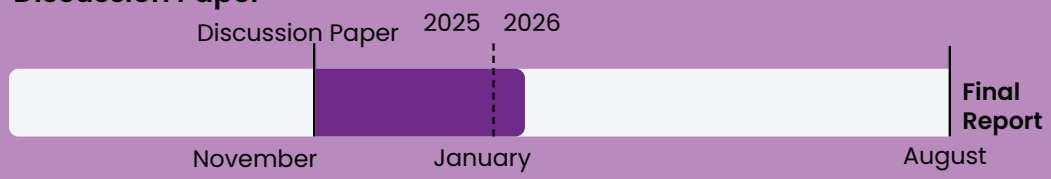
You can read our submission policy **here**.

1 *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).

How do I participate?

Make a formal submission

Discussion Paper



You can send your submission to us until 23 January 2026

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

1. A nationally harmonised regulatory framework

Contents

The problems we are addressing

1.1 The HTAs were originally adopted separately by each state and territory, without coordination.[1] Lacking mechanisms to coordinate subsequent amendments consistently — such as a formal agreement made by a ministerial council or in accordance with an intergovernmental agreement, or the creation of a national regulator[2] — inconsistencies in the HTAs have increased over time.[3]

1.2 We heard that these inconsistencies have led to uncertainty among medical practitioners and researchers about how and in what circumstance the HTAs apply.[4] Inconsistency has also created barriers to research using human tissue,[5] and unnecessary complexity and administrative burdens.[6] It can also be difficult to understand the legal obligations created by the different HTAs. Another problem is that there are gaps in the regulation and oversight of the tissue banking and research biobanking sectors.[7]

1.3 There is a need for a regulatory framework for human tissue that can adapt in response to emerging technologies, developing medical knowledge, and changing social values.

1.4 This discussion has two parts. It proposes:

- a new regulatory framework for human tissue laws, including a National Regulator (or alternative) and new human tissue legislation that can be consistently updated when necessary; and
- options for how to implement and maintain the consistency of new human tissue legislation.

1 The process may be seen as a form of what Dr Hill calls 'spontaneous harmonisation' — 'a process through which Australian jurisdictions harmonise their legal rules in a voluntary, unprompted and uncoordinated way': Guzyal Hill, *National Uniform Legislation* (Springer Nature Singapore, 2022) 27.

2 Ibid.

3 This is, perhaps, why the HTAs are not listed as national uniform legislation by the Australian Parliamentary Counsel's Committee: Australasian Parliamentary Counsel's Committee, *Australian National Uniform Law Schemes and Associated Legislation of Participating Jurisdictions* (May 2025).

4 Faculty of Medicine and Health at UNSW, *Submission 25*; Cardiac Transplant Advisory Committee of TSANZ, *Submission 30*; Centre for Law and Genetics, *Submission 47*; University of Sydney, *Submission 60*; Law Council of Australia, *Submission 61*; Clinical Training and Evaluation Centre, University of Western Australia, *Submission 88*.

5 Consortium for Australian Children's Trials in Brain Cancer, *Submission 14*; University of Sydney, *Submission 60*; The Kids Research Institute Australia, *Submission 63*; Children's Cancer Institute, *Submission 66*.

6 For areas where inconsistency has contributed to unnecessary complexity or administrative burdens, see, eg, Children's Cancer Institute, *Submission 66*; Clinical Training and Evaluation Centre, University of Western Australia, *Submission 88*.

7 See, eg, Australasian Biospecimen Network Association, *Submission 29*.

Reform proposals: a new regulatory framework for human tissue laws

National legislative framework

Proposal 1

The retrieval, storage, and use of human tissue in Australia for medical, educational or scientific purposes should be regulated either:

a. with substantial consistency across states and territories through a coordinated and harmonised set of state, territory, and Commonwealth legislation; or

b. uniformly by Commonwealth legislation.

A single National Regulator should be established (**Proposal 3**) and responsible for setting codes of practice, guidelines and standards, and for enforcing compliance.

Proposal 2

The regulatory framework established by **Proposal 1** should be structured so that:

a. the substance of any obligation, right, entitlement, or prohibition conferred or imposed, is dealt with in legislation; and

b. any necessary corresponding detail is dealt with by delegated legislation, or codes of practice, guidelines or standards set by the National Regulator (**Proposal 3**) or other responsible agencies or organisations.

National Regulator

Proposal 3

The Australian Government should establish a National Regulator by:

a. expanding the powers and functions of the Organ and Tissue Authority by amending the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth); or

b. establishing a new statutory regulatory body, which would incorporate the Organ and Tissue Authority as a branch within the new statutory regulatory body; or

c. establishing a new statutory regulatory body, which would supplement and support the existing powers and functions of the Organ and Tissue Authority in a way that is consistent with the goal for national governance set out in the National Strategy for Organ Donation, Retrieval and Transplantation.

The National Regulator could have the following powers and functions:

- set national policies in relation to human tissue;
- create binding codes of practice and standards;
- provide guidelines for medical practitioners, researchers, and organisations that retrieve, store or use human tissue;
- provide educational material for the general public about tissue donation;
- accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors;
- monitor, collect data, investigate, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.

To avoid duplication of responsibility for areas that are already regulated, in establishing the National Regulator, regard should be had to the scope of other regulatory entities in Australia, such as the:

- Therapeutic Goods Administration;
- National Blood Authority; and
- the Organ and Tissue Authority.

The Human Tissue Regulator should be adequately funded to carry out its powers and functions.

Background

1.5 We have heard support for nationally consistent human tissue laws, achieved through national law.[8]

1.6 We have also heard about interest in the United Kingdom model where human tissue laws are centrally regulated by the Human Tissue Authority (UK). The Human Tissue Authority (UK) has powers and functions in areas that are not currently regulated in Australia, such as a complaints mechanism for unauthorised use of human tissue,[9] and oversight of research institutions and biobanks.[10] We say more about the role of the Human Tissue Authority (UK) beneath the heading, 'International comparison', below.

1.7 As Australia has a federal system, a variety of regulatory models are possible. **Table 1** sets out some other areas of Australian health law that operate as 'national uniform legislation',[11] with a federal regulator and state and territory legislation.

8 Consortium for Australian Children's Trials in Brain Cancer, *Submission 14*; Centre for Law and Genetics, *Submission 47*; Name withheld, *Submission 71*; Law Council of Australia, *Submission 61*; Clinical Training and Evaluation Centre, University of Western Australia, *Submission 88*; Australian and New Zealand Intensive Care Society, Death and Organ Donation Committee, *Submission 93*.

9 See, eg, Centre for Law and Genetics, *Submission 47*. See also Australian Alliance for Indigenous Genomics, *Submission 50*.

10 Australian Academy of Health and Medical Sciences, *Submission 87*.

11 'National uniform legislation' is defined below in the discussion of **Proposal 4**.

Table 1: Regulatory frameworks in Australia

Gene technology[12]

Regulatory framework in overview
The Commonwealth, state and territory governments entered into the Gene Technology Agreement.[13] This establishes: • nationally consistent legislation where states and territory legislation correspond to Commonwealth legislation; • a Ministerial Council consisting of a minister from each state and territory government. The Ministerial Council's role is to issue policy, guidelines, codes of practice, oversee implementation of the framework, agree on future amendments, and initiate regular reviews of the gene technology laws; • a Commonwealth Gene Technology Regulator; and • an Advisory Committee and Ethics and Consultative Committee that include skilled and experienced members in the gene technology field. Their role is to provide expert advice to the Ministerial Council and Regulator.
Scope of regulator powers and functions
The Ministerial Council has multiple powers and functions, including to: • issue policy principles, guidelines, and codes of practice; • approve regulations; • approve the appointment of the Regulator and chairperson of the Advisory Committee and Ethics and Consultative Committee; and • agree on proposed amendments.[14] The Gene Technology Regulator has multiple powers and functions, including to: • perform duties in relation to licensing; • develop policy principles, guidelines, and codes of practice at the direction of the Ministerial Council; • give advice to the Ministerial Council; • give guidance and advice on gene technology to other agencies and the public; and • undertake and commission research in relation to gene technology risk assessments.[15]

12 Gene technology is an example of national uniform legislation that uses a hybrid structure of applied and mirror legislation: Australasian Parliamentary Counsel's Committee (n 3) 19–20.

13 Intergovernmental Agreement between the Commonwealth, States and Territories, *Gene Technology Agreement* (11 September 2001) <www.genetechnology.gov.au/sites/default/files/2022-01/gene-technology-agreement.pdf>.

14 Ibid cl 23; *Gene Technology Act 2000* (Cth) pt 2 div 4 subdiv B.

15 *Gene Technology Act 2000* (Cth) s 27.

Therapeutic goods[16]

Regulatory framework in overview
• Regulation of therapeutic goods has a long history in Australia.[17] • The current Therapeutic Goods Administration (TGA) is a risk-based regulator which administers the Therapeutic Goods Act 1989 (Cth).[18] • The TGA is part of the Department of Health (Cth). • Despite the *Therapeutic Goods Act 1989* (Cth) existing since the late 1980s, the states and territories did not implement the law as national uniform legislation until recently.
Scope of regulator powers and functions
• The TGA regulates therapeutic goods, medicines, and medical devices to ensure the supply of these products are safe for use.[19] • There may be some overlap with human tissue laws as the TGA regulates the manufacture, supply, import, and export of 'biologicals'. Biologicals are products that comprise, contain or are derived from human cells or tissue, and are used for medical purposes as specified in the *Therapeutic Goods Act 1989* (Cth).[20] • The TGA has broad functions including management of a national register (the Australian Register of Therapeutic Goods), licensing functions, and powers to enforce their functions including through criminal offences and civil penalties.[21]

Health practitioner regulation[22]

Regulatory framework in overview
• Health practitioner regulation was established by Queensland in the *Health Practitioner Regulation National Law Act 2009* (Qld), Schedule. The other states and territories then implemented national uniform legislation. • This law established a Ministerial Council, the Australian Health Practitioner Regulation Agency (AHPRA), and National Boards.

16 Therapeutic goods is an example of national uniform legislation that uses applied legislation: Australasian Parliamentary Counsel's Committee (n 3) 31.
17 John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Therapeutic Goods Administration, 2007).
18 Therapeutic Goods Administration, 'Our Regulatory Framework' (2020) <https://www.tga.gov.au/products/regulations-all-products/regulation-essentials/regulation-basics/our-regulatory-framework>.
19 *Therapeutic Goods Act 1989* (Cth) s 4.
20 Ibid s 32A(1).
21 Ibid chs 2, 3, 5A. See also Therapeutic Goods Administration (n 18).
22 Health practitioner regulation is an example of national uniform legislation that uses applied legislation: Australasian Parliamentary Counsel's Committee (n 3) 19.

Scope of regulator powers and functions
• AHPRA and the National Boards operate together as a risk-based regulator to maintain a register of health practitioners who are trained, qualified, and safe to practice.[23] • AHPRA sets up agreements with the National Boards about their annual budgets and services provided by AHPRA so that the National Boards can carry out their functions.[24] • The functions of the National Boards include creating and approving standards, codes and guidelines;[25] taking action to suspend or impose conditions on a health practitioner's registration; interim prohibition orders; investigative powers; health and performance assessments; and referral of matters to the responsible tribunal for professional misconduct.[26]

***Food regulation*[27]**

Regulatory framework in overview
• The Commonwealth, state and territory governments agreed under the Food Regulation Agreement to commit to nationally consistent food laws. The Agreement included a model law for each state and territory to adopt as complementary law.[28] • The state and territory Food Acts refer to the Food Standards Code, which is a legislative instrument developed by the Food Standards Australia New Zealand (FSANZ). The FSANZ was established by the *Food Standards Australia New Zealand Act 1991* (Cth).
Scope of regulator powers and functions
• The functions of the FSANZ include developing codes of practice, standards and guidelines, and coordinating with state and territory governments to harmonise procedures, food recalls, and food education for the public.[29] • FSANZ has no direct enforcement powers but can coordinate with relevant jurisdictions for consistent enforcement. State and territory government agencies, the Department of Agriculture, Fisheries and Forestry (Cth), and local councils are responsible for enforcing the Food Acts and Food Standards Code.[30]

23 *Health Practitioner Regulation National Law Act 2009* (Qld) sch 1, s 3; Australian Health Practitioner Regulation Agency, 'About AHPRA and the National Boards' <www.ahpra.gov.au/About-Ahpra.aspx>.

24 Australian Health Practitioner Regulation Agency, 'Health Profession Agreements' (2024) <www.ahpra.gov.au/Publications/Health-profession-agreements.aspx>.

25 *Health Practitioner Regulation National Law Act 2009* (Qld) sch 1, pt 5, div 3.

26 Ibid sch 1, pt 8.

27 Food regulation is an example of national uniform legislation that uses a hybrid structure of applied and mirror legislation: Australasian Parliamentary Counsel's Committee (n 3) 17–18.

28 Intergovernmental Agreement between the Commonwealth, States and Territories, *Food Regulation Agreement* (6 July 2010) <www.foodregulation.gov.au/sites/default/files/2024-01/food-regulation-agreement-fra.pdf>.

29 *Food Standards Australia New Zealand Act 1991* (Cth) s 13.

30 For a list of state and territory enforcement agencies, see Food Standards Australia New Zealand, 'Food Regulatory Agencies' (2023) <www.foodstandards.gov.au/contact/food-regulatory-agencies>.

Research involving human embryos and human cloning[31]

Regulatory framework in overview
• The Commonwealth, state, and territory governments entered into an intergovernmental agreement to ensure national consistency in the regulation of research involving human embryos and prohibition of human cloning.[32] • This agreement established an NHMRC Licensing Committee with monitoring and compliance powers for administering the Acts.
Scope of regulator powers and functions
• The NHRMC Licensing Committee has functions to monitor, issue, and renew licenses. It has investigative and monitoring powers to ensure compliance with the legislation.[33] There are also criminal offences for non-compliance.[34]

International comparison

1.8 The Human Tissue Authority (UK) was established in 2005 and administers the *Human Tissue Act 2004* (UK).[35] This regulatory framework was set up in response to issues arising from a practice in some hospitals of retaining organs and tissue, including from the bodies of children, without consent.[36] The regulatory framework in the UK focuses on the importance of obtaining consent to use human tissue, and the need to foster and maintain public trust.[37] The Human Tissue Authority (UK) regulates several broad activities in relation to human tissue including anatomical examination, post-mortem examinations, public display, organ donation and transplantation, and research uses.[38] The powers and functions of the Human Tissue Authority (UK) include:

- provision of guidelines for professionals, codes of practice, and informative material for the general public;[39]
- giving advice to government on developments in the field;[40]
- licensing, monitoring, auditing, and enforcing compliance with organisations carrying on specified activities and uses in relation to human tissue;[41] and
- giving approval for living donation.[42]

31 Australasian Parliamentary Counsel's Committee (n 3) 20–1.
32 Intergovernmental Agreement between the Commonwealth, States and Territories, *Research Involving Human Embryos and Prohibition of Human Cloning Agreement* (31 March 2004) <www.federation.gov.au/about/agreements/research-involving-human-embryos-and-prohibition-human-cloning>.
33 *Research Involving Human Embryos Act 2002* (Cth) ss 14–15. See also National Health and Medical Research Council, *Annual Report 2023–2024* (2024) 67.
34 *Research Involving Human Embryos Act 2002* (Cth) pt 2 div 2.
35 *Human Tissue Act 2004* (UK) s 13(1).
36 Christian Lenk, Judit Sándor and Bert Gordijn (eds), *Biobanks and Tissue Research: The Public, the Patient and the Regulation*, vol 8 (Springer Netherlands, 2011) 173; Department of Health (UK), *Triennial Review of the Human Tissue Authority* (Review Report, 2017) 12.
37 Lenk, Sándor and Gordijn (n 36) 173; Department of Health (UK) (n 36) 12.
38 *Human Tissue Act 2004* (UK) sch 1.
39 Ibid ss 15, 26.
40 Ibid s 15.
41 Ibid pt 3.
42 Ibid s 33.

How our reform proposals could solve the problems we have identified

1.9 **Proposals 1** and **2** seek to reform the human tissue regulatory landscape to increase and maintain national consistency and enable flexibility for future changes. **Proposal 3** establishes a national regulator that provides and maintains nationally consistent standard-making and compliance functions.

1.10 **Proposals 1** and **2** would place primary obligations in legislation, making it easier for medical practitioners and researchers to understand and comply with the law. Prescriptive detail would go into delegated legislation (regulations or legislative instruments).[43] **Proposal 3** would establish a National Regulator to support the regulatory landscape described in **Proposals 1** and **2.** A national regulator can help to maintain consistency across Australia and provide guidance to the medical and research communities on their obligations under the law. For example, clarity on what is included in the scope of the definition of 'tissue' for the purposes of the human tissue laws could be provided by a regulator (see **Proposals 8** and **9**). Establishing a national regulator could maintain:

- public trust in the human tissue system through mechanisms such as licensing, accreditation, and transparent processes;[44]
- national consistency by providing guidance on how the law applies to new circumstances arising from changes in technology or medical practice;[45] and
- adaptability by being a forum to instigate reviews of human tissue laws and coordinated law reform.[46]

1.11 Research has shown that a regulator is 'a powerful mechanism' for maintaining consistency in laws that require a national approach within Australia.[47] The absence of a national regulator for human tissue laws may help explain the extensive inconsistencies across the current HTAs.

1.12 The first option includes expanding the powers and functions of OTA. This option would require amendment to the OTA Act. In 2022, the Australian Government and all state and territory governments agreed to the National Strategy for Organ Donation, Retrieval and Transplantation, and a Transition Action Plan. The National Strategy and Transition Action Plan seeks to expand the role of OTA.[48] However, we have heard that implementation of the Strategy and Plan has stalled. In practice, OTA's current regulatory scope focusses on organ donation. In relation to the tissue sector, OTA has an Eye and Tissue Advisory Committee;[49] helps to obtain consent for tissue donation from deceased donors through the DonateLife Network; and facilitates referrals between hospitals and tissue banks for the purposes of donation.[50] However, OTA does not regulate the broader tissue sector, which involves retrieval, transplantation, storage, primary and secondary research uses, processing for therapeutic products and medicines, and use for other scientific purposes.

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43 See generally Australian Law Reform Commission, *Interim Report B: Financial Services Legislation* (Report No 139, 2022). This report examined where material should be located within the legislative hierarchy, in particular that rights and obligations should be located in primary legislation, with prescriptive detail in delegated legislation. For a summary of Interim Report B, see Australian Law Reform Commission, *Interim Report B Summary: Financial Services Legislation* (Report No 139, 2022).

44 Arie Freiberg, *Regulation in Australia* (Federation Press, 2nd ed, 2025) 54–9.

45 Hill (n 1) 108.

46 Ibid 107.

47 Ibid 108.

48 Department of Health and Aged Care (Cth), *National Strategy for Organ Donation, Retrieval and Transplantation* (2022) 9; Department of Health, Disability and Ageing (Cth), *Transition Action Plan: National Organ and Tissue Donation, Retrieval and Transplantation System* (2022) 5.

49 Organ and Tissue Authority, 'Our Committees' (2024) <www.donatelife.gov.au/about-us/who-we-are/our-committees>.

50 Department of Health and Aged Care (Cth), *National Eye and Tissue Sector Framework* (2022) 8–9.

1.13 It may not be desirable to expand OTA to create a broader National Regulator. The second option in **Proposal 3** contemplates establishing a new regulatory body which would incorporate OTA as a branch. The third option in **Proposal 3** considers establishing a new regulatory body that is separate to OTA but which would supplement and support OTA. These options could potentially advance the goals of national governance in the National Strategy and Transition Action Plan, and improve national governance in the Eye and Tissue Framework.[51]

1.14 We would like to hear feedback on these options, including whether you have a preference for a particular option (and why); or if you think one or more of the options will not work (and why). Alternatives to the introduction of a National Regulator are discussed below.

1.15 **Proposal 3** sets out a broad range of powers and functions for the National Regulator. This is because the scope of human tissue laws in Australia is broad, and different areas may require different methods of regulation. For example, regulation of trade in relation to transplant tourism might require criminal penalties. By comparison, regulation of the tissue sector might require powers to investigate, collect data, and potentially enforce compliance with civil penalties.[52] A National Regulator could potentially regulate retrieval, storage, and use of human tissue in Australia for therapeutic and other scientific purposes.

1.16 For any of the above options, it will be important that the National Regulator's scope does not duplicate and increase existing regulatory burdens, or create unnecessary complexity in areas that are already regulated. This includes in relation to the work of OTA, the National Blood Authority (NBA), and the TGA. Intergovernmental cooperation and collaboration between Commonwealth, state, and territory governments will be required to ensure this. **Table 2** outlines the purpose of some regulators in Australia whose work may overlap with human tissue laws.

Table 2: Regulatory purposes

Regulatory body	Relevant statutes and instruments	Purpose of regulatory framework
Organ and Tissue Authority	*Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth)	A 'national approach to provide world leading access to transplants and transplant outcomes for Australians'.[53]
Therapeutic Goods Administration	*Therapeutic Goods Act 1989* (Cth)	A 'national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods' which are produced or used in Australia, or exported from Australia.[54]
National Blood Authority	*National Blood Authority Act 2003* (Cth) *National Blood Agreement*[55]	A nationally consistent framework to 'provide an adequate, safe, secure and affordable supply of blood, blood related products and blood related services in Australia'.[56]

51 Department of Health and Aged Care (Cth) (n 48) 9; Department of Health, Disability and Ageing (Cth) (n 48) 5; Department of Health and Aged Care (Cth) (n 50) 8–9.
52 See generally Attorney-General's Department (Cth), *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (2024).
53 Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 (Cth).
54 *Therapeutic Goods Act 1989* (Cth) s 4(1)(a).
55 Intergovernmental Agreement between the Commonwealth, States and Territories, *National Blood Agreement* (28 February 2003) <www.blood.gov.au/national-blood-agreement>.
56 Ibid 1–2.

Regulatory body	Relevant statutes and instruments	Purpose of regulatory framework
National Health Medical Research Council	*National Health and Medical Research Council Act 1992* (Cth)	A national body designed to help foster a nationally consistent approach to health standards, health research and training, and ethical issues relating to health.[57]

Alternative options

1.17 While a National Regulator is likely to be the most effective mechanism for ensuring the ongoing consistency and adaptability of human tissue laws, and the effective implementation of these laws, there are alternative options.

1.18 One option includes state and territory departments and agencies regulating their own state and territory legislation. An intergovernmental agreement to create national uniform legislation can include establishing a ministerial council whose role is to support consistency in legislative amendments. A ministerial council may also make decisions about policy, guidelines, and codes of practice.[58] This option is likely to be less flexible, responsive, and quick to make decisions than an option that includes a national regulator.

1.19 Another option is to divide and extend administration of new human tissue legislation between existing regulators like OTA, the TGA, the NBA, and the NHMRC. This would likely require amendment and expansion of the powers and functions of these regulatory bodies. This option could lead to a fragmented and complex regulatory system, but it could reduce regulatory overlap.

1.20 We are interested to hear about additional options for regulating human tissue laws that do not involve a single national regulator (**Proposal 3**), and your views on the advantages and disadvantages of these options.

1.21 Because a single national regulator may not be the preferred option, we refer to 'the National Regulator (or alternative)' in some of our other reform proposals and questions.

Reform proposal: options to implement the new regulatory framework

Implementing a national legislative framework

Proposal 4

To implement **Proposals 1–3**, the Commonwealth, states, and territories should come to an intergovernmental agreement to implement national uniform legislation. The structures of national uniform legislation that could be implemented include:

a. referred legislation;

b. applied legislation;

c. mirror legislation; or

d. hybrid legislation — referred/applied legislation or mirror/applied legislation.

57 *National Health and Medical Research Council Act 1992* (Cth) s 3.

58 See, eg, Intergovernmental Agreement between the Commonwealth, States and Territories, *Gene Technology Agreement* (n 13) pt 3.

1.22 **Proposal 4** seeks to address the issue of inconsistencies between state and territory human tissue laws that have increased over time. A controlled and coordinated harmonisation process is needed to ensure that implementation of our proposed regulatory framework (**Proposals 1**–**3**) and future legislative amendments are nationally consistent. This is best achieved through national uniform legislation, which can have varying structures. **Proposal 4** lists the available structures.[59] Each structure can achieve varying levels of consistency, and there are varying degrees of complexity associated with the application of each structure.

Referred legislation

- With referred legislation, power is referred to the Commonwealth under s 51 (xxxvii) of the Australian Constitution (or s 122 for territories).[60]
- Traditionally, the health system in Australia has been regulated at a state and territory level. It is unusual for areas of health law to be referred to the Commonwealth. However, aspects of health law and policy that support a national health system are currently regulated by the Commonwealth, such as Medicare, the Pharmaceutical Benefits Scheme, and the collection of the Medicare levy.[61]
- State and territory willingness to refer their powers in respect of human tissue laws will likely depend on widespread support, advocacy, and negotiation.[62]

Applied legislation

- With applied legislation, a host jurisdiction drafts and enacts a template Act. This template is then enacted and applied in every other jurisdiction.
- By comparison with referred and mirror legislation, applied legislation is complicated to draft, implement, and use.[63] This is because legislation can be applied in two different ways. Some states and territories adopt the legislation so that future amendments are adopted automatically. Others apply the legislation so that future amendments pass through the state or territory's parliament before being implemented.[64]
- This occurred with the health practitioner laws. Queensland is the host jurisdiction and drafted the *Health Practitioner Regulation National Law Act 2009* (Qld). The Northern Territory adopted the Act, while Western Australia applied it.[65] Examples of applied legislation also include human embryo research, and therapeutic goods.[66]

Mirror legislation

- With mirror legislation, a host jurisdiction or the Australian Parliamentary Counsel's Committee drafts and enacts model legislation. The other states and territories then enact this legislation in their own jurisdiction, usually with some modifications.[67]
- While it can be difficult to co-ordinate consistent future amendments, this structure can be drafted to achieve very high levels of initial consistency.[68] States and territories can make amendments and repeal the legislation at any time after enactment.[69]

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59 National uniform legislation is 'the result of intended harmonisation with a degree of uniformity across several jurisdictions': Hill (n 1) 29. Use of the term 'uniform' is being used broadly to mean legislation that is consistent and not identical.
60 Guzyal Hill, 'Referred, Applied and Mirror Legislation as Primary Structures of National Uniform Legislation' (2019) 31(1) *Bond Law Review* 99.
61 Fiona McDonald and Deanna Sedgwick Fincher, 'The Legal Framework of the Australian Health System' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 82–3.
62 Hill (n 1) 31.
63 Ibid 32–3.
64 Ibid; Australasian Parliamentary Counsel's Committee, *Protocol on Drafting National Uniform Legislation* (4th ed, February 2018) 2–3.
65 Hill (n 60) 104–5.
66 Australasian Parliamentary Counsel's Committee (n 3) 19–21, 31.
67 Australasian Parliamentary Counsel's Committee (n 64) 3; Hill (n 1) 33.
68 Australasian Parliamentary Counsel's Committee (n 64) 3; Hill (n 1) 35.
69 Hill (n 1) 33.

- An example of mirror legislation with substantial consistency are work, health and safety laws.[70] In contrast, surrogacy laws are an example of mirror legislation with low levels of consistency.[71]

Hybrid legislation

- Hybrid legislation can be a mix of referred/applied legislation or mirror/applied legislation.
- Examples of hybrid legislation include gene technology and food standards laws.[72]
- Gene technology laws are an example of mirror/applied legislation. The intergovernmental agreement for these laws is an example of how states and territories can be notified of any amendments, to maintain consistency over time. In this agreement, a state or territory that wishes to amend its gene technology legislation submits the proposal for approval by the Ministerial Council.[73]

1.23 In submissions to our Issues Paper, the Law Council of Australia suggested national uniform legislation as an option for reducing 'legal uncertainty and regulatory fragmentation', listing corporations law and the health practitioner law as examples.[74] The Department of Health for Western Australia supported the applied legislation structure. The Department's submission says that 'this model is a more efficient mechanism than jurisdictions maintaining separate legislation, and by its nature enables a collaborative approach to policy development'.[75]

1.24 We seek feedback from other state and territory governments, agencies, and stakeholders about their views on national uniform legislation, and their preferred structure for this legislation, if any.

1.25 As we are proposing a system that may consist of state and territory legislation with a Commonwealth National Regulator, it is important to note the constitutional powers that can be used as a basis for this regulatory framework.

1.26 There is no explicit power to regulate health in the Australian Constitution.[76] However, in the 1940s there was movement towards a 'welfare state' and increasing recognition of 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[77] Several different heads of power in the Australian Constitution have been used to allow for the creation of national uniform legislation and for certain aspects of the regulation of the health system by the federal government. **Table 3** sets out some of these powers.

70 Ibid 34.
71 Australian Law Reform Commission, *Review of Surrogacy Laws* (Issues Paper No 52, 2025) 21; Hill (n 1) 34.
72 Australasian Parliamentary Counsel's Committee (n 3) 17–19.
73 Intergovernmental Agreement between the Commonwealth, States and Territories, *Gene Technology Agreement* (n 13) pt 5.
74 Law Council of Australia, *Submission 61*.
75 Department of Health for Western Australia, *Submission 23*.
76 McDonald and Sedgwick Fincher (n 61) 81.
77 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) art 12. See generally McDonald and Sedgwick Fincher (n 61) 82.

Table 3: Constitutional powers used in health law[78]

Constitutional provision	Examples of use
s 51(i) commerce and trade power	*Gene Technology Act 2000* (Cth).[79] Regulation of pharmaceuticals and medical devices.
s 51(ii) taxation power	Collection of Medicare levy.
s 51(xi) census and statistics power	Collection of statistics, for example by the Australian Institute of Health and Welfare.
s 51(xiv) insurance power	Regulation of private health insurance.
s 51(xx) corporations power	Regulates privatised health services.
s 51(xxiiiA) health and welfare benefits power	Medicare. Pharmaceutical Benefits Scheme.
s 51(xxix) external affairs power	WHO's International Health Regulations 2005.
s 51(xxxix) incidental power	The creation of the NHMRC Embryo Research Licensing Committee to administer the state and territory Research Involving Human Embryos Acts and Prohibition of Human Cloning for Reproduction Acts.[80]
s 51(v) communications power	Allows OTA to use television, radio and the internet to provide education material to the community.[81]

78 Unless specified otherwise, this table has been created with reference to information in McDonald and Sedgwick Fincher (n 61) 82–3.

79 Explanatory Memorandum, Gene Technology Bill 2000 (Cth) cl 13. Many other constitutional provisions listed in Table 3 apply as the basis for this Act as well.

80 Revised Explanatory Memorandum, Research Involving Embryos Bill 2002 (Cth) cl 4. This clause also highlights that most of the constitutional powers in **Table 3** are used as a basis these Acts.

81 Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 (Cth) cl 11.

2. The objects of human tissue laws

Contents

The objects of human tissue laws

Proposal 5

New human tissue legislation should include an opening section explaining that the objects of the legislation are to:

a. modernise and ensure adaptability and consistency in the laws and regulatory frameworks governing the donation of human tissue, and use of human tissue for medical, educational and scientific purposes;

b. increase access to human tissue, and to the benefits of human tissue donation, transplantation and use;

c. ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia's international human rights obligations;

d. promote equity and reduce inequities in access to human tissue and the benefits of human tissue use;

e. ensure respect for individual dignity and autonomy, and for the human body;

f. prevent the exploitation of individuals in relation to how their tissue is removed, and used for medical, educational and scientific purposes; and

g. promote public trust in the laws and regulatory frameworks that govern human tissue donation and use for medical, educational or scientific purposes.

Question 1

Do you agree with the objects listed in **Proposal 5** for human tissue legislation?

Question 2

Aside from the objects set out in **Proposal 5**, should new human tissue legislation include other objects?

National Regulator to have regard to the objects

Proposal 6

In carrying out its functions, including in relation to the creation of guidelines and codes of practice, the National Regulator (or alternative) (**Proposal 3**) must have regard to the objects of the new human tissue legislation.

The role of objects sections

2.1 Objects sections are provisions near the start of an Act that explain the purpose or objectives of the Act. Objects sections are a useful interpretative tool. They help courts, regulators and others understand:

- parliament's intention;
- the rights, benefits, and principles the legislation seeks to promote;
- the problems the legislation attempts to solve and wrongs it addresses or prohibits.[1]

2.2 Objects sections are a way for Parliament to indicate the values that should guide policy development and administrative action in the area the legislation addresses.[2] Research suggests that objects sections can 'positively influence the design or practical application of executive policy documents'.[3] To influence policy design and application effectively, objects sections should be relatively straightforward and specific. It should also be possible to interpret each object consistently with each other, in a way that is mutually supporting.[4]

2.3 In its submission in response to our *Issues Paper*, the Law Council of Australia emphasised 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.[5]

Creating a clear, principled, and ethical framework for the regulation of human tissue

2.4 The HTAs do not currently include 'objects' sections, and when they were introduced, little was said about their underlying objectives.[6] Some ethical principles are included in specific provisions of the HTAs. For example, the *Human Tissue Act 1982* (Vic) requires that anatomical examinations are carried out and bodies handled 'in a proper and decent manner'.[7] In New South Wales,

1 See *Acts Interpretation Act 1901* (Cth) s 15AA; *Encyclopaedic Australian Legal Dictionary* (online at 24 October 2025) 'objects clause' (statutes).

2 Darren O'Donovan and Narelle Bedford, 'Are Objects Provisions Valuable to Primary Decision-Makers? The Case of Australia's National Disability Insurance Scheme' in Jeffrey Barnes (ed), *The Coherence of Statutory Interpretation* (The Federation Press, 2019) 180.

3 Ibid.

4 Ibid.

5 Law Council of Australia, *Submission 61*.

6 For example, neither the Explanatory Statement to the adoption of the *Transplantation and Anatomy Ordinance 1978* (ACT) (as it then was) in the Australian Capital Territory, nor the Explanatory Notes to the Victorian Human Tissue Bill 1982 (Vic), explain the rationale or justification for the legislation. The Australian Capital Territory Explanatory Statement notes that the legislation was drafted 'in accordance with' our 1977 *Human Tissue Transplants* report, but with some variations to penalties: Explanatory Statement, Transplantation and Anatomy Ordinance 1978 (ACT); Explanatory Notes, Human Tissue Bill 1982 (Vic). The Tasmanian Anatomy Act is an exception of sorts, because its long title describes it as an Act to – among other things – 'ensure that [anatomical] examinations are undertaken with due regard to the dignity of deceased persons'. *Anatomical Examinations Act 2006* (Tas).

7 *Human Tissue Act 1982* (Vic) s 31; see also *Anatomy Act 1977* (NSW) s 16A.

post-mortem examinations must be conducted with regard 'to the dignity of a deceased person'.[8] The provisions of the HTAs also reflect broader ethical principles, including the need for informed consent, restrictions on the commodification of human tissue, and requirements to respect living persons and the human body.[9]

2.5 Our 1977 report did not discuss in detail the underlying aims of the draft legislation we proposed. But we described 'the principle of personal autonomy' as 'basic to our [reform] proposals'.[10] We also said our report sought to achieve:

> the benefits available to society … from the use of human tissue … and a sufficient supply of human tissue … without improperly disturbing attitudes widely held in the community on the subject of bodily integrity.[11]

2.6 The *Organ and Tissue Transplantation Authority Act 2008* (Cth) requires OTA to have regard to certain objectives, including 'improving access to organ or tissue donation and transplantation services',[12] and improving public confidence in these services.[13]

2.7 The objects we are proposing are consistent with what appear to be the underlying aims of the current HTAs. However, the objects also:

- respond to problems with the HTAs that new human tissue legislation is designed to fix (by referring to the need for human tissue laws to be responsive and able to adapt to new technology, and consistent across different jurisdictions); and
- respond to how community expectations have changed over the past fifty years (for example, equity and the need to reduce inequities are now central considerations for law reform).[14]

2.8 The objects are consistent with the objectives in the OTA Act and in clinical and ethical guidelines. We have heard support for these objects from a range of stakeholders.

Adaptability and consistency

2.9 Many people who work in the human tissue sector have told us that the HTAs are difficult to understand and apply. In responding to our *Issues Paper*, many people emphasised the need to modernise human tissue laws and make sure they are adaptable and responsive to emerging medical practice and technology.[15] Medical and clinical knowledge and practice are continually developing, and the law needs to be able to respond effectively. We discuss some of the ways in which the HTAs are now outdated elsewhere in this paper (for example, **Chapter 5**, **Chapter 7**, and **Chapter 8**).

2.10 We have also heard strong support for nationally consistent laws.[16] We point to some of the problems that inconsistent laws are creating (for example, **Chapter 7**).

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8 *Human Tissue Act 1983* (NSW) s 31D.

9 As we pointed out in our *Issues Paper*: Australian Law Reform Commission, *Review of Human Tissue Laws* (Issues Paper No 51, 2025) 6.

10 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 72.

11 Ibid 9.

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

13 Ibid s 12(a)(ix).

14 Our Terms of Reference say that in undertaking our review, we should consider 'equity and ethical approaches to improving access to cell, tissue and organ transplantation'.

15 See, eg, D Verran, *Submission 5*; Transplant Australia, *Submission 24*; Faculty of Medicine and Health at UNSW, *Submission 25*; Cardiac Transplant Advisory Committee of TSANZ, *Submission 30*; Norton Rose Fulbright, *Submission 44*; Australian Alliance for Indigenous Genomics, *Submission 50*.

16 For example, D Verran, *Submission 5*; Consortium for Australian Children's Trials in Brain Cancer, *Submission 14*; Transplant Australia, *Submission 24*; Faculty of Medicine and Health at UNSW, *Submission 25*; Australasian Biospecimen Network Association, *Submission 29*; Norton Rose Fulbright, *Submission 44*; Australian Alliance for Indigenous Genomics, *Submission 50*; Donor Families Australia, *Submission 55*; Victorian Cancer Biobank Consortium, *Submission 68*.

Increasing access to human tissue and its benefits

2.11 There is a shortage of organs for transplantation in Australia. Statistics suggest that:

> at any one time there are 1,850 people on the transplant waiting list. But this is only the tip of the iceberg – there are 13,000 people on dialysis who could benefit from a transplant.[17]

2.12 Being unable to access organs and other tissues for transplantation has 'enormous personal costs', leading to poor health and quality of life for many people.[18] The first priority area in the 2022 National Strategy for Organ Donation, Retrieval and Transplantation is a national approach to optimising organ donation.[19]

2.13 We have also heard that medical research in Australia is hampered by inadequate supplies of human tissue.[20] The need to increase access to human tissue is widely recognised.[21]

Consistency with human rights

2.14 Efforts to increase access to human tissue should not compromise the rights of individuals in Australia or overseas. Making sure new human tissue laws are consistent with Australia's international human rights obligations will help create a modern, ethical and principled framework for human tissue donation and use. Australia's relevant human rights obligations include to respect and promote:

- equality, and the right of individuals to equal protection of the law;[22]
- the 'inherent dignity of the human person';[23]
- the right to health;[24]
- the right to privacy;[25]
- the right to benefit from scientific progress;[26] and
- the rights of First Nations peoples, including to self-determination.[27]

2.15 Some of these rights as so important that they should be standalone objects of new human tissue legislation, and we discuss these further below. More generally, we heard strong support for rights-based reform. TASC Legal and Social Justice Services described 'the adoption of a

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17 Transplant Australia, 'Statistics' (2025) <www.transplant.org.au/statistics/>. The Transplantation Society of Australia and New Zealand notes that 'whatever process is used [to allocate organs], there will still be many patients who might benefit from an organ transplant but will not be able to receive one because of the limited supply of organs': Transplantation Society of Australia and New Zealand, *Clinical Guidelines for Organ Transplantation from Deceased Donors* (Version 1.13, August 2024) x.

18 As we point out in our *Issues Paper*, when OTA was first established, the Minister for Health and Ageing (Cth) explained its purpose was to address 'the enormous personal costs' for Australians on organ transplant waiting lists because of the shortage of organs for transplantation: Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 (Cth) 1; Australian Law Reform Commission (n 9) 6.

19 Department of Health and Aged Care (Cth), *National Strategy for Organ Donation, Retrieval and Transplantation* (2022) 8–11.

20 See, eg, Victorian Institute of Forensic Medicine, *Submission 45*; Victorian Cancer Biobank Consortium, *Submission 68*.

21 See, eg, Transplant Australia, *Submission 24*; Law Council of Australia, *Submission 61*; W Duncan, *Submission 69*.

22 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) preamble, arts 2(2), 3; *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) preamble, arts 2, 3, 26.

23 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) preamble; *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) preamble.

24 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) art 12(1).

25 *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) art 17.

26 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) art 15(1)(b).

27 *Declaration on the Rights of Indigenous Peoples*, GA Res 61/295, UN Doc A/RES/61/295 (2 October 2007, adopted 13 September 2007) arts 1, 2, 3 ('UNDRIP').

nationally consistent, rights-based approach to human tissue legislation' as 'not only a legal imperative but a moral one'.[28]

Promoting equity and reducing inequities

2.16 Efforts to increase access to human tissue should promote equity and reduce existing inequities.[29] The equality of all people and, based on this, the principle of non-discrimination, are foundational human rights. As general principles they are enshrined in international human rights covenants.[30] Equitable access to tissue donation and transplantation, and to the benefits of other uses of tissue, are specifically enshrined in other international instruments endorsed by Australia.[31] Equitable access to transplantation is also a priority area in the 2022 National Strategy.[32]

2.17 There is a consensus among people we have spoken to that the regulation of human tissue should ensure equitable access to the benefits of human tissue transplantation and use.[33] Equity should also be considered in relation to wider 'ethical and cultural considerations'.[34] We discuss the barriers that some groups experience in **Chapter 3**.

Respecting individual dignity and autonomy, and the human body

2.18 Like the recognition of equality, recognition of the 'inherent dignity of the human person' is a foundational human right. All other human rights are said to derive from the 'inherent dignity of the human person'.[35] Article one of the Universal Declaration of Human Rights provides that all 'human beings are born free and equal in dignity and rights'.[36] Giving people autonomy, or the right to freely choose how to live their life and the decisions they make about their own body, is a way of recognising and giving meaning to their inherent dignity. Respect for the human body is also connected to recognition of the dignity of the human person, such as

> how we treat bodies [and] body parts matters because they represent once-living people with contexts, histories, and relationships.[37]

28 TASC Legal and Social Justice Services, *Submission 1*.

29 National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 37.

30 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) preamble, art 2(2); *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) preamble, arts 2(1), 26 (equality before the law).

31 The Transplantation Society and International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition) 3; 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) 2.

32 Department of Health and Aged Care (Cth) (n 19) 12–13.

33 See, eg, TASC Legal and Social Justice Services, *Submission 1*; Department of Health for Western Australia, *Submission 23*; Transplant Australia, *Submission 24*; Faculty of Medicine and Health at UNSW, *Submission 25*; Law Council of Australia, *Submission 61*; Victorian Cancer Biobank Consortium, *Submission 68*.

34 Australian Alliance for Indigenous Genomics, *Submission 50*.

35 *International Covenant on Economic, Social and Cultural Rights*, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976) preamble; *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) preamble.

36 *Universal Declaration of Human Rights*, GA Res 217A(III), UN GAOR, UN Doc A/810 (10 December 1948) art 1.

37 Imogen Jones, 'Pathology and Forensic Science: Dignity, Respect, and the Dead Body' (2024) 6(3) *WIRES Forensic Science* 1, 1. This was also a point we made in our 1977 report, where we said that 'in our society the corpse is … regarded as so strongly connected with, and part of, the person who has died, that non-consensual interference with it is generally seen as an affront to humanity. Perhaps the identification of the dead body with the living person is such that the dignity of one, and the respect accorded to it, is regarded by many as the right and entitlement of the other': Australian Law Reform Commission (n 10) 8.

2.19 Ethical guidelines, and contributors to our inquiry, emphasise the importance of respect for individual dignity and autonomy, and for the human body.[38]

Preventing exploitation

2.20 Preventing exploitation is a way to enshrine respect for people's inherent dignity. It is especially important in relation to human tissue donation and use because a person's bodily integrity is widely regarded as closely related to their dignity.[39]

2.21 Preventing exploitation is also important because:

- there have been historical cases of exploitation,[40]
- the risks of exploitation are high where there is a shortage of supply;
- the need for human tissue is potentially a matter of life or death; and
- developing products using human tissue can be financially lucrative.

2.22 International and national guidelines highlight the need for human tissue laws to include safeguards against exploitation,[41] and people we have spoken to and heard from strongly agree.[42] Many emphasise that safeguards against exploitation are a necessary precondition for public trust in human tissue laws.[43]

Promoting public trust

2.23 Making the benefits of human tissue transplantation and other uses of human tissue accessible will be impossible if the public does not have confidence in human tissue laws and regulatory frameworks.[44] People will not participate in Australia's organ and tissue donation and transplantation system, or support the use of human tissue for other medical, educational or scientific purposes, if they do not trust that the system and use of human tissue for other purposes are safe and ethical.

2.24 The other objects in **Proposal 5** are intrinsically important. They are also important because laws that recognise and promote these objects will serve to uphold and promote public trust.

38 See, eg, National Health and Medical Research Council (n 29) 37; Australian Christian Lobby, *Submission 21*; Department of Health for Western Australia, *Submission 23*; Faculty of Medicine and Health at UNSW, *Submission 25*; Australasian Biospecimen Network Association, *Submission 29*; Norton Rose Fulbright, *Submission 44*; Donor Families Australia, *Submission 55*; Law Council of Australia, *Submission 61*; Name withheld, *Submission 71*: B McDowell, *Submission 74*; L Campbell, *Submission 76*; G Harrison, Submission 85, H Northern, Submission 86; C Politi, Submission 89.

39 Australian Law Reform Commission (n 10) 8.

40 See our discussion in **Chapter 10** in relation to tissue samples that may have come from First Nations peoples. For discussion of issues that arose in the United Kingdom: Jones (n 37).

41 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); National Health and Medical Research Council (n 29) principle 11, 39; see also Legal and Social Issues References Committee, Parliament of Victoria, *Register and Talk about It: Inquiry into Increasing the Number of Registered Organ and Tissue Donors* (2024) 33; TASC Legal and Social Justice Services, *Submission 1*.

42 See, eg, Law Council of Australia, *Submission 61*.

43 See, eg, Legal and Social Issues References Committee, Parliament of Victoria (n 41) 33.

44 See, eg, National Health and Medical Research Council (n 29) 37; TASC Legal and Social Justice Services, *Submission 1*; D Verran, *Submission 5*; Transplant Australia, *Submission 24*; Law Council of Australia, *Submission 61*.

Conclusion — the benefits of the proposed objects section

2.25 Including the objects of new human tissue legislation in an opening section clearly identifies and signals the importance of these objects. It provides an accessible guide to interpreting the legislation. This may contribute to greater public trust in how human tissue is used, and in the organ and tissue donation and transplantation system. It will guide decision-making about how the laws and subordinate regulations and guidelines apply and should be interpreted. It can support the executive and policy makers to design policy that supports and advances the objects.

2.26 Many of our other proposals for legislative reform are designed to advance the objects set out in **Proposal 5**. Clarity about the objects of the legislation may assist the effective implementation of these reforms.

2.27 We are proposing the creation of a National Regulator (or alternative) (**Proposal 3**). Achievement of the objects we have set out will be encouraged by requiring the regulator to take them into account when carrying out its functions.

3. Removing barriers and promoting equitable access to human tissue

Contents

Promoting equity

Question 3

Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?

Removing barriers

Question 4

If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (**Question 3**), what are the specific barriers that new human tissue legislation needs to address?

In considering this question, please ignore:

- *definitions of senior next of kin that may be outdated and unsuitable (we address these in* **Proposal 25***); and*
- *disclosure of information provisions that in some jurisdictions prevent the families of deceased donors talking about their family member's experience (we address these in* **Proposals 46** *and* **48***).*

Introduction

3.1 The HTAs do not include provisions dealing with equitable access to human tissue donation, transplantation, and use. However, removing barriers and promoting equity are core goals of organ and tissue policy in Australia. Despite this, First Nations peoples and some other groups in Australia face barriers to donating organs and do not have equal access to organs for transplantation. It is likely that they do not share equally in other benefits of human tissue use. Our initial research suggests that these inequities are not in most cases directly related to human tissue laws or policy. Instead, they appear to relate to service delivery and to stem from systemic issues with health provision in Australia.

3.2 Many people who responded to our *Issues Paper* told us that equity should be an objective of human tissue laws.[1] In **Proposal 5** we suggest that promoting equity and reducing inequities in access to human tissue and the benefits of human tissue use should be included as an object of new human tissue legislation. Our questions here are about whether new human tissue legislation should contain additional provisions designed to promote equitable access, and if so, what the specific legal barriers to equitable access are that these provisions should address.

Human tissue policy is designed to promote equitable access

3.3 In performing its functions, OTA must consider equity,[2] and equitable access to organ transplantation and post-transplantation care is one of four priority areas in the *National Strategy for Organ Donation, Retrieval and Transplantation* (National Strategy).[3] The National Strategy aims to support:

- policy and programs that break down barriers and improve access to transplantation; and
- a nationally consistent, equitable and transparent wait list for organ allocation, offer and acceptance processes.[4]

3.4 The TSANZ is the body responsible for developing, on OTA's behalf, eligibility criteria for organ transplantation, and allocation protocols for organs from deceased donors. TSANZ says that its allocation processes are designed to:

- be equitable and transparent, and
- avoid unlawful or unreasonable discrimination on the basis of race, religious belief, gender, marital status, sexual orientation, social or other status, disability, or age.[5]

3.5 'Safe and equitable access to life-saving and life-altering tissue and tissue-based product transplantation' is also an objective of *The National Eye and Tissue Sector Framework*.[6]

3.6 Relevant clinical and ethical guidelines similarly address the need for equity in access to human tissue and its benefits. For example, the National Health and Medical Research Council's *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* provide that efforts to increase access to human tissue should promote equity and reduce existing inequities.[7]

1 See, eg, TASC Legal and Social Justice Services, *Submission 1*; Transplant Australia, *Submission 24*; Law Council of Australia, *Submission 61*.

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

3 Department of Health and Aged Care (Cth), *National Strategy for Organ Donation, Retrieval and Transplantation* (2022) 12–13.

4 Ibid.

5 The Transplantation Society of Australia and New Zealand is funded by OTA to maintain 'nationally uniform eligibility criteria to ensure that there are equitable and transparent criteria by which patients are listed for organ transplantation'. The ethical principles on which eligibility criteria and allocation protocols developed by TSANZ are based include the need to avoid unlawful or unreasonable discrimination on the basis of race, religious belief, gender, marital status, sexual orientation, social or other status, disability or age: Transplantation Society of Australia and New Zealand, *Clinical Guidelines for Organ Transplantation from Deceased Donors* (Version 1.13, August 2024) ix. See also Australian Law Reform Commission, *Review of Human Tissue Laws* (Issues Paper No 51, 2025) 18.

6 The Framework also includes equitable access to tissue transplantation, and access for 'all Australians to affordable, ethically-sourced, high standard [tissue] products and services' as a guiding principle: Department of Health and Aged Care (Cth), *National Eye and Tissue Sector Framework* (2022) 5.

7 National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 38.

Barriers for First Nations groups

3.7 First Nations peoples have higher needs for donated organs than other groups,[8] but are less likely to receive them.[9] We heard from people with extensive experience gathering relevant data that once First Nations people are included on transplant waiting lists, the likelihood they will receive a transplant appears to be comparable to that for members of other groups.[10] However, First Nations people are less likely to be included on a waiting list,[11] with research suggesting there is:

> inequitable access to [organ] transplant waiting lists for Aboriginal and Torres Strait Islander people and … added challenges experienced by patients in rural and remote areas of Australia.[12]

3.8 These inequities stem from multiple causes, including the lack of place-based health services in regional and rural areas.[13] We have also heard that the current donation and transplantation framework is built on cultural norms that do not align with First Nations' cultures. Barriers can be created by a system that responds to individuals in isolation from their culture, community, and life experience.[14] The expectation that First Nations people with kidney disease should leave their Country and community to get dialysis is an example of this.[15] First Nations patients suffering from chronic and end stage kidney disease have 'described a pervasive and persisting experience of bias in the delivery of kidney health services',[16] and an experience of these services as not being 'culturally safe'.[17]

3.9 Recognising this problem, the Australian Alliance for Indigenous Genomics told us it is important to define equity broadly, with reference to 'ethical and cultural considerations', as well as in terms of access to organs and other tissue, and their benefits.[18]

3.10 We heard from people who engage with First Nations communities in the Northern Territory that restrictions on disclosing information that identifies a deceased donor or recipient can be a problem. It may prevent people sharing their family members' stories, which can be a powerful way for First Nations people to de-mystify what is involved in organ donation or transplantation.

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8 Hughes and her co-authors attribute this to the 'sustained and systematic effects of colonisation — which enabled the combined denial of Aboriginal and Torres Strait Islander people's self-determination, autonomy, leadership, and capability to mobilise health-benefiting resources': Jaquelyne T Hughes et al, 'Advancing Accessible Kidney Transplantation for Aboriginal and Torres Strait Islander People: The National Indigenous Kidney Transplantation Taskforce' (2023) 219 (8 Supp) *Medical Journal of Australia* S3, S3.

9 Jaquelyne T Hughes et al, 'Advancing Accessible Kidney Transplantation for Aboriginal and Torres Strait Islander People: The National Indigenous Kidney Transplantation Taskforce' (2023) 219(S8) *Medical Journal of Australia* S3; Department of Health and Aged Care (Cth) (n 3) 5; Transplantation Society of Australia and New Zealand, *Performance Report: National Indigenous Kidney Transplantation Taskforce* (2022); Heather J Baldwin et al, 'Closing the Gap in Kidney Disease: Validating the Reporting of Aboriginal and/or Torres Strait Islander Identification in a Clinical Quality Registry Using Linked Data' (2025) 222(5) *Medical Journal of Australia* 240; Paul Secombe et al, 'Aboriginal and Torres Strait Islander Attitudes to Organ Donation in Central Australia: A Qualitative Pilot Study' (2024) 10(9) *Transplantation Direct* e1692.

10 However, some research on access to kidney transplants suggests that after the first year on the transplantation waiting list, during which outcomes for First Nations people are similar to those for members of other groups, access to transplants is 'significantly lower for Indigenous patients in subsequent years'. Namrata Khanal et al, 'Disparity of Access to Kidney Transplantation by Indigenous and Non-Indigenous Australians' (2018) 209(6) *Medical Journal of Australia* 261, 265.

11 Hughes et al, (n 9) 4.

12 Department of Health and Aged Care (Cth) (n 3) 5.

13 See Ibid 12; Menzies School of Health Research, *Indigenous Patient Voices: Gathering Perspectives: Finding Solutions for Chronic and End Stage Kidney Disease* (2017) 13–15.

14 The 2017 Symposium report, *Indigenous Patient Voices* points to the importance of using the 'life experiences' of First Nations peoples as 'a base upon which to build effective systems of health care to improve health outcomes and realise health equity for people with chronic and end stage kidney disease: Menzies School of Health Research (n 13) 12.

15 Ibid 13–15.

16 Ibid 14.

17 The 2017 Symposium report, Indigenous Patient Voices points to the importance of using the 'life experiences' of First Nations peoples as 'a base upon which to build effective systems of health care to improve health outcomes and realise health equity for people with chronic and end stage kidney disease: Ibid 17.

18 Australian Alliance for Indigenous Genomics, *Submission 50*.

We propose reforms to allow the families and kin of deceased organ donors to share their stories below (**Proposal 48**).

3.11 Some of the HTAs have restrictive definitions of next of kin or senior next of kin, which do not capture the range of kinship relationships recognised by some people and groups. We suggest replacements for these definitions in **Proposal 25**.

Barriers for other groups

3.12 Previous inquiries have identified a range of barriers to equitable access to organ and tissue donation. A 2024 Victorian parliamentary inquiry pointed to a need for greater cultural and ethnic diversity in the donation specialist workforce.[19]

3.13 The same inquiry recommended that:

> The Victorian Government consult with community leaders, Elders and organisations to co-design and tailor engagement projects to provide opportunities to share information and talk about organ and tissue donation, including:
>
> - The production of resources to engage with digitally disadvantaged Victorians through mail drops as well as easy-read and translated resources
> - The provision of translated resources in different formats to promote registration and family discussion when Victorians engage with government touchpoints, including through driver licence applications and renewals
> - Programs to support intergenerational discussion in families from multicultural and faith-based communities
> - A First Nations organ and tissue donation ambassador program.[20]

3.14 A Western Australian inquiry recommended that OTA and DonateLife update and review the DonateLife website to make sure that:

- all statements of religious and cultural support contain up-to-date information and are clearly marked with the date they were last reviewed;
- the content meets accessibility standards; and
- there are prominent options to translate important information into various languages.[21]

3.15 Providing options for translation of materials on the DonateLife website into languages other than English could help improve accessibility. Similarly, it would be helpful to have translation options for the organ donor registration form that is available for download from the Organ Donor website.[22]

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19 In response to this need, the inquiry recommended that the Commonwealth Department of Health, Disability and Ageing and Organ and Tissue Authority build capacity for DonateLife to establish recruitment strategies to grow the cultural and ethnic diversity of the donation specialist workforce: Legal and Social Issues References Committee, Parliament of Victoria, *Register and Talk about It: Inquiry into Increasing the Number of Registered Organ and Tissue Donors* (2024) rec 15, xxvii. A Western Australian inquiry recommended that DonateLife staff should be trained in the religious and cultural aspects of organ donation: Standing Committee on Public Administration, Parliament of Western Australia, *The Donation Conversation: Organ and Tissue Donation in Western Australia* (2024) rec 10, 67.

20 Legal and Social Issues References Committee, Parliament of Victoria (n 19) rec 21, xxx. A similar recommendation was made by a Western Australian inquiry, which recommended there was a need to 'provide grants for 'grassroots' tailored consultation with culturally and linguistically diverse communities. This consultation should address specific concerns of the relevant community about organ and tissue donation and should occur in: - collaboration with community and faith leaders; and - environments familiar to the relevant community.': Standing Committee on Public Administration, Parliament of Western Australia (n 19) recommendation 11.

21 Standing Committee on Public Administration, Parliament of Western Australia (n 19) rec 9, 67.

22 The website does have an option to listen to the information, making it accessible for visually impaired people: Services Australia, 'Australian Organ Donor Register' 2021 <https://www.servicesaustralia.gov.au/australian-organ-donor-register>. Separately, the DonateLife website has a 'Join the register' page with a web form people can use to join the register. While simply and clearly presented, the information is not available in languages other than English: Organ and Tissue Authority, DonateLife, 'Join the Register' <https://www.donatelife.gov.au/register-donor-today>.

Strategies that are already promoting equitable access

3.16 OTA supports community and private organisations to develop tailored communication strategies for groups that are unfamiliar with the process or benefits of organ donation, or who experience other barriers to donation and transplantation. For example:

- Queensland Remote Aboriginal Media has been funded to support 'First Nations artists and community members [to] co-design a series of culturally relevant and engaging animations and audio segments that [will be] distributed nationally to promote registering as an organ and tissue donor'.[23]
- The National Ethnic and Multicultural Broadcasters' Council has received a grant to develop 'an audio explainer series [that] will be … distributed in English and Australia's 9 most-spoken languages: Mandarin, Arabic, Vietnamese, Cantonese, Punjabi, Greek, Italian, Hindi, and Spanish'.[24]
- A social media marketing company will develop and implement an 'influencer strategy … to spread the word about organ and tissue donation to young people'.[25]

3.17 In an effort to break down barriers to equitable participation, some First Nations communities have been supported to have conversations about organ donation and transplantation.[26] Aboriginal Liaison Officers work in the Northern Territory and Western Australia to create culturally sensitive links with organ donation and transplantation services.[27] Health providers like Purple House in Central and Northern Australia offer culturally safe, place-based support for people suffering from renal disease and other health conditions. They train 'patient preceptors' who have lived experience of renal disease and treatment, and who can provide advice, support and advocacy for First Nations dialysis and transplant patients.[28]

3.18 The National Indigenous Kidney Transplantation Taskforce (NIKTT) collects data, targets cultural bias, and embeds Aboriginal and Torres Strait Islander self-determination and authority in the models of care it promotes.[29]

23 Organ and Tissue Authority, 'Our New 2025 Community Partners' <https://www.donatelife.gov.au/news-events/news/2025/our-new-2025-community-partners>.
24 Ibid.
25 Ibid.
26 See, eg, Clair Scrine and Rose Murray, *Addressing Aboriginal Rates of Organ Donation in WA: Report on the Community Awareness Grant* (Kulunga Research Network and Telethon Institute for Child Health Research, December 2011).
27 Secombe et al (n 9) 2.
28 Purple House, *'Our Work Is for Our People': Panuku Renal Patient Preceptors Workforce Development Project Report* (2019).
29 Jaquelyne Hughes et al, 'Cultural Bias in Kidney Care and Transplantation: Review and Recommendations to Improve Kidney Care for Aboriginal and Torres Strait Islander People' (2023) 219 (8 Suppl) *Medical Journal of Australia* S11; National Indigenous Kidney Transplantation Taskforce, 'Position Statement: Transplantation Equity for Aboriginal and Torres Strait Islander Peoples with Kidney Disease', *NIKTT* (20 February 2025) <https://www.niktt.com.au/positionstatement>.

Strategies that could improve equitable access

3.19 A stronger commitment to place-based and culturally safe health care could address the barriers faced by First Nations peoples.[30]

3.20 In its submission to our *Issues Paper*, the Australian Alliance for Indigenous Genomics identified a range of additional strategies to overcome barriers for First Nations people, including:

- recognising [Aboriginal and Torres Strait Islander] cultural norms and values in human tissue laws;
- strengthening governance and redress mechanisms; and
- supporting culturally safe storage, repatriation, and disposal of tissue.[31]

We discuss issues relating to the repatriation of human tissue that came originally from First Nations people in **Chapter 10** (**Questions 31–33**).

Conclusion

3.21 Currently, First Nations peoples and some other groups do not have equal access to organ donation or organs for transplantation. It is likely that these groups do not share equally in other benefits of human tissue use — for example, benefits from medical advances or the development of therapeutic products. Rather than specific barriers in the HTAs, the most significant barriers appear to relate to inadequate resourcing and to systemic issues with the provision of health services in Australia.

3.22 OTA and DonateLife are working to remove barriers and to provide equitable and culturally safe access to organ donation and transplantation for groups such as First Nations people. The NIKTT, and Indigenous health providers and services like Purple House, are doing important work. In the case of the NIKTT, progress has been hampered by not having access to ongoing funding. The NIKTT released a report in August 2023 providing extensive recommendations to address bias and other issues that prevent equitable service delivery for First Nations people in the human tissue sector.[32] This report was presented to the Australian Government's Jurisdictional Organ Tissue Steering Committee and continues to inform the implementation of the National Strategy.[33]

3.23 Aside from including equity as an explicit object of new human tissue legislation (**Proposal 5**), updating the definition of senior next of kin (**Proposal 25**), and reforming disclosure of information provisions (**Proposals 46** and **48**), we have not yet identified specific reforms to human tissue laws, or new legislative provisions, that could effectively promote equitable access to human tissue and its uses. We are keen to receive feedback about if there is a need for human tissue laws to include provisions designed to promote equitable access to human tissue donation, transplantation and use, and if so, the specific barriers these provisions should be designed to address.

30 Hughes et al, 'Cultural Bias in Kidney Care and Transplantation: Review and Recommendations to Improve Kidney Care for Aboriginal and Torres Strait Islander People' (n 29). A recent Victorian inquiry recommended a review of: 'support arrangements for end of life care services for First Nations patients and families to ensure … Aboriginal Liaison Officers are involved to help donation specialists lead culturally appropriate donation conversations and to assist families with decision making': Legal and Social Issues References Committee, Parliament of Victoria (n 19) rec 14, xxvii.

31 Australian Alliance for Indigenous Genomics, *Submission 50*.

32 These recommendations focus on three key areas for action: immediate improvements to access and services; establishing an ongoing secretariat to monitor and progress transplantation equity; and investigating additional measures to address drivers of inequity: Katie Cundale et al, *Final Report: National Indigenous Kidney Transplantation Taskforce* (National Indigenous Kidney Transplantation Taskforce, 2023) 3.

33 Department of Health and Aged Care (Cth) (n 3) 13.

4. Reforms relating to the definition of tissue

Contents

Definition of human 'tissue'

Proposal 7

New human tissue legislation should include a definition of human 'tissue' (or an alternative label for human tissue) that is broad and provides for a flexible mechanism to adjust the definition.

Question 5

How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?

In your response, you might consider the following options:

a. tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the *Human Tissue Act 2004* (UK)); or

b. tissue means the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from human cells (a definition based on section 7 of the *Human Tissue Act 2008* (NZ)).

Question 6

In new human tissue legislation, should the word 'tissue' be replaced with another label?

In your response, you might consider alternative options such as:

a. 'substance of human origin';

b. 'human material'; or

c. 'cell, organ, and tissue'.

Adjusting the scope of the definition

Proposal 8

The human tissue regime should have a mechanism to adjust the scope of the definition of 'tissue' (or an alternative label) by authorising the National Regulator (or alternative) to make delegated legislation for this purpose.

Guidelines to support the definition

Proposal 9

The National Regulator (or alternative) should, as part of its function, create guidelines to provide interpretive guidance and clarity about the definition and scope of 'tissue' (or an alternative label).

Exclusions from the definition

Question 7

Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?

- Human milk.
- Foetal tissue.
- Faecal tissue.
- Gametes (from deceased donors).
- Cell lines.

If you think some of the above materials should be excluded from human tissue laws (either completely or for particular purposes, circumstances, or provisions), why?

Are there other types of tissue that you think should or should not be regulated by human tissue laws?

In your response, you may want to consider **Proposal 5** (the objects of human tissue laws) **Proposals 40–44** (reforms relating to the prohibition of domestic trade) and **Proposals 32–39** (reforms relating to tissue donation for research).

The problems we are addressing

4.1 Clarity about the meaning and scope of 'tissue' is essential because it determines the boundaries of what is and is not regulated by human tissue legislation. There are several problems with how the current HTAs define tissue. These include:

- what is included and excluded from the scope of the definition varies across state and territory HTAs;
- what types of tissue are included in the definition, and therefore, regulated by the HTAs; and
- how the HTAs use 'tissue' as a catch-all to refer to cells, organs, and other kinds of tissue creates confusion. We heard that in in industry and clinical practice, and the OTA Act, 'tissue' has a narrower meaning, referring to parts of the body or substances extracted from the body that are not organs. For example, heart valves, bone, tendons, and corneas.

4.2 This section seeks feedback on:

- an alternative label and definition (**Proposal 7**, **Questions 5** and **6**);
- a proposal for an adaptable and flexible legislative framework to manage the scope of the definition, and thereby the regulatory boundaries of human tissue laws (**Proposals 8** and **9**); and
- whether specific types of tissue should be excluded from the new human tissue legislation (**Question 7**).

4.3 While we are considering alternative terms, this Discussion Paper uses 'tissue' in a broad way to encompass the alternative options we are considering.

Background to the problems

4.4 Aside from stylistic differences, the HTAs currently define tissue as including 'an organ, or part, of a human body or a substance extracted from, or a part of, the human body'.[1] For living donation, jurisdictions exclude foetal tissue, sperm, and eggs.[2] There are also variations. These include:

- New South Wales includes blood, foetal tissue, and gametes in the definition unless specified otherwise;[3]
- in Queensland, a human foetus and part of a human foetus is included in the definition of tissue that applies for deceased donation;[4]
- Queensland excludes immunoglobulins, laboratory reagents, and human milk from the definition of tissue that applies for both living and deceased donation;[5]
- Tasmania excludes human milk from the definition of tissue for living donation;[6]
- Western Australia excludes human embryos from the definition of tissue for living donation.[7]

4.5 The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) defines tissue as 'part of a human body (other than an organ), or part of an organ, or a substance extracted from, or from a part of an organ or any other part of a human body'.[8] Organ is defined separately as 'an organ of a human body (within the ordinary meaning of that expression)'.[9] The regulations then exclude substances that are not considered to be tissue for the purposes of the Act. Currently the regulations exclude blood and blood products, reproductive tissue, foetal tissue, and stem cells.[10] The regulations are intended to be used to exclude substances from the definition of tissue in a flexible and timely manner that is responsive to changes in the medical field.[11]

4.6 In our consultations and submissions, we heard that the definition of 'tissue' should be as broad as possible, to accommodate future developments.[12] We also heard that there is uncertainty about whether:

- derivative materials like cell lines and organoids are included in the definition of tissue;[13]
- the word 'tissue' should be used to include solid organs and cells;[14]

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

2 *Transplantation and Anatomy Act 1978* (ACT) s 6; *Human Tissue Act 1983* (NSW) s 6; *Transplantation and Anatomy Act 1979* (NT) s 6; *Transplantation and Anatomy Act 1979* (Qld) s 8; *Transplantation and Anatomy Act 1983* (SA) s 7; *Human Tissue Act 1985* (Tas) s 5; *Human Tissue Act 1982* (Vic) s 5; *Human Tissue and Transplant Act 1982* (WA) s 6.

3 *Human Tissue Act 1983* (NSW) s 4 (definition of 'tissue' para (2A)).

4 *Transplantation and Anatomy Act 1979* (Qld) s 4 (definition of 'tissue').

5 Ibid.

6 *Human Tissue Act 1985* (Tas) s 5.

7 *Human Tissue and Transplant Act 1982* (WA) s 6.

8 *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) s 4 (definition of 'tissue').

9 Ibid s 4 (definition of 'organ').

10 *Australian Organ and Tissue Donation and Transplantation Authority Regulations 2020* (Cth) reg 6.

11 Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008 (Cth) cl 4.

12 See, eg, Australasian Biospecimen Network Association, *Submission 29*.

13 See, eg, Children's Medical Research Institute, *Submission 20*; Children's Cancer Institute, *Submission 66*; Health Law Group, Monash University, *Submission 67*.

14 See, eg, National Health and Medical Research Council, *Submission 6*; Lions Eye Donation Service, *Submission 28*.

- the current definition adequately encapsulates the entire human body for deceased body donation;[15] and
- if foetal tissue should be considered as tissue of the mother or as separate.[16]

4.7 We heard that the current uncertainties are creating a barrier to research in Australia.[17]

4.8 Some submissions, and people we consulted with, suggest that the label 'tissue' should be replaced with either 'substances of human origin'; 'cells, organ and tissue'; or 'human biologicals'.[18] These alternatives are designed to address the issues highlighted above: inconsistencies across different HTAs; that 'tissue' may not be broad enough to encompass all the materials that should be regulated by human tissue legislation now or in the future; and the confusion created by the broad definition of 'tissue' in the HTAs and the word's narrower meaning in OTA legislation and in clinical and industry practice.[19]

International comparison

4.9 We have heard some alternative labels and definitions for 'tissue' which draw on international sources. **Table 4** sets out some of these sources. We have included the language and definitions used in the United Kingdom, New Zealand, and European Union for comparative purposes, noting that:

- the United Kingdom has a broad definition and uses legislative instruments to regulate its scope, which is a similar approach to that used in the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth);
- New Zealand uses the word 'tissue', combined with a definition in its primary legislation that provides a list about what can be included and excluded from the scope of tissue; and
- the European Union has recently adopted the label 'substance of human origin' to encapsulate cells and tissue to address some similar problems that are occurring in Australia, including the issue of inconsistent use of the label and definition of 'tissue' across states.[20]

Table 4: Describing and defining human tissue — international comparisons

Jurisdiction and instrument	Label	Definition
United Kingdom — *Human Tissue Act 2004*	Relevant material	'(1) In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells. (2) In this Act, references to relevant material from a human body do not include— (a) embryos outside the human body, or (b) hair and nail from the body of a living person'.[21]

15 See, eg, Norton Rose Fulbright, *Submission 44*; R Jenkin, *Submission 48*.
16 See, eg, Macquarie University, *Submission 19*; Australian Christian Lobby, *Submission 21*.
17 See, eg, Consortium for Australian Children's Trials in Brain Cancer, *Submission 14*; R Balleine, *Submission 17*; Children's Medical Research Institute, *Submission 20*; Australasian Biospecimen Network Association, *Submission 29*.
18 See, eg, Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand, *Submission 81*.
19 See, eg, R Jenkin, *Submission 48*; Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand, *Submission 81*.
20 *Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC and 2004/23/EC* [2024] OJ L 1938/1, recitals 5, 7, 26.
21 *Human Tissue Act 2004* (UK) s 53.

Jurisdiction and instrument	Label	Definition
New Zealand — *Human Tissue Act 2008*	Tissue	'**Human tissue** or **tissue** means material that— (a) is, or is derived from, a body, or material collected from a living individual or from a body; and (b) is or includes human cells; and (c) is not excluded, for the purposes of some or all of the provisions of this Act, by subsection (2) or (3). (2) A human embryo or human gamete is not human tissue for the purposes of any provision of this Act. (3) Cell lines derived from human cells are human tissue for the purposes of the following sections, but not for the purposes of any other provisions of this Act: (a) sections 47 and 74 (which relate to standards for collection or use of human tissue for non-therapeutic purposes): (b) sections 66 and 75 (which relate to standards, etc, for export and import of human tissue). (4) Examples of human tissue therefore include the following: (a) all or any part of a body: (b) whole human organs (for example, hearts, kidneys, livers, and lungs) or parts of them (for example, heart valves): (c) human stem cells or other human cells (for example, stem cells obtained from human embryos): (d) human blood: (e) human bone marrow: (f) human eyes: (g) human hair, nails, and skin: (h) human lung washouts: (i) human mucus, sputum, or urine'.[22]
European Union — *Regulation 2024/1938*	Substance of human origin	'Any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including substance of human origin preparations resulting from the processing of such substance'.[23] Does not include organs.[24]

22 *Human Tissue Act 2008* (NZ) s 7.
23 *Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC and 2004/23/EC* [2024] OJ L 1938/1, art 3(1).
24 Ibid recital 26.

4.10 We have heard that one alternative approach to solving the problems outlined above could be to define cells, organs, and tissue separately instead of having a single overarching label. This would be similar to the way the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) approaches the definitions of 'organs' and 'tissue'. The World Health Organization has a Global Glossary on Donation and Transplantation which defines:

- '*Cells* — The smallest transplantable and functional unit of living organisms';
- '*Organ* — Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy'; and
- '*Tissue* — All constituent parts of the human body formed by cells.'[25]

How our reform proposal could solve the problems

The definition and label of 'tissue'

4.11 The aim of **Proposal 7** is to have a label and definition of 'tissue' that is broad. This will avoid regulatory gaps by encompassing human material that might be developed and used in the future and allow for any appropriate exclusions to be carved out of the new human tissue legislation.

4.12 A broad definition puts all human material within the scope of the definition unless it is expressly excluded. This approach is captured by the phrase 'it's in, unless it's out'.[26] Paired with powers to exclude material from a definition, this approach can be more flexible than approaches that rely on specific lists of included and excluded material.[27] While the specific list approach can provide some certainty,[28] considering the pace of change in the area, a more flexible definition is preferable. Mechanisms to exclude materials from any broad definition are discussed below ('Adjusting the scope of the definition of "tissue"').

4.13 **Question 5** asks whether one of the two suggested options is suitable as a broad definition of 'tissue'. The two options draw on the definitions used in human tissue laws in the United Kingdom and New Zealand (**Table 4**), modified to suit Australian purposes and the mechanism suggested in **Proposals 8** and **9**. The EU's 'substance of human origin' is also provided in **Table 4** as an example, as this may be a useful label to replace 'tissue'.

4.14 We would also like to hear if you have a preferred definition that we have not considered in this Discussion Paper.

4.15 **Question 6** seeks feedback on a preferred 'catch-all' label that might be more suitable than 'tissue', and why it is preferred. As highlighted above, the word 'tissue' has a meaning for many people that is narrower than the current definition in the HTAs. This is a source of confusion. We have considered the following labels but they have not been included as options as we have concerns about them:

- Human biologicals — the Therapeutic Goods Administration (TGA) defines and regulates 'biologicals', which include products made from human cells or tissue.[29] Using this phrase in new human tissue legislation could cause confusion, as it would have to be defined differently. For example, the TGA definition is confined to things that are used for a range of

25 World Health Organization, *Global Glossary on Donation and Transplantation* (2009) 8, 12, 14.
26 For a similar approach, see generally Australian Law Reform Commission, *Interim Report A: Financial Services Legislation* (Report No 137, 2021) 301, 318–19.
27 See generally Ibid 275–6, 316–17; Australian Law Reform Commission, *Confronting Complexity: Reforming Corporations and Financial Services Legislation* (Final Report No 141, 2023) 208.
28 Australian Law Reform Commission, *Interim Report A: Financial Services Legislation* (Report No 137, 2021) 317.
29 *Therapeutic Goods Act 1989* (Cth) s 32A.

specified clinical purposes, whereas our definition would need to apply to a broader range of medical, educational and scientific purposes.

- Medical product of human origin — use of this phrase by WHO contemplates human tissue being used for medical purposes.[30] Medical purposes are too narrow for human tissue legislation in Australia, which contemplates a range of educational and scientific purposes, including research. Including the word 'product' may also raise concerns about objectification or commercialisation of the body, detracting from the principle of respect for the human body, which is one of the objects we are proposing could be included in new human tissue legislation (**Proposal 5**).

4.16 We would also like to hear whether you have a preferred label that is not listed in **Question 6**.

4.17 Depending on the feedback we receive, we may recommend in our Final Report that 'tissue' be replaced in new legislation with a different label.

Adjusting the scope of the definition of 'tissue'

4.18 **Proposal 8** seeks to provide a flexible mechanism for adjusting the scope of the definition, and thereby the scope of the new human tissue legislation. The aim of an amended definition of 'tissue' is to be broad. It may generally be assumed that related materials fall within the definition — that is, the material 'is in, unless it's out'. To enable flexibility and timely changes to the scope of the definition of 'tissue', the National Regulator (or alternative) could be authorised to make delegated legislation for this purpose.[31] This mechanism would be flexible because it can consider whether new or emerging types or uses of material should be regulated by the new human tissue legislation or parts of the human tissue legislation.

4.19 It is appropriate to have delegated legislation for the following purposes:

- to streamline and simplify primary legislation;
- the legislation is dealing with something that is likely to change regularly or frequently; and
- it is suitable for subject matter experts to make legislation about technical and detailed aspects of the law, rather than Parliament.[32]

4.20 Adjusting the scope of the definition of 'tissue' meets these purposes. Delegated legislation can adjust the scope of 'tissue' through the use of exclusions. Exclusions 'carve-out' a material, class of material, or circumstance to exclude them from the application of particular provisions in the primary legislation, or the human tissue regime generally.[33]

4.21 Reasons to adjust the scope of the definition could be to ensure consistency with the objects of the new human tissue legislation, or because the material or class of material is better regulated by another area of law for ethical, social, or other reasons.

4.22 There are ways to make delegated legislation so that adjustments to the scope of the definition are located in one place, these include:

- regulations — this is the approach that has been taken to exclude types of tissue in the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth); or

30 'Medical products of human origin are derived wholly or in part from the human body and intended for clinical application. They include blood and blood products, organs, bone marrow, cord blood, corneas and tissues': World Health Organization, *Blood and Other Medical Products of Human Origin*, EB136/32 (5 December 2014) (136th session of the Executive Board) 1.

31 Delegated legislation are 'laws made under the authority of Acts by persons or bodies other than the Parliament': Department of the Prime Minister and Cabinet (Cth), *Legislation Handbook* (2017) 85; Australian Law Reform Commission (n 27) 42.

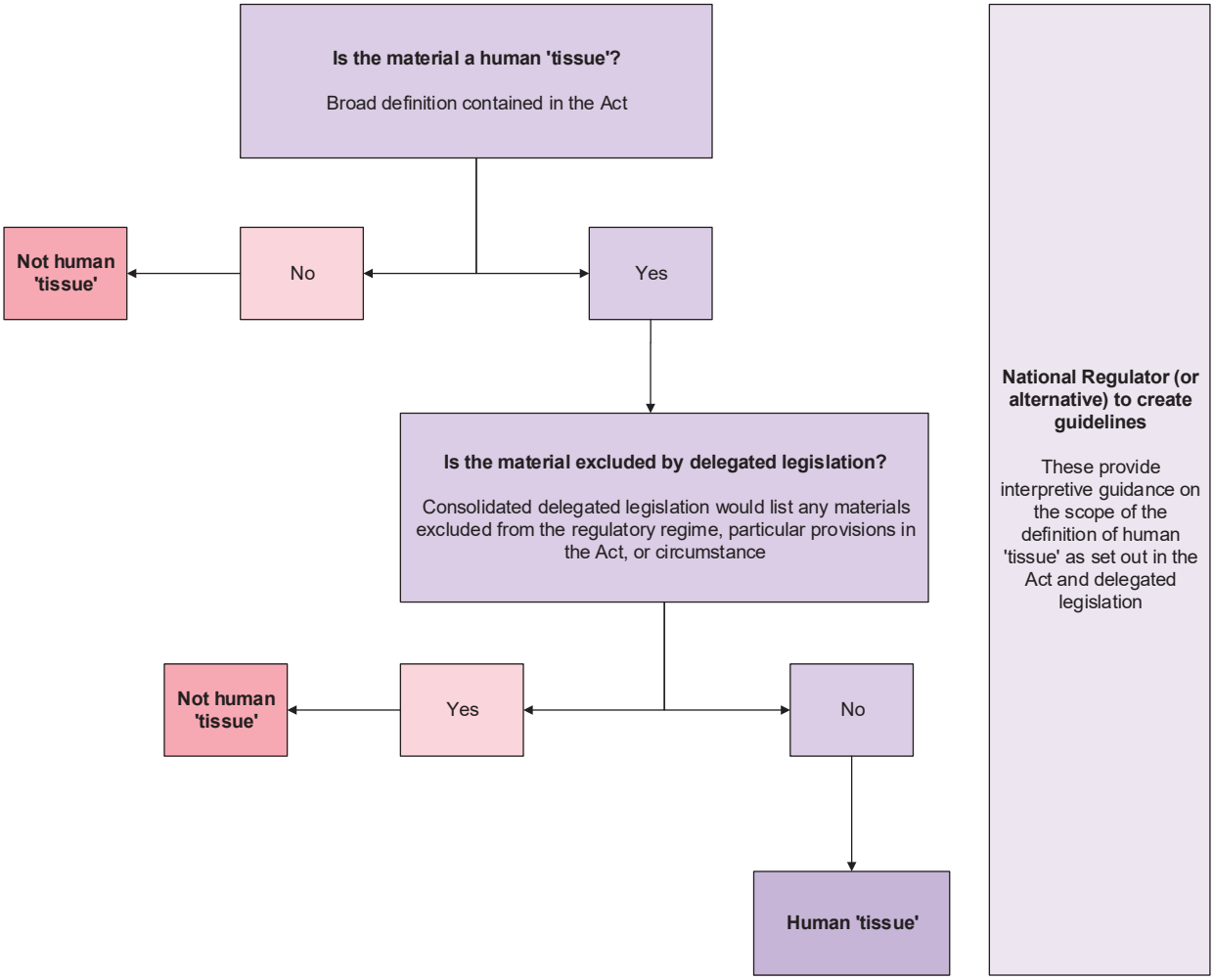
32 Department of the Prime Minister and Cabinet (Cth) (n 31) 33; Australian Law Reform Commission, Australian Law Reform Commission, *Principled Regulation: Federal Civil and Administrative Penalties in Australia* (Report No 95, 2002) 227; Australian Law Reform Commission, *Interim Report B: Financial Services Legislation* (Report No 139, 2022) 115.

33 Australian Law Reform Commission (n 27) 42.

- a Scoping Order — 'a single legislative instrument that adjusts the regulatory boundaries set by primary legislation'.[34] A Scoping Order was recommended in our Financial Services Legislation Inquiry to reduce complexity and make it easier for users to locate application provisions, exclusions, and exemptions from financial services legislation.[35]

4.23 In conjunction with the new human tissue legislation and delegated legislation, **Proposal 9** suggests that the National Regulator (or alternative) create guidelines that provide interpretive guidance about the scope of the definition of 'tissue'. Guidelines can be a useful reference for users of the legislation as they can provide an informal indication of how a regulator intends to interpret the law.[36] **Figure 1** provides a flow chart for how **Proposals 8** and **9** would apply a new definition of 'tissue'.

Figure 1: Applying a proposed definition of 'tissue'



4.24 **Question 7** asks if materials that are a current cause of uncertainty should be:

- Excluded from the definition of 'tissue' (or an alternative label) in the new human tissue legislation. This exclusion could be placed in the primary Act if the material should not be

34 Ibid 80.
35 Ibid 81.
36 Australian Law Reform Commission, *Principled Regulation: Federal Civil and Administrative Penalties in Australia* (Report No 95, 2002) 246, 250; Australian Law Reform Commission, *Interim Report B: Financial Services Legislation* (Report No 139, 2022) 111.

regulated by human tissue laws at all because including it does not meet the objects of the new human tissue legislation.

- Excluded for particular purposes, circumstances, or parts of the primary Act. This exclusion could be placed in delegated legislation. For example, we heard that there is uncertainty over whether cell lines should be excluded from the definition of 'tissue' (or alternative label) so that they are not regulated by human tissue laws at all; excluded from the definition of 'tissue' for specific provisions in the Act, such as those relating to trade; or excluded from the definition of 'tissue' for particular purposes or circumstances, such as for use in research.[37]

4.25 To decide what materials should be excluded from the definition of tissue (or its alternative), we will consider whether:

- regulation of the material aligns with and supports ethical principles and the objects of new human tissue legislation (**Proposal 5**);[38]
- the material would be better regulated by another regime, or if excluding the material from human tissue legislation would cause undesirable gaps in the law (for example, as could occur if posthumous gametes are excluded);
- the exclusion of the material should depend on how it is used, for example for research purposes, or for the purposes of trade;[39] and

4.26 We will also consider any feedback we receive in response to **Questions 5** and **6**, and **Proposals 7**, **8**, and **9**.

4.27 We have heard there is a need to clarify if the materials listed in **Question 7** are regulated by human tissue laws, parts of human tissue laws, or other regulatory regimes.[40] We have received some initial feedback about human milk and posthumous gametes.

Human milk

4.28 In some states and territories, human milk is part of the definition of tissue. In other states and territories, human milk is regulated as food.[41] These differences create additional compliance and administrative costs for organisations that operate nationally.

4.29 We have also heard that human milk could potentially be regulated by the TGA in a similar way to how faecal microbiota transplant products are regulated by the TGA as 'biologicals'.[42]

4.30 Nevertheless, there may still be gaps that human tissue legislation could fill. For example, we are considering whether proposals for consent to donate tissue and the prohibition of trade in tissue should apply to human milk.

Posthumous gametes

4.31 By comparison with other kinds of tissue, gametes raise distinctive ethical and legal issues related to the potential to create life.[43] Some of the HTAs have been interpreted as applying to

37 See, eg, Consortium for Australian Children's Trials in Brain Cancer, *Submission 14*; Children's Medical Research Institute, *Submission 20*.
38 Health Law Group, Monash University, *Submission 67*.
39 See Australian Academy of Health and Medical Sciences, *Submission 87*.
40 See, eg, National Health and Medical Research Council, *Submission 6*; Children's Cancer Institute, *Submission 66*.
41 For example, Queensland made amendments to make it clear that human milk is regulated under its *Food Act 2006* (Qld): Explanatory Notes, Health and Other Legislation Amendment Bill 2021 (Qld) 13. See also A Johnston, *Submission 73*.
42 Department of Health, Disability and Ageing (Cth), *Donor Human Milk Banking in Australia* (Issues and Background Paper, 2014) 10–11. For a description of faecal microbiota transplantation, see: Therapeutic Goods Administration, 'Faecal Microbiota Transplant Products Regulation' (2023) <www.tga.gov.au/products/biologicals-blood-and-tissues-and-advanced-therapies/biologicals/faecal-microbiota-transplant-products-regulation>.
43 Australian Academy of Health and Medical Sciences, *Submission 87*.

situations where a surviving spouse seeks to retrieve gametes from their deceased partner.[44] There is a question about whether the HTAs are the most appropriate regulatory frameworks for this issue. In Queensland, assisted reproductive technology legislation now regulates these situations rather than human tissue legislation.[45]

4.32 Alternatively, the HTAs could be amended to provide specific regulations for posthumous gamete retrieval. A bill that is currently being considered by the parliament of Western Australia would amend the *Human Tissue and Transplant Act 1982* (WA) to allow for retrieval of gametes from a deceased person if consent is obtained from the spouse or de facto partner of the deceased person, or the senior available next of kin. Under the proposed amendments, the gamete may then be transferred to a licensed assisted reproductive technology service for later use.[46]

4.33 There is concern that there will be a legal gap if posthumous gametes are removed from the scope of the new human tissue legislation.[47] We have heard that until a cohesive framework addressing retrieval and use of posthumous gametes is developed, retrieval of posthumous gametes should remain in human tissue legislation.[48]

44 *Noone v Genea Ltd* [2020] NSWSC 1860; *Re H, AE (No 3)* [2013] SASC 196; *P v Melbourne Health* [2019] VSC 500; *GLS v Russell-Weisz* (2018) 52 WAR 413.

45 *Assisted Reproductive Technology Act 2024* (Qld) div 5.

46 Assisted Reproductive Technology and Surrogacy Bill 2025 (WA) cl 326. See also Department of Health for Western Australia, *Submission 23*.

47 C Stern, *Submission 12*; S Page, *Submission 62*; Health Law Group, Monash University, *Submission 67*.

48 We also heard about donation of living gametes and the need for consistent and cohesive laws in this area: M Sharman, *Submission 8*; T Trevor, *Submission 27*; S Page, *Submission 62*.

5. Reforms relating to the determination of death

Contents

New statutory provisions for determining death

Proposal 10

Statutory provisions for determining death should contain the following:

Section X *When death occurs*

1. For the purposes of the law, a person dies when there has been a permanent cessation of the person's critical brain functions, determined in accordance with **section Y**, where 'permanent' means:
   a. that the critical functions of the person's brain cannot resume on their own; and
   a. that the critical functions of the person's brain will not be restored through intervention because:
      i. it is not possible to restore those functions through intervention; or
      ii. intervention would violate a valid end-of-life decision made by or on behalf of the person; or
      iii. intervention or the continuation of intervention would be contrary to accepted medical practice in end-of-life care.

2. In this section-

a cessation of the critical functions of a person's brain requires the complete absence of any form of consciousness (wakefulness and awareness) and brainstem functions, including the ability to breathe independently.

Section Y *Determination of death*

1. A determination that a person has died under **section X** must be made according to accepted medical practice.

2. Regulations may identify professional standards or guidelines for the purpose of determining accepted medical practices under **(1).**

3. To determine the death of a person where the person's respiration is being maintained by artificial means, two registered medical practitioners, one of whom is a specialist and both of whom have been registered medical practitioners for a period of at least five years, must each confirm in writing that they have carried out a clinical examination of the person and, in their opinion, the person has suffered a permanent cessation of the critical functions of the person's brain, within the meaning of **section X**.

New statutory location for the determination of death provisions

Proposal 11

Commonwealth, state and territory legislation should contain a consistent legal standard for determining death, as set out in **Proposal 10**. By an intergovernmental agreement, measures should be put in place to maintain consistency of this definition over time.

Consequences of a determination of death provision that applies for all purposes

Question 8

If the proposed determination of death provisions apply for all purposes rather than only for the purpose of human tissue laws, will there be any adverse and unintended consequences in areas of law other than human tissue laws?

We note that with the exception of Queensland, current state and territory legislative provisions relating to the determination of death apply for all purposes rather than only for the purpose of human tissue laws.

Maintaining national consistency

Question 9

To maintain national consistency, which of the following statutory locations or approaches would be most appropriate for provisions relating to the determination of death, assuming that these provisions apply for all purposes?

a. A 'Uniform Death Act', adopted as national uniform legislation in each state and territory; or

b. New human tissue legislation (**Proposal 1**); or

c. Each state and territory decide where to locate the determination of death provisions but make an intergovernmental agreement that there be a consistent approach to future amendments to these provisions.

Post-mortem interventions

Proposal 12

The following provision should be included in new human tissue legislation:

When tissue will be removed for the purpose of transplantation into the body of another person or for other medical, educational or scientific purposes, any post-mortem interventions must be conducted in accordance with accepted medical practice.

For the purpose of determining accepted medical practice, regulations can specify professional standards or guidelines to be complied with.

The Dead Donor Rule

Proposal 13

New human tissue legislation should include provisions that provide safeguards to ensure deceased donation only proceeds after it has been determined that a person has died. These provisions should provide that:

1. Where deceased donation of tissue is occurring for transplantation or other medical, educational or scientific purposes, tissue cannot be removed from the body until there has been a confirmation of death in accordance with this section.
2. Where a deceased person's respiration is being maintained by artificial means:
    a. the confirmation of death requirements under **section Y(3)** must be met; and
    b. neither medical practitioner confirming death can be involved in or responsible for:
        i. the removal of tissue or medical care of a recipient of the removed tissue, or
        ii. any medical, educational or scientific use of the removed tissue.
3. Where the deceased person's respiration is not being maintained by artificial means:
    a. a registered medical practitioner must confirm in writing that they have carried out a clinical examination of the person and, in their opinion, there has been a permanent cessation of the critical functions of the person's brain, within the meaning of **section X**; and
    b. the medical practitioner confirming death cannot be involved in or responsible for:
        i. the removal of tissue or medical care of a recipient of the removed tissue, or
        ii. any medical, educational or scientific use of the removed tissue.

The problems we are addressing

5.1 Current provisions for determining death are unclear, not in line with contemporary medical practice, and have not kept up with changing technology.

5.2 Current provisions for determining death, and the statutory location of the provisions, are also inconsistent:

- in most states and in the territories the provisions are in HTAs, but in South Australia and Western Australia they are in other legislation;[1]
- in Queensland, the provisions apply specifically to deceased organ and tissue donation,[2] while in other states and territories they apply to all contexts;[3] and
- the provisions include different safeguards. For determinations of death based on a lack of brain function (known as 'neurological determinations'), two medical practitioners must

1 *Death (Definition) Act 1983* (SA); *Interpretation Act 1984* (WA) s 13C. There is also a definition of death in: *Criminal Code Act 1995* (Cth) dictionary (definition of 'death'). This provision was added to the *Criminal Code Act 1995* (Cth) by the *Criminal Code Amendment (United Nations and Associated Personnel) Act 2000* (Cth).

2 *Transplantation and Anatomy Act 1979* (Qld) s 45.

3 *Transplantation and Anatomy Act 1978* (ACT) s 45; *Human Tissue Act 1983* (NSW) s 33; *Transplantation and Anatomy Act 1979* (NT) s 23; *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.

independently determine death. But the states and territories have varying requirements about if the medical practitioners responsible for determining if a person has died are prohibited from being involved in tissue donation or transplantation, and if at least one of the two must be a specialist. For circulatory determinations of death, based on cessation of blood circulation, Victoria imposes a requirement that before tissue donation can occur, a medical practitioner must certify in writing that, in the medical practitioner's opinion, the person has died.[4] This requirement does not apply anywhere else.

Background to the problems

Why it is important to have a law for determining death

5.3 The 'dead donor rule' is a foundational ethical principle. It means that if a person or their authorised decision-maker consents to donate tissue after the person dies, it is important that the tissue is not removed when the person is still alive. The NHMRC states that one

> of the most important ethical norms in donation and transplantation is the requirement that organs or tissues should not be removed from a person for the purpose of transplantation if their removal is expected to result in the death of the donor. That is, donation should not cause the death of the donor; donation should only take place after the donor has died.[5]

5.4 However, because death is a process rather than a singular event, deciding whether death has occurred is not straightforward. Before our 1977 inquiry into human tissue laws, deceased organ donation generally had to occur after what was known as 'brain death' — death determined by the absence of brain function. At the time, there was no legislation providing how death should be determined. Brain death was still a relatively new concept, and it was unclear whether people who had irreversibly lost all brain function were legally dead.

5.5 The HTAs include provisions setting out when death occurs with reference to 'irreversible cessation' of either 'all function of the brain' or of the 'circulation of blood' in a person's body.[6] The introduction of these laws provided legal confirmation that the removal of organs from brain dead donors did not violate the dead donor rule, and transplant surgeons were given legal certainty that they were not committing homicide by removing organs from brain dead donors.

5.6 There are reasons beyond organ and tissue donation for having a legal standard for determining death. The legal status of a person changes depending on if they are alive or dead. For example, the time of death in accordance with the legal determination has implications for estate law, criminal law, and medical law. The inclusion of provisions in the original HTAs setting out criteria for the determination of death was a response to the need for legal clarity about whether organ removal from a brain dead person was consistent with the dead donor rule.[7] But the intention behind the original legal standard was for it to apply in all contexts, not just for the purposes of organ donation.[8]

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4 *Human Tissue Act 1982* (Vic) s 26(7).

5 National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 200.

6 In some jurisdictions, the parts of the Acts explaining when death occurs are titled 'Definition of death', but it is more accurate to describe these laws as setting a legal standard for the determination of death: *Human Tissue Act 1983* (NSW) s 33; *Transplantation and Anatomy Act 1979* (NT) s 23; *Interpretation Act 1984* (WA) s 13C. *Transplantation and Anatomy Act 1978* (ACT) s 45; *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.

7 Cameron Stewart, George Skowronski and Ian Kerridge, 'Debates about Death Definitions: Six Truths We Need to Accept' (2025) 32(2) *Journal of Law and Medicine* 298, 303.

8 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 63.

The best statutory location for determination of death provisions

5.7 Western Australia and South Australia took a long time to legislate provisions for determining death. This was because of debate about the appropriate place to locate a standard for determining death that applies to all areas of law. Ultimately, Western Australia and South Australia introduced statutory provisions for determining death that are located outside their HTAs.[9]

5.8 In their submission in response to our *Issues Paper*, the Australian and New Zealand Intensive Care Society's Death and Organ Donation Committee recommended that:

> the definition of death be in an Act separate from the jurisdictional HTAs in order to signify that the necessity for a definition of death is not linked to organ and tissue donation.[10]

5.9 The Society also suggested that this Act be a single national law to ensure the determination is uniform across Australia.[11] We have heard similar views in our consultations with the medical profession that new provisions could be implemented inconsistently across Australia if left to the states and territories, with negative consequences for medical practice and deceased organ and tissue donation.

Difficulty applying the current provisions

5.10 As noted earlier, the HTAs include provisions setting out when death occurs with reference to 'irreversible cessation' of either 'all function of the brain' or of the 'circulation of blood' in a person's body.[12] The term, 'irreversible', is not defined in the HTAs. The dictionary definition of 'irreversible' is 'cannot be reversed'.[13] Problems have arisen in applying both the neurological and the circulatory branches of the legal test for determining when a person has died.

Difficulty applying the provisions relating to neurological determinations of death

5.11 For neurological determinations of death, death is based on the 'irreversible cessation' of 'all function of the brain of the person'. The approach for determining death in Australian legislation differs from the common law approach, which requires a person's 'brainstem' to stop functioning.[14] There are different justifications for using brain death to determine that a person has died, and different views about the best criteria for establishing brain death. The following discussion briefly explains some of these issues.

5.12 It is generally accepted that death of an organism (human or animal) does not require that each individual cell within the body die, as some biological activities continue in tissues and cells for some time after death. The difficult question is determining when the 'organism as a whole' can be regarded as dead despite this ongoing activity.[15] This question is important in brain death,

9 *Death (Definition) Act 1983* (SA); *Interpretation Act 1984* (WA) s 13C. Legislated criteria for determining death are widely considered to provide more certainty than a common law standard, and are preferred for that reason: see, eg, Australian and New Zealand Intensive Care Society, Death and Organ Donation Committee, *Submission 93*; Australian Law Reform Commission (n 8) 59–60; Law Reform Commission of Western Australia, *Medical Treatment for the Dying* (Report, Project 84, 1991) 31; Russell Gordon Smith, 'Refining the Definition of Death for Australian Legislation' (1983) 14(2) *Melbourne University Law Review* 199, 237.

10 Australian and New Zealand Intensive Care Society, Death and Organ Donation Committee, *Submission 93*.

11 Ibid.

12 The parts of the Acts explaining when death occurs are titled, 'Definition of death', but it is more accurate to describe these laws as setting a legal standard for the determination of death. The provisions have minor differences in wording or structure, but in substance their meaning is the same: *Human Tissue Act 1983* (NSW) s 33; *Transplantation and Anatomy Act 1979* (NT) s 23; *Interpretation Act 1984* (WA) s 13C. *Transplantation and Anatomy Act 1978* (ACT) s 45; *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. The *Criminal Code Act 1995* (Cth) defines 'death' using the same wording as the HTAs, except that it specifies that 'all function of a person's brain' includes the brain stem: *Criminal Code Act 1995* (Cth) Dictionary.

13 *Macquarie Dictionary* (online at 20 Sept 2025) 'irreversible'.

14 For a discussion of the common law definition, see Andrew McGee and Dale Gardiner, 'Differences in the Definition of Brain Death and Their Legal Impact on Intensive Care Practice' (2019) 74(5) *Anaesthesia* 569.

15 The President's Council on Bioethics, *Controversies in the Determination of Death* (2008) 59.

as the biological functions of respiration and blood circulation — which were once thought crucial for life — can be supported to continue with the use of technology, despite the absence of brain function.

5.13 For a long time, the key conceptual justification for using brain death to determine that a person has died was that the brain is central to the integrated functioning of the organism as a whole.[16] On this view, it should not matter that biological activity continues in individual cells or tissues, so long as they are not functioning in an 'integrated' way. It was thought that the brain played a crucial role in integrating bodily functions, and death of the brain could therefore justify a conclusion that the organism as a whole had died, given integrated functioning was no longer possible.[17] In other words, without brain function, 'there is only a mere collection of parts, and not an organism'.[18]

5.14 However, this view is no longer widely held. It has become clear that 'the organism' remains capable of integrated functioning without the brain to orchestrate it.[19] For example, when respiration, hydration, and nutrition are maintained using technology, parts of the body can work together to 'fight infection, heal wounds, and maintain temperature' without brain function to coordinate them.[20]

5.15 An alternative justification for using the cessation of brain function to establish that the organism as a whole has died was advanced by the United States President's Council on Bioethics. The Council suggested that consciousness and the ability to breathe independently are the key indicators that a person has died because consciousness and independent breathing are the 'fundamental vital *work* of a living organism'.[21] Vital work was understood to be 'the work of self-preservation, achieved through the organism's need-driven commerce with the surrounding world'. [22]

5.16 The focus on consciousness and the ability to breathe independently have since been adopted in international clinical guidelines for determining death (discussed further below). While most experts accept the clinical criteria for determining brain death,[23] there are some who assert that death of the brain does not mean that it is appropriate to conclude that the organism as a whole has died.[24] The prioritisation of consciousness and the ability to breathe independently over other functions compatible with life has been criticised as lacking justification,[25] with the prioritisation of breathing described as 'arbitrary and ad-hoc'.[26]

5.17 Other approaches and points of view that maintain that brain death can be understood as death of the whole organism include that:

16 Alan Shewmon, 'Brain Death: Can It Be Resuscitated?' (2009) 39(2) *Hastings Center Report* 18, 18–19.
17 Ibid; The President's Council on Bioethics (n 15) 59–60.
18 Ari Joffe, Gurpreet Khaira and Allan de Caen, 'The Intractable Problems with Brain Death and Possible Solutions' (2021) 16(1) *Philosophy, Ethics, and Humanities in Medicine* 11, 2.
19 Shewmon (n 16) 19; Andrew McGee, Dale Gardiner and Melanie Jansen, 'A New Defence of Brain Death as the Death of the Human Organism' (2023) 48(5) *The Journal of Medicine and Philosophy* 434, 439.
20 The President's Council on Bioethics (n 15) 60. See also Joffe, Khaira and de Caen (n 18) 2.
21 The President's Council on Bioethics (n 15) 60–5.
22 Ibid 60.
23 A scoping review of healthcare professionals' understanding of the determination of death found that, although there are variable levels of knowledge about brain death, most physicians feel confident diagnosing brain death. Controversies surrounding brain death were found to be more prevalent in the literature than clinical practice: Katina Zheng et al, 'Healthcare Professionals' Understandings of the Definition and Determination of Death: A Scoping Review' (2022) 8(4) *Transplantation Direct* 1, 9. There are also recommendations on the clinical determination of brain death from the World Brain Death project which 'have widespread international society endorsement': David Greer et al, 'Determination of Brain Death/Death by Neurologic Criteria: The World Brain Death Project' (2020) 324(11) *JAMA* 1078, 1093.
24 Shewmon (n 16); Joffe, Khaira and de Caen (n 18).
25 Shewmon (n 16) 20.
26 Joffe, Khaira and de Caen (n 18) 7.

- People who have been determined to be 'brain dead' do not fit into traditional concepts of life or death, and therefore a decision must be made as to whether the definition of 'life' or the definition of 'death' should be expanded to accommodate them.
- By treating people who are brain dead as 'dead', it becomes necessary to prioritise which biological functions are more important than others, and then decide where to draw the line separating the living from the dead.
- In this respect, the ability to breathe on one's own is justified as a function that must be lost (jointly with conscious awareness and wakefulness) to regard a person as dead. This is because, although the mechanics of respiration can be replaced by machines, the innate *feeling* of the need to breathe cannot. This subjective experience of *feeling* a need to breathe is a rudimentary form of consciousness that should be absent before anyone can be regarded as dead.
- The absence of consciousness more broadly is a justifiable criterion for concluding that a person has died because this is ultimately what matters to most people, and subjectively, as soon as *my* consciousness permanently ceases, *I* no longer exist.
- The absence of consciousness is a justifiable criterion for determining the biological death of the *organism* because consciousness is a biological phenomenon.[27]

5.18 International clinical guidelines have since been developed that use the criteria of absence of consciousness and absence of brainstem function (which includes the ability to breathe independently) to determine death. These include:

- international consensus guidelines developed in consultation with the World Health Organisation (WHO), which define death as 'the permanent loss of capacity for consciousness and all brainstem functions';[28] and
- the World Brain Death Project, which explains brain death as 'the complete and permanent loss of brain function as defined by an unresponsive coma with loss of capacity for consciousness, brainstem reflexes, and the ability to breathe independently'.[29]

5.19 An approach that specifies the critical functions of the brain that must be lost, such as consciousness and the ability to breathe independently, may be preferable to the current reliance in the HTAs on loss of 'all' function of the brain. This is because, in addition to the arguments regarding the centrality of consciousness outlined above:

- clinical guidelines for determining brain death generally allow for some continued neuroendocrine function (which has no impact on consciousness);
- most practicing doctors view residual neuroendocrine functions as irrelevant to determining death, given that they have no impact on consciousness;[30] and
- we have heard that the imaging studies required to prove infarction, or death of tissue, from a lack of blood flow to the entire brain:
    - are not practical in all hospital settings;
    - can be burdensome to families and hospitals; and
    - are not required in most situations by international standards.

5.20 The World Brain Death Project specifies that '[p]ersistence of cellular-level neuronal and neuroendocrine activity does not preclude the determination [of death]'.[31] American Academy of

27 For a detailed analysis of these arguments, see McGee, Gardiner and Jansen (n 19).
28 Sam Shemie et al, 'International Guideline Development for the Determination of Death' (2014) 40(6) *Intensive Care Medicine* 788, 794.
29 Greer et al (n 23) 1081.
30 Nicholas B Murphy et al, 'Rationale for Revisions to the Definition of Death and Criteria for Its Determination in Canada' (2023) 70(4) *Canadian Journal of Anesthesia/Journal canadien d'anesthésie* 558, 564; Andrew McGee and Dale Gardiner, 'Brainstem Death Is Dead: Long Live Brainstem Death!' (2024) 24(1) *The American Journal of Bioethics* 114, 115.
31 Greer et al (n 23) 1081.

Neurology guidelines say that a patient can meet the criteria for brain death 'despite evidence of neuroendocrine function'.[32] ANZICS guidelines state that someone can be declared dead even if they do not have diabetes insipidus.[33] An absence of diabetes insipidus suggests that the hypothalamus and pituitary, which are parts of the brain, continue to play a role in the neuroendocrine function of the body.[34] But as these functions do not play any role in consciousness or brainstem function, their continuation does not prevent someone from being determined dead under clinical guidelines.

5.21 However, we recognise that any proposal to remove the current legal requirement for a loss of 'all' brain function may cause concern. The Australian Catholics Bishops Conference told us that '[p]ressures to change the way death is determined from the loss of all brain function to the loss of some brain function should be resisted'.[35] The Conference noted that the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia indicates that 'total and irreversible loss of all brain function, accompanied by an evident cause, is … a valid medical criterion for death'.[36]

5.22 Currently in the United States, legislation requires the loss of all brain function for a neurological determination of death.[37] Determinations of death made in accordance with clinical guidelines such as those we have been discussing have given rise to debate about what constitutes a 'function'.[38] This led to concern that people who are not legally dead — because of continued neuroendocrine 'function' — are nevertheless being declared dead in the United States.[39] This demonstrates the importance of consistency between legal and clinical approaches to determining death, and how public trust in clinical practice can be undermined when the two diverge. As the Health Law Group at Monash University points out, aiming for 'consistency between the legal definition of death and clinical definitions of death requires justification in and of itself', given that clinical practice is subject to change.[40]

5.23 Law reform should only seek consistency with clinical guidelines and practice that are based on the best available evidence and have the interests and dignity of the dying person at their core. **Proposal 10** is designed to achieve this consistency with evidence-based clinical guidelines that have the interests and dignity of the dying person at their core by:

- defining critical brain functions broadly to include consciousness with reference to both awareness and wakefulness; and
- requiring an absence of brainstem function, including the ability to breathe independently.

5.24 Together, these requirements represent a conservative standard. Different parts of the brain serve different functions. While the brainstem is generally regarded as 'hous[ing] the seat … of consciousness'[41] by working as 'an on/off switch' for conscious awareness,[42] some have

32 David Greer et al, 'Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Guideline: Report of the AAN Guidelines Subcommittee, AAP, CNS, and SCCM' (2023) 101(24) *Neurology* 1112, 1128.

33 Australian and New Zealand Intensive Care Society, *The Statement on Death and Organ Donation* (4.1 ed, 2021) 19. Diabetes insipidus has been suggested as a marker of the absence of *all* brain function, and hence as necessary for determining that a patient has died if a neurological determination of death requires the absence of any brain function at all: Michael Nair-Collins, 'The Uniform Determination of Death Act Is Not Changing: Will Physicians Continue to Misdiagnose Brain Death?' (2025) 25(9) *The American Journal of Bioethics* 44, 45–6.

34 Nair-Collins (n 33) 45–7. Some have debated whether it is correct to characterise these continued abilities as a 'function' or an 'activity'. For example, some characterise this as an 'activity': Greer et al (n 23) 1080–1. Cf Nair-Collins (n 33) 49.

35 Australian Catholic Bishops Conference, *Submission 79*.

36 Ibid.

37 National Conference of Commissioners on Uniform State Laws, *Uniform Determination of Death Act* (1980) 5.

38 See, eg, Greer et al (n 23) 1080–1; Nair-Collins (n 33) 49.

39 Nair-Collins (n 33).

40 Health Law Group, Monash University, *Submission 67*.

41 James Bernat et al, 'The Concept of Death by Neurologic Criteria/Death by Neurologic Criteria' supplement 3 to David Greer et al, 'Determination of Brain Death/Death by Neurologic Criteria: The World Brain Death Project' (2020) 324(11) *Journal of American Medical Association* 1078.

42 McGee, Gardiner and Jansen (n 19) 447.

expressed a concern that limiting the criteria to only the brainstem may leave open the possibility that 'some form of residual conscious awareness' could persist in rare cases.[43]

5.25 Conversely, a standard that only focuses on the absence of conscious awareness — which is regarded as a 'higher brain' function of the cerebral cortex — rather than the brainstem, is dangerous because:

- it can be difficult to diagnose correctly;
- the division between the roles of the brainstem and cerebral cortex in consciousness may not be entirely clear; and
- a functioning brainstem enables the 'capacity to feel thirst, hunger, and air hunger', which some regard as subjective experiences that reflect a rudimentary form of consciousness.[44]

5.26 **Proposal 10** therefore requires the absence of all forms of consciousness, regardless of where in the brain they originate from,[45] and regardless of whether or not they are rudimentary in nature, for a person to be determined to be dead.

Difficulty applying the provisions relating to circulatory determinations of death

5.27 The problem with linking death to cessation of circulation of blood in a person's body that cannot be reversed is that, with technology, it is possible to recirculate blood in a person's body after their heart has stopped beating, and long after it would be possible to revive them. Some experts suggest that determinations of death should not depend on either a failed attempt at cardiopulmonary resuscitation (CPR) to demonstrate that circulation has been lost irreversibly; or waiting after a person's heart stops beating until it would be impossible to restart blood circulation by any means, which could be several hours with modern technology.[46] Linking death to 'irreversible' loss of blood circulation, or loss of blood circulation that 'cannot be reversed' is out of step with modern medical technology and understandings of death.

5.28 It also causes problems in the context of deceased organ donation. For the following reasons, 'permanent' loss of circulation has emerged as the preferred term to 'irreversible' in clinical practice and ethical guidelines for organ donation.

5.29 For deceased organ donors, the current process for determining death based on cessation of blood circulation involves waiting for five minutes after a person's heart has stopped beating before death is pronounced and organs are removed.[47] Studies of the dying process have shown that 'auto-resuscitation', where a heart that has stopped beating begins beating again on its own, is possible. However, the longest period observed between a heart stopping beating, and starting again on its own, is four minutes and 20 seconds.[48] In all cases, after restarting, the heart soon stopped beating permanently, usually within seconds.[49] By waiting for five minutes after a person's heart has stopped beating to pronounce the person dead and to remove their organs, the current Australian practice makes sure the point has passed beyond which auto-resuscitation has been known to occur.

5.30 Often deceased donation involves a person with a critical illness from which they will not recover where a decision has been made to withdraw life support because continued treatment

43 James Bernat, 'The Whole-Brain Concept of Death Remains Optimum Public Policy' (2006) 34(1) *Journal of Law, Medicine & Ethics* 35, 39; James Bernat et al (n 41).
44 McGee, Gardiner and Jansen (n 19) 447–8.
45 See Ibid 447.
46 Dale Gardiner, Andrew McGee and David Shaw, 'Two Fundamental Ethical and Legal Rules for Deceased Organ Donation' (2021) 21(8) *BJA Education* 292, 295.
47 Organ and Tissue Authority, DonateLife, *Best Practice Guideline for Donation after Circulatory Determination of Death (DCDD) in Australia* (2021) 13.
48 Sonny Dhanani et al, 'Resumption of Cardiac Activity after Withdrawal of Life-Sustaining Measures' (2021) 384(4) *New England Journal of Medicine* 345, 350.
49 Ibid.

is not in their best interests.[50] After life support is removed and the person's heart stops beating, it would be unethical to try to revive the person with CPR or other medical interventions. Instead, they are allowed to die from their injuries or underlying illness. As a result, although it may not be true to say that a lack of circulation of blood in the person's body five minutes after their heart stopped beating is irreversible (as resuscitation efforts could be used to try to restore circulation and technology could be used to recirculate blood in the person's body), the loss of circulation is 'permanent' because a decision has been made not to attempt resuscitation.

5.31 The Australian and New Zealand Intensive Care Society's (ANZICS's) *Statement on Death and Organ Donation,*[51] the NHMRC's ethical guidelines,[52] and OTA's best practice guidelines each explain that the term 'permanent' is preferable by comparison with 'irreversible'.[53] The NHMRC Guidelines explain that irreversible:

> is taken to mean "permanent", with it either being not possible to reverse the absence of the circulation or understood that no attempt will be made to reverse it.[54]

5.32 OTA explains that 'permanent' in this context 'mean[s] that the circulation will not resume spontaneously and there will be no attempt to restore it through intervention'.[55]

Applying the 'unified brain-based approach' to determining death

5.33 Our original report on human tissue laws was published in 1977. In 1980, the National Conference of Commissioners on Uniform State Laws in the United States published a model law: the *Uniform Determination of Death Act*.[56] The approach we recommended, and which was adopted in the HTAs and the approach taken in the United States, are similar in that both have two distinct criteria for determining death: one based on brain function, and one based on circulation (and in the United States, also on respiration).

5.34 Criticism of this approach followed soon after its introduction in the United States.[57] The problem with having two different criteria, and no explanation of how they are intended to relate to one another, is that it gives the impression that there are 'two recognized types of death':[58] circulatory death and brain death.

5.35 However, as we explained in our 1977 report, 'brain death' was a relatively new concept at the time, and there was a need to provide clarity for medical practitioners that this was a legally valid basis for determining death.[59] The prefatory note to the Uniform Determination of Death Act explains that the purpose of the circulatory branch of the provision was to 'codif[y] the existing common law basis for determining death – total failure of the cardiorespiratory system', while the brain function branch 'extend[ed] the common law to include the new procedures for determination of death based upon irreversible loss of all brain functions'.[60]

5.36 Brain death was regarded as something exceptional, and as supplementing existing criteria for determining death, which at the time in the United States were based on circulatory function (the ability to circulate blood), and respiratory function (the ability to breath).

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50 Australian and New Zealand Intensive Care Society (n 33) 34.
51 Ibid 12.
52 National Health and Medical Research Council (n 5) 18.
53 Organ and Tissue Authority, DonateLife (n 47) 13.
54 National Health and Medical Research Council (n 5) 18.
55 Organ and Tissue Authority, DonateLife (n 47) 13; Australian and New Zealand Intensive Care Society (n 33) 23.
56 National Conference of Commissioners on Uniform State Laws, *Uniform Determination of Death Act* (1980).
57 James Bernat, 'Challenges to Brain Death in Revising the Uniform Determination of Death Act' (2023) 101(1) *Neurology* 30, 32.
58 Murphy et al (n 30) 562.
59 Australian Law Reform Commission (n 8) 53–63.
60 National Conference of Commissioners on Uniform State Laws, *Uniform Determination of Death Act* (1980) 3.

5.37 An alternative approach — known as the 'unified brain-based approach' — is to understand all death as 'brain-based'. According to this view, the reason we should care about a lack of blood circulation is because it means that blood has stopped flowing to the brain, which causes the brain to stop functioning, resulting in death.

5.38 A 1981 report of the Law Reform Commission of Canada recommended a unified brain-based approach. The Canadian model law stated that '[a] person is dead when an irreversible cessation of all that person's brain functions has occurred'.[61] It provided that this could be determined either by:

- 'the prolonged absence of spontaneous cardiac and respiration functions'; or
- 'any means recognized by the ordinary standards of current medical practice' in situations where cardiac and respiratory functions are being maintained by artificial support.[62]

5.39 This example shows that a unified brain-based approach still allows for different ways to assess if someone has died — either by examining their brain function or by a prolonged period without heart function. Both methods aim to establish if the relevant functions of the person's brain have stopped. An absence of blood circulation to determine an absence of brain function is justified because if no blood is circulating in the brain, this 'triggers a physiologic cascade: cessation of brain perfusion leading to cessation of brain neuronal activity leading to cessation of brain function'.[63]

5.40 The Law Reform Commission of Canada's recommendation was for the federal government to enact the model law into federal legislation of general application.[64] While this recommendation was not implemented, the idea of a single brain-based criterion for determining death has had a resurgence. Participants in a 2014 international consensus forum held in consultation with the WHO agreed that '[d]eath is the permanent loss of capacity for consciousness and all brainstem functions' which can result from lost circulation or catastrophic brain injury.[65]

5.41 Canadian clinical practice guidelines now reflect a uniform brain-based approach.[66] A submission we received from the ANZICS Death and Organ Donation Committee supports this approach, noting that '[i]nternational consensus now favours a unified definition of death based on the principle that a person dies only when the brain has ceased to function permanently'.[67] And the uniform brain-based approach is being discussed extensively in relation to normothermic reginal perfusion (NRP).[68]

Normothermic regional perfusion (NRP)

5.42 NRP is a technique used in the removal of organs from donors after death who do not meet the test for 'brain death'. In jurisdictions that use NRP, doctors wait for five minutes after a donor's heart stops beating before recirculating blood in the donor's body using 'ECMO', or 'extracorporeal membrane oxygenation' technology. ECMO can help repair organs before they are removed, so they will work better when transplanted into the body of the recipient. The term, 'normothermic

61 Law Reform Commission of Canada, *Criteria for the Determination of Death* (No Report 15, 1981) 15.
62 Ibid.
63 James L Bernat et al, 'Understanding the Brain-Based Determination of Death When Organ Recovery Is Performed With DCDD In Situ Normothermic Regional Perfusion' (2023) 107(8) *Transplantation* 1650, 1651.
64 Law Reform Commission of Canada (n 61) 24–5.
65 Shemie et al (n 28) 794.
66 Sam Shemie et al, 'A Brain-Based Definition of Death and Criteria for Its Determination after Arrest of Circulation or Neurologic Function in Canada: A 2023 Clinical Practice Guideline' (2023) 70(4) *Canadian Journal of Anesthesia* 483, 484.
67 Australian and New Zealand Intensive Care Society, Death and Organ Donation Committee, *Submission 93*.
68 Bernat et al (n 63); James Bernat, 'The Unified Brain-Based Determination of Death Conceptually Justifies Death Determination in DCDD and NRP Protocols' (2024) 24(6) *The American Journal of Bioethics* 4; L Syd M Johnson, '"Time Is Brain": DCDD-NRP Invalidates the Unified Brain-Based Determination of Death' (2024) 24(6) *The American Journal of Bioethics* 84; David Rodríguez-Arias and Anne Dalle Ave, 'The Unified Brain-Based Determination of Death: Conceptual Challenges' (2024) 24(6) *The American Journal of Bioethics* 57.

regional perfusion', refers to how blood is circulated at body temperature (normothermic), in particular regions of the body that exclude the brain, to 'perfuse' organs (bringing organs oxygen-rich blood) while they remain in the body.

5.43 There are two different types of NRP:

- abdominal NRP (A-NRP) — where blood is circulated to the abdominal organs such as the kidney, liver, and pancreas; and
- thoracoabdominal NRP (TA-NRP) — where blood is also circulated to the heart and lungs.

5.44 NRP is practiced in many countries in Europe, the United States,[69] and will commence in New Zealand in 2026.[70] It is not practiced in Australia because of concerns that NRP is contrary to the current legal provisions for determining death.[71]

5.45 To comply with the dead donor rule, organs may only be removed after death. If a person does not meet the criteria for brain death, the current law requires 'irreversible cessation of circulation of blood in the body of the person' for a person to be determined dead. NRP is problematic because blood needs to be recirculated in the body of the person.

5.46 We have heard from many stakeholders that there are benefits to NRP that are not available in Australia because of our current approach to determining death, including:

- 'NRP is a transformative technology that improves transplant outcomes, reduces healthcare costs, and increases donor organ utilisation',[72] 'enabling donors and their families to realise their altruistic intent while supporting improved outcomes for recipients and delivering broader health system benefits'.[73]
- NRP could be particularly useful in treating children with organ failure, providing 'increased access … [to] better-quality donor organs' with 'the potential to save the lives of Australian Children requiring a kidney (and/or liver) transplant'.[74]
- NRP has the potential to help Australian diabetics by enabling more kidney-pancreas transplants to address the underlying cause of kidney failure in diabetes patients.
- 'Australia's current legal restrictions on NRP are out of step with international practice', making Australia 'an outlier among developed nations in prohibiting this evidence-based, ethically applied practice'.[75]
- Deceased donation can sometimes be distressing for healthcare staff,[76] and NRP helps to reduce this harm by easing the high stress and time pressured environment in which donation often occurs.
- Australian researchers are not able to collaborate internationally on many deceased donation research projects because our donation protocols have fallen behind.

5.47 We have also heard that any change to the legal determination of death needs to be navigated with public trust in mind, and that the introduction of NRP might be good for some organs like the kidney and liver.[77] But NRP would need careful implementation to ensure that

69 Mario Royo-Villanova et al, 'Normothermic Regional Perfusion in Controlled Donation After the Circulatory Determination of Death: Understanding Where the Benefit Lies' (2025) 109(3) *Transplantation* 428, 429.
70 Louise Barbier, 'Normothermic Regional Perfusion: Implementation in New Zealand' (Speech, The Transplantation Society of Australia and New Zealand, 43rd Annual Scientific Meeting, 24 June 2025).
71 National Health and Medical Research Council (n 5) 215.
72 Liver and Intestinal Transplant Advisory Committee of TSANZ, *Submission 37*.
73 Australian Centre for Transplantation Excellence and Research, *Submission 65*.
74 Paediatric Transplant Advisory Committee of TSANZ, *Submission 38*.
75 Liver and Intestinal Transplant Advisory Committee of TSANZ, *Submission 37*.
76 Australian and New Zealand Intensive Care Society (n 33) 53.
77 Transplantation Society of Australia and New Zealand, *Submission 35*; Lung Transplant Advisory Committee of TSANZ, *Submission 36*.

kidney and liver donation is not prioritised at the expense of other organs, such as the heart and lungs.[78]

5.48 As discussed above, a unified brain-based approach to determining death focuses on the function of the brain as key to determining if someone has died. During NRP, it is important that the recirculation of blood does not reach the brain to prevent the 'potential for brain reanimation'.[79] Scientific understanding of how much blood flow is needed to generate brain function,[80] or how long the brain must go without blood flow before it is unable to regain function, is limited.[81] For this reason, various techniques are used to prevent blood flow to the brain, such as blocking vessels (using a balloon or clamp),[82] monitoring blood flow, 'venting' vessels by exposing them to the air so blood flows out of the body rather than to the brain, and using imaging to detect if a person has unusual vessels that might otherwise be missed.[83]

5.49 The legality and ethics of NRP have been debated.[84] Some points of debate include questions about whether NRP invalidates legal requirements for death, whether a donor is 'resuscitated' when NRP restores circulation or heart function (in TA-NRP), and whether NRP causes death by ensuring the lost brain function remains permanent.[85] The need to maintain public trust is often raised in this debate and there is broad agreement that ensuring the safety of NRP donors is important.[86] In this respect, there are recent studies that have examined the effect of NRP on the brain.

5.50 One study examined blood pressure at the base of the brain in deceased donors where NRP was used in organ removal and found that the blood pressure did not change after NRP began. This showed that the brain was not being 'perfused' during NRP.[87] Recent research using modern imaging techniques also found that NRP did not restore blood flow to the brain.[88] While these studies involved small sample sizes, they demonstrate the possibility of performing NRP without restoring blood flow to the brain.

78 Cardiac Transplant Advisory Committee of TSANZ, *Submission 30*; Transplantation Society of Australia and New Zealand, *Submission 35*; Lung Transplant Advisory Committee of TSANZ, *Submission 36*.

79 Mary Ott et al, 'Sowing "Seeds of Trust": How Trust in Normothermic Regional Perfusion Is Built in a Continuum of Care' (2024) 24(11) *American Journal of Transplantation* 2045, 2046.

80 Guillaume Maitre et al, 'Knowledge Gaps in the Definition and Determination of Death' (2023) 70(4) *Canadian Journal of Anesthesia/Journal canadien d'anesthésie* 610, 612; Bernat et al (n 63) 1652.

81 Sam Shemie and Dale Gardiner, 'Circulatory Arrest, Brain Arrest and Death Determination' (2018) 5 *Frontiers in Cardiovascular Medicine* 1, 4.

82 Royo-Villanova et al, 'Normothermic Regional Perfusion in Controlled Donation After the Circulatory Determination of Death: Understanding Where the Benefit Lies' (n 69) 430.

83 Sam Shemie and Christopher Watson, 'Normothermic Regional Perfusion in Donation after Circulatory Determination of Death: Confirming the Absence of Brain Reperfusion' (2025) 25(8) *American Journal of Transplantation* 1596, 1597.

84 See Symposium, 'Normothermic Regional Perfusion' (2024) 24(6) *American Journal of Bioethics* 1.

85 Nicholas B Murphy et al, 'Ethical Issues in Normothermic Regional Perfusion in Controlled Organ Donation After Determination of Death by Circulatory Criteria: A Scoping Review' (2025) 109(4) *Transplantation* 597, 603.

86 Ibid 604–5; Ott et al (n 79) 2051.

87 Mario Royo-Villanova et al, 'Maintaining the Permanence Principle of Death during Normothermic Regional Perfusion in Controlled Donation after the Circulatory Determination of Death: Results of a Prospective Clinical Study' (2024) 24(2) *American Journal of Transplantation* 213, 219.

88 Mario Royo-Villanova et al, 'A Scintigraphic Look at the Dead Donor Rule in Donation after the Circulatory Determination of Death with the Use of Normothermic Regional Perfusion: A Single-Center Interventional Trial' (2025) 25(8) *American Journal of Transplantation* 1670; Jennifer Frontera et al, 'Thoracoabdominal Normothermic Regional Perfusion in Donation after Circulatory Death Does Not Restore Brain Blood Flow' (2023) 42(9) *The Journal of Heart and Lung Transplantation* 1161.

How our reform proposals could solve the problems

Creating a clearer standard for determining death

5.51 **Proposal 10** provides a unified brain-based approach to the determination of death. This aligns with growing international consensus that death is 'brain-based'[89] and could help clarify misconceptions that there are different 'types' of death.

5.52 This approach also overcomes the problem with circulatory determinations of death requiring irreversible cessation of blood circulation in a person's body. Under **Proposal 10**, the ability to intervene to recirculate blood in a person's body would no longer be relevant to determining death once critical brain functions have been permanently lost.

5.53 'Permanent' is defined to mean that a person's critical brain function either cannot or will not be restored because the person is beyond the point where auto-resuscitation is possible, and:

- any attempt to restore function would violate a valid end-of-life decision made by, or on behalf of, the person; or
- it would otherwise be contrary to accepted medical practice in end-of-life care.

5.54 Situations where critical brain function cannot be restored include situations where it is obvious that critical brain functions cannot be restored, such as a body with signs of rigor mortis, which is the stiffening that occurs after death; or where unsuccessful attempts have been made to restore brain function, for example, by using CPR on a person whose heart has stopped beating.

5.55 Situations where a person's critical brain function will not be restored include circumstances where it would not be ethical to try to restore a person's lost brain function. These include situations of voluntary assisted dying; where there is a planned withdrawal of life-sustaining treatment; where an advance care directive refuses lifesaving interventions; where interventions would violate a resuscitation plan or goals of care for a patient; or where starting or continuing lifesaving measures will not benefit the person or otherwise be inconsistent with accepted standards for end-of-life care.[90]

5.56 In these circumstances, it is not necessary to wait until the point at which it would become physically impossible to restore function. Such a point is imprecise, and impossible to predict for any given person. Instead, death can be determined at the point where auto-resuscitation is no longer possible. This is the point at which function cannot be restored without intervention. Because a decision has been made not to intervene, at that point, the absence of critical brain function becomes permanent.

5.57 We considered using the following recommendations from a submission by the ANZICS Death and Organ Donation Committee:

> A person has died when there is permanent cessation of the critical functions of a person's brain, including the brainstem.
>
> This can result from devastating brain injury or from cessation of blood circulation in the brain after circulatory arrest.
>
> The determination of death must be made according to accepted medical standards.

89 Shemie et al (n 28) 794–5; Shemie and Gardiner (n 81) 2.

90 See generally Australian and New Zealand Intensive Care Society, *ANZICS Statement on Care and Decision-Making at the End of Life for the Critically Ill* (ANZICS, 2014) for a discussion of the situations in which it is appropriate to withdraw or withhold treatment.

> Critical functions of a person's brain include the complete absence of any form of consciousness (wakefulness and awareness) and the absence of brainstem function, including the ability to breathe independently.[91]

5.58 The submission also defines permanent to mean 'will not resume spontaneously and will not be restored through intervention'.[92]

5.59 At this stage of our Inquiry, we agree with the substance of this submission. **Proposal 10** and the ANZICS proposal both:

- use a unified brain-based approach;
- use similar definitions of 'permanent';
- use a threshold of 'critical' brain function; and
- require death to be determined in accordance with accepted medical standards.

5.60 **Proposal 10** does not include a provision stating that a devastating brain injury or cessation of blood circulation can cause the required lack of critical brain function. While we agree that this is true, **Proposal 10** requires that death be determined in accordance with accepted medical practice, which allows death to be determined by assessing a lack of circulation or a lack of neurological function from a devastating brain injury.[93] In our view, reference to possible causes does not add meaning to the other provisions. However, we recognise the likely purpose of this statement is to clarify that there are still two methods for determining whether death has occurred. Whether this information should be conveyed as a legislative provision, a legislative note, or in the explanatory memorandum is an issue we are considering.

5.61 **Proposal 10** enables guidelines, such as the ANZICS *Brain Death Determination Statement* or *Statement on Death and Organ Donation* to be designated in regulations to set a standard of accepted medical practice.[94] As medical knowledge and technology develop, the specific methods or tests that should be used in particular contexts to determine death will change over time. This approach avoids specifying these tests in legislation (which is difficult to change) but gives added weight and authority to clinical guidelines developed by medical experts. We also received a suggestion that 'permanent' should be understood to mean 'lasting or intended to last indefinitely; remaining unchanged', which is how the dictionary defines 'permanent'.[95]

5.62 When a valid decision has been made not to attempt to restore brain function, the lost function is 'intended to last' indefinitely. Once auto-resuscitation is no longer possible, there is a strong likelihood that the lost function would be indefinite without any intervention. However, by adding the requirement of 'intention' to the understanding of 'permanent', it is not clear whose intention is relevant.

5.63 Depending on the circumstances, any number of people might intend for the absence of critical brain function to continue. The person, themselves; their surrogate decision-maker; their treatment team; and/or the person making a declaration of death all might have this intention. Given that the person or people needing to have the required 'intention' will change depending on the circumstances, it is our view that referring to the circumstances, rather than the mental state giving rise to them, is clearer and more easily implemented. For this reason, **Proposal 10** refers to circumstances where intervention would be contrary to accepted practice in end-of-life

91 Australian and New Zealand Intensive Care Society, Death and Organ Donation Committee, *Submission 93*.
92 Ibid.
93 For a description on the different approaches to determining death in these two contexts, see generally Australian and New Zealand Intensive Care Society, 'The Statement on Death and Organ Donation' (n 33).
94 Australian and New Zealand Intensive Care Society, 'Brain Death Determination Statement' <www.anzics.org/death-and-organ-donation/>; Australian and New Zealand Intensive Care Society, 'The Statement on Death and Organ Donation' (n 33).
95 *Macquarie Dictionary* (online at 19 September 2025) 'permanent'.

care or situations where a valid decision has been made against intervention as the relevant circumstances for determining whether the lack of critical brain function is permanent.

Specifying the functions needed to be lost for death to be determined

5.64 **Proposal 10** changes the requirement from loss of 'all' brain function to a loss of 'critical' brain function. We then specify that a loss of 'critical functions' requires the complete absence of consciousness and brainstem functions, including the ability to breathe independently. This change reflects international consensus guidelines, aligns with Australian clinical practice guidelines, is supported by the ANZICS Death and Organ Donation Committee, and is generally consistent with the common law approach to determining death that focuses on brainstem function.

5.65 When determining the death of a person whose circulation or respiration is being maintained through artificial means (people who have traditionally been thought of as 'brain dead'), **Proposal 10** includes a recommendation that the determination of death must be certified by two senior doctors, one of whom must be a specialist. In these circumstances, a high degree of skill and training is required to correctly apply and interpret the necessary tests to determine whether critical brain function has been lost. We note that there may be some concern about changing the required brain function that must be lost for the determination of death. However, we have recommended these safeguards in order to maintain public trust and to help ensure that the loss of 'critical' brain functions is accurately assessed.

Allowing for NRP to develop in Australia

5.66 Implementing **Proposal 10** for the legal determination of death may open the door for the practice of NRP.[96] There are potential benefits of NRP and growing evidence of the safety of NRP as well as international acceptance of NRP. These factors mean that NRP should not be legally prohibited despite the continued ethical concerns. Instead, protocols for use of NRP in Australia should be developed to ensure it can be practiced safely and ethically. This should happen in conjunction with, and informed by, public engagement to make sure that the use of NRP has public support, and does not compromise public trust, or heart or lung donation rates.

5.67 We have recommended in **Proposal 12** that any post-mortem interventions (such as NRP) be done in accordance with accepted medical practice, with clinical guidelines specified in regulations to help define what accepted medical practices are. The development of ethically robust protocols for NRP, and their designation in regulations, will help to facilitate high standards of practice for a consistent and transparent approach to NRP.

Protecting the dead donor rule through consistent safeguards

5.68 **Proposal 13** reflects the dead donor rule, which requires that death occur before organs are removed. The proposal requires that death be confirmed by medical practitioners who are not involved in, or responsible for, the removal or use of tissue. This addresses the risk of a conflict of interest, which could arise if a doctor responsible for determining death is also treating a potential recipient of donated organs, or wanting to use donated tissue in research or for other purposes.

5.69 We have heard support for maintaining the dead donor rule.[97] But we have also heard that some would like to change this rule. In donations from people who do not meet the criteria for brain death, a person's heart generally has to stop beating within a particular timeframe after life support is withdrawn for organs to be donated. For people who do not die in this timeframe, that means their desire to donate, and their families' support of that desire, cannot be fulfilled. This can

96 Bernat (n 68); Bernat et al (n 63).
97 Australian Catholic Bishops Conference, *Submission 79*.

be distressing for families who 'experience a secondary loss' when donation is unsuccessful.[98] It means fewer organs are transplanted into patients on transplant waitlists.

5.70 In a submission responding to our *Issues Paper*, a mother shared a story about trying to donate her son's organs after his death. As his heart did not stop beating in time after life-sustaining treatment was withdrawn, organ donation could not proceed. She described the additional grief caused to her and her family because donation could not occur, and their disappointment that her son's wish to donate could not be fulfilled. Because of this experience, she supports making it

> legal for doctors to perform active euthanasia in an operating theatre, where organs are removed under general anaesthetic, as an alternative to, or simultaneous with, withdrawal of life support.[99]

5.71 This would avoid having to wait to see if a potential donor will die in a timeframe within which organ donation is possible.

5.72 Arguments of this nature raise compelling points. However, changing the law to allow a new form of euthanasia is outside the terms of reference for this inquiry and would represent a significant change that would require careful consideration and consultation. The NHMRC Guidelines also note that allowing an exception to the dead donor rule in these circumstances could undermine public trust and create potential conflicts of interest.[100] For these reasons, we are proposing to maintain a legal standard that requires a determination of death prior to organ removal.

Creating consistency in the location of the determination of death provisions and scope of application

5.73 **Proposal 11** seeks to encourage national consistency for a new legal standard for the determination of death. In our 1977 report, we highlighted that the determination of death provisions should be applicable for all purposes of the law.[101] Upon implementing their determination of death provisions, South Australia noted that having the same determination of death across Australia was important.[102] The importance of maintaining a consistent standard for the determination of death remains valid. It is preferable for certainty and public trust reasons to avoid any situation where a person may be determined to be dead in one state and not dead in another due to differences in the law.

5.74 The *Criminal Code Act 1995* (Cth) defines 'death' similarly to the state and territory determination of death provisions.[103] In **Proposal 11**, we are proposing that Commonwealth, state and territory legislation contain a consistent legal standard for determining death. We note the implementation of this proposal would therefore require the amendment or repeal of the Commonwealth definition.

5.75 **Question 8** asks for feedback on whether the proposed determination of death provision should apply for the purposes of all law. This would maintain the current position in every state and territory, except for Queensland. The Health Law Group at Monash University encouraged us to consider any possible unintended legal consequences of a new determination of death that

98 Ott et al (n 79) 2051.
99 S Catt, *Submission 80*.
100 National Health and Medical Research Council (n 5) 201.
101 Australian Law Reform Commission (n 8) 63.
102 South Australia, *Parliamentary Debates*, Legislative Council, 19 November 1980, 1986, 1988; South Australia, *Parliamentary Debates*, Legislative Council, 5 November 1980, 1757, 1762. See also Standing Committee on Uniform Legislation and Intergovernmental Agreements, Parliament of Western Australia, *Organ Donation and Transplantation* (2000) rec 3.
103 *Criminal Code Act 1995* (Cth) Dictionary (definition of 'death'). In comparison to state and territory determination of death provisions, the dictionary of the *Criminal Code Act 1995* (Cth) specifies that irreversible cessation of all function of a person's brain includes the brain stem.

applies to all areas of law.[104] In our view, there are unlikely to be unintended legal consequences because the proposed determination of death provision (**Proposal 10**):

- is not intended to change how death is determined in medical practice; and
- identifies a trigger event for certain areas of law to stop applying, and other areas of law to apply. For example, after death is determined to have occurred the inheritance process for property can commence. It is unlikely that our proposed provision for the determination of death will affect rights and obligations under other areas of law.

5.76 Applying the determination of death provision to human tissue laws alone may itself open the way for unintended legal consequences. For example, it could lead to the development of different statutory determinations of death in other areas of law,[105] or reliance on the common law approach to determining death in some circumstances and statutory approaches in others.

5.77 As this Inquiry focuses on human tissue law, **Question 8** asks for feedback about any unintended legal consequences that implementing **Proposal 10** on how death should be determined could have in areas of law that we have not contemplated.

5.78 **Question 9** asks for feedback on the most appropriate statutory location for the determination of death. Some options are provided, including:

- The creation of a Uniform Death Act that is enacted as national uniform legislation by intergovernmental agreement. This option can ensure a high degree of consistency so that the determination is uniform across Commonwealth, state, and territory jurisdictions. This option also has the benefit of making any necessary future amendments easier. As discussed in **Chapter 1**, there are various structures that could be used to enact national uniform legislation including referred, mirror, and applied.[106]
- A determination of death provision in human tissue legislation. This option has the risk of affecting public trust as it may create a misconception that the determination of death is only relevant for transplantation. It is also possible that Western Australia and South Australia may not be interested in moving the location of their current provisions after reform developments led to the exclusion of the determination of death from the HTAs in those states (discussed above).
- Give each state and territory the choice to keep the determination of death provision in human tissue legislation, create a separate Act, or put it in their Interpretation Acts. This option would require a mechanism, such as an intergovernmental agreement, to coordinate a consistent approach to any future amendments. It would also allow states and territories to determine which statutory location for provisions relating to the determination of death is most appropriate within the context of their own jurisdiction. However, there is a risk that inconsistent locations of the determination of death may cause confusion for users of legislation when operating across multiple jurisdictions.

5.79 We are interested to hear whether you have a preference for the location of the determination of death provisions. We would also like to know whether there is another preferred option which has not been considered.

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104 Health Law Group, Monash University, *Submission 67*.

105 A different determination of death provision was considered for the purpose of homicide in Model Criminal Code Officers Committee of the Standing Committee of Attorneys-General, *Chapter 5: Fatal Offences Against the Person* (Discussion Paper, 1998) 21. For example, 'irreversible cessation of more than 90% brain function' or 'incapable of independently maintaining blood circulation due to irreversible condition'. The purpose was to determine death as occurring at an earlier point in time than the current definition. These considerations were disregarded due to its wide reaching and undesirable ramifications.

106 For a description of the different structures of national uniform legislation, see **Chapter 1**.

6. Reforms related to the donation of tissue by living persons

Contents

Reforms relating to the donation of tissue by adult donors

Consent and authorisation for removal of tissue from living persons

Proposal 14

New human tissue legislation should provide:

1. That an adult may give valid consent to the removal of tissue from their body for the purpose of transplantation into the body of another person, or for other medical, educational or scientific purposes;
2. Valid consent is:
   a. given voluntarily;
   b. given at a time when the adult who is consenting has decision-making capacity;
   c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal;
   d. given after the adult who is consenting has been informed about the intended use of the tissue after it has been removed; and
   e. able to be withdrawn at any time before the removal of the tissue.
3. Valid consent is sufficient legal authority for the removal and use of the specified tissue for the specified purpose(s).
4. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in **Proposal 32** must be met.

Additional safeguards

Question 10

Are there additional safeguards aside from those set out in **Proposal 14** that should be set out in new human tissue legislation?

The problems we are addressing

6.1 Living donation requires careful regulation because it often involves donors agreeing to a medical procedure for the benefit of someone else rather than for their own therapeutic benefit. Because the medical risks of tissue donation vary, safeguards need to be appropriately tailored. For example, in the context of organ donation for transplantation, donating a kidney comes with health risks to the donor and there is a danger that a donor may be exploited or pressured into donating to save the life of a recipient. Safeguards should take this danger into account. On the other hand, donating excess tissue from a surgical procedure (such as donating placenta tissue after a caesarean section) does not involve any physical risk beyond the risks of the surgery itself. Less strict safeguards may be appropriate for this kind of donation.

6.2 Current laws create complex consent and authorisation frameworks. These were originally designed to provide tailored safeguards, matching the degree of medical risk and danger of exploitation associated with donation. The frameworks are based on a distinction between donating regenerative tissue — which has fewer safeguards; and donating non-regenerative tissue — which has more safeguards.[1] As a result of medical developments, this distinction no longer makes sense. For example, the liver can be classified as regenerative tissue, but liver donation involves more medical risks for donors than kidney donation, even though the kidney is non-regenerative.[2]

6.3 Current legislation also limits the uses that can be made of different types of tissue. In many jurisdictions, adults can only donate non-regenerative tissue for purposes of transplantation; whereas regenerative tissue can be donated for purposes of transplantation or other therapeutic, medical or scientific purposes.[3] However, we have heard that this restriction is overly broad.[4] In particular, the scientific value of tissue does not depend on whether it is regenerative. And given that the regenerative nature of tissue does not necessarily correspond to the level of risk of its removal, the distinction could be eliminated and risks of coercion and exploitation addressed in a more nuanced way. We discuss this issue specifically in the research context (**Chapter 8**).

6.4 Submissions in response to our *Issues Paper* raised several additional issues with current consent and authorisation frameworks, including that:

- inconsistencies across jurisdictions make it harder to coordinate successful donation programs;[5]
- the wording is complex and difficult for clinicians to apply;[6]
- requirements for informed consent may be inadequate, including in relation to the details of kidney paired donation, and the need for donors to be informed about the particular purposes for which their donation will be used;[7] and
- there is insufficient oversight when 'leftover' tissue removed during surgery is used for commercial purposes.[8]

1 See Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 14.
2 Organ and Tissue Authority, DonateLife, 'Understanding Living Donation' <www.donatelife.gov.au/all-about-donation/understanding-living-donation>.
3 See, eg, *Human Tissue Act 1983* (NSW) ss 7, 8; *Transplantation and Anatomy Act 1983* (SA) ss 9, 10; *Human Tissue Act 1982* (Vic) ss 7, 8.
4 See, eg, R Balleine, *Submission 17*.
5 PlusLife, *Submission 22*.
6 Australian Centre for Transplantation Excellence and Research, *Submission 65*.
7 Ibid.
8 See NSW Organ & Tissue Donation Service, *Submission 40*.

Background to the problems

6.5 The common law regarding medical decision-making requires that consent to medical treatment is:

- given voluntarily;
- by someone with decision-making capacity; and
- who is informed about the basic nature of the treatment.[9]

6.6 There is also an obligation on the treatment provider to provide material information, including risks that a reasonable person in the circumstances would want to know.[10]

6.7 These are fundamental requirements that should be met before removal of all types of tissue. Whether additional safeguards should be included in legislation is a question we are considering.

6.8 The HTAs distinguish between blood, regenerative tissue, and non-regenerative tissue. For non-regenerative tissue, there is a mandatory 24-hour cooling off period and, in some jurisdictions, a requirement that consent cannot be signed in the presence of family members.[11]

6.9 While the principle that donations with higher medical risks should have stronger safeguards remains valid, distinctions based on whether tissue is regenerative or non-regenerative are no longer appropriate. Instead, there is a need to tailor safeguards to the types of:

- tissue donated — including kidney, liver, and bone marrow/stem cells; and
- donation — including directed donation to a specific recipient, and non-directed donation to anonymous strangers.

6.10 Legislation is not the best place to provide this level of detail. Creating statutory rules to cater for a range of alternatives can lead to regulatory frameworks that are complex and inflexible.

6.11 Regulation in this area should be flexible and responsive because the relative risks of donation, and the types of tissue that can be donated, will change over time. For example, we have heard that a 24-hour cooling off period currently works well for kidney donation, but more flexible consent requirements may be needed for liver donation in situations of clinical urgency.[12] We have also heard that adding complexity to the consent process for haematopoietic stem cell donation may pose operational problems.[13]

6.12 Safeguards that are fundamental to valid and informed consent should be legislated. Additional safeguards that are required in specific contexts can be provided for in clinical practice and other policy documents, such as:

- government policy directives;[14]
- NHMRC ethical guidelines;[15] or
- clinical practice guidelines developed by relevant professional bodies and/or transplant programs.

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9 Bernadette Richards, 'General Principles of Consent to Medical Treatment' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 143.

10 Tina Cockburn and Bill Madden, 'Negligence' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 335.

11 See, eg, *Transplantation and Anatomy Act 1978* (ACT) s 9; *Transplantation and Anatomy Act 1979* (Qld) s 11; *Human Tissue Act 1982* (Vic) s 8; *Transplantation and Anatomy Act 1983* (SA) s 10; *Human Tissue and Transplant Act 1982* (WA) s 9.

12 Australian Centre for Transplantation Excellence and Research, *Submission 65*.

13 J Chapman, *Submission 59*.

14 See, eg, NSW Government, 'Living Kidney Donation and Transplantation Policy Directive' <www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2022_036.pdf>.

15 National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 67–86.

6.13 As long as these guidelines and directives are consistent with the fundamental consent requirements we have identified, they should continue to be used and developed as required in response to future donation developments.

6.14 Sometimes tissue removed during a therapeutic procedure, such as surgery, can be used for other purposes. For example, during hip replacement surgery, part of the removed bone may be donated for use in another person's medical treatment.[16] The tissue banking sector, which collects, processes, and distributes tissue and tissue products, is made up of a mix of government, private, not-for-profit, and commercial entities.[17] Currently, people who donate tissue removed during a therapeutic procedure may not be fully informed that their donated tissue could be used in commercial contexts.[18] To appropriately respect donors' dignity and autonomy, and right to make decisions about how their tissue is used, there should be a requirement to obtain informed consent in relation to how tissue left over from a surgical procedure may be used, including in commercial applications.[19]

How our reform proposal could solve the problems

6.15 **Proposal 14** sets out fundamental criteria for valid consent. Including the fundamental criteria for valid consent in nationally consistent legislation will make the law clearer and more accessible. This approach simplifies existing requirements that differ between types of tissue. It allows the legal criteria to be supplemented by more detailed and tailored safeguards that are developed through clinical practice, and policies that can be regularly updated. We are, however, seeking feedback in **Question 10** about whether legislation should include additional safeguards.

6.16 **Proposal 14** also specifies that in order for consent to be valid, potential donors must be informed about the intended use of their tissue. This ensures donors are aware of, and can consider, any potential commercial uses of their donated tissue before deciding to donate.

Reforms relating to the donation of tissue by people without decision-making capacity

Definition of 'adult' and 'child'

Proposal 15

New human tissue legislation should define an adult as a person who is 18 years of age or older, and a 'child' as a person who is under 18 years old.

Donation of blood

Proposal 16

New human tissue legislation should provide that for the purpose of blood donation, a child aged 16 years or older is deemed to be an adult.

16 Ibid 32.
17 Ibid 13.
18 NSW Organ & Tissue Donation Service, *Submission 40*.
19 National Health and Medical Research Council (n 15) 75.

Donation of tissue by children

Proposal 17

New human tissue legislation should:

a. allow a parent or guardian of a child, or a child with decision-making capacity, to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the child's body for the purpose of transplantation, or for other medical, educational or scientific purposes; and

b. provide that an application to the Committee is not required for the removal of tissue for use in research that satisfies the requirements of **Proposal 35**.

Proposal 18

The Committee (**Proposal 17**) should have the power to authorise removal of tissue if it is in the child's best interests. For the purpose of determining whether a valid application has been made by a child, the Committee should be empowered to determine if the child has decision-making capacity.

Proposal 19

New human tissue legislation should provide that in determining if removal of tissue for transplantation or for other medical, educational or scientific purposes is in a child's best interests, the Committee (**Proposal 17**) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the child's views, if any, given, where appropriate, directly by the child;
- the child's age and level of understanding;
- the child's physical and psychological wellbeing;
- the child's relationship with the intended tissue recipient;
- the views of the child's parent(s) or guardian(s) or other persons who have a significant relationship with the child;
- the support available for the child after removal of their tissue; and
- the availability of an alternative donor.

Additionally:

- Where a child does not have decision-making capacity, donation should only be approved with the consent of a parent or a guardian.
- If a child has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

Question 11

Are the considerations listed, and the guidance provided, in **Proposal 19** appropriate? Are there additional considerations that the Committee (**Proposal 17**) should take into account?

Question 12

Aside from the removal of tissue from a child for use in research (**Proposal 35**), are there situations where the removal of tissue from a child should not require approval by a Committee, and where new human tissue legislation should require only parental consent, or individual consent where a child has decision-making capacity?

Donation of tissue by adults who do not have decision-making capacity

Proposal 20

New human tissue legislation should enable a legally authorised substitute decision-maker or guardian of an adult who does not have decision-making capacity to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the person's body for the purpose of transplantation or for other medical, educational or scientific purposes.

Proposal 21

The Committee (**Proposal 20**) should have the power to authorise donation if it is in the proposed donor's best interests.

Proposal 22

New human tissue legislation should provide that in determining if a donation is in the best interests of an adult who does not have decision-making capacity, the Committee (**Proposal 20**) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the proposed donor's views, given, where appropriate, directly by the proposed donor, or from sources reflecting the proposed donor's views from a time when they had decision-making capacity;
- the proposed donor's physical and psychological wellbeing;
- the proposed donor's level of understanding;
- the proposed donor's relationship with the intended recipient;
- the support available for the proposed donor after the removal of their tissue; and
- the availability of an alternative donor.

Additionally, if the proposed donor has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

Question 13

Are the considerations listed, and the guidance provided, in **Proposal 22** appropriate? Are there additional considerations that the Committee (**Proposal 20**) should take into account?

Question 14

Are there situations where donation from adults who do not have decision-making capacity should not require approval by a Committee and where new human tissue legislation should require only consent by a legally authorised substitute decision-maker?

See also **Question 28** where we are seeking feedback on whether specific consent requirements should exist to allow adults without decision-making capacity to donate tissue for research purposes.

Composition of committee

Question 15

What is an appropriate composition for a Committee under **Proposals 17** and **20**?

We are seeking input about the qualifications and/or experience of people who should be on the Committee; and also if there should be a national Committee or multiple state and territory Committees.

The problems we are addressing

6.17 Children, and adults with limited decision-making capacity, should be protected from coercion and exploitation but supported to:

- express their views (if any) about donating tissue; and
- donate tissue when donation is in their best interests.

6.18 There may be circumstances in which donation for the purposes of transplantation is in the best interests of a child or adult who does not have decision-making capacity, such as where the proposed donor has a close relationship with the proposed recipient, and the physical risk of tissue removal is minor. However, because a parent, guardian, or substitute decision-maker may be the proposed tissue recipient, or closely related to the proposed recipient, the potential for conflicts of interest, and the danger of exploitation and coercion, are high.[20] Strong safeguards are required to manage these risks.

Children

6.19 Current laws are inflexible and do not allow for contextual evaluation of whether donation in particular circumstances should be permitted. For example, some of the HTAs prohibit children from donating to anyone other than a sibling or parent.[21] But children may have close relationships with people other than their siblings or parents. It may be appropriate to take these relationships into account when considering if a proposed donation is ethically justified.

6.20 The HTA frameworks for donation by children are also inconsistent. Inconsistencies include:

- the type of tissue that can be donated;
- the purposes for which tissue can be donated;
- how children and parents are defined; and
- the role and involvement of children and parents in decision-making.[22]

6.21 In some jurisdictions, a person's marital status as well as their age is relevant to whether they are defined as an adult or a child.[23] This reflects an outdated notion of the connection between a person's marital status and their decision-making capacity.

Adults with limited decision-making capacity

6.22 With the exception of South Australia, the HTAs require adults to be of 'sound mind' to donate tissue.[24] The concept of a 'sound mind' comes from the common law and can have different meanings in different contexts. It is now an outdated term. More modern terminology refers to a person's decision-making capacity.

6.23 Under current substitute decision-making legislation, substitute decision-makers or legal guardians may be able to consent to certain types of tissue donation (such as stem cell donation) on behalf of people whose decision-making capacity is limited.[25] Tribunals or courts may be able

20 Ibid 103.
21 *Human Tissue Act 1983* (NSW) s 10; *Transplantation and Anatomy Act 1979* (Qld) s 12B; *Human Tissue Act 1982* (Vic) s 15(1).
22 Maeghan Toews, 'Organ and Tissue Donation and Transplantation' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 839–48; Shih-Ning Then, 'Young Children as Regenerative Tissue Donors: Considering the Need for Legal Reform in Light of Divergent Ethical Approaches' (2011) 19(1) *Journal of Law and Medicine* 172, 173.
23 *Transplantation and Anatomy Act 1979* (NT) s 4 (definition of 'child'); *Transplantation and Anatomy Act 1983* (SA) s 5 (definition of 'child'); *Human Tissue Act 1982* (Vic) s 3 (definition of 'child').
24 *Transplantation and Anatomy Act 1978* (ACT) s 10; *Human Tissue Act 1983* (NSW) s 9; *Transplantation and Anatomy Act 1979* (NT) s 10; *Transplantation and Anatomy Act 1979* (Qld) s 12; *Human Tissue Act 1985* (Tas) s 9; *Human Tissue Act 1982* (Vic) s 9; *Human Tissue and Transplant Act 1982* (WA) s 8. In South Australia, the legislation requires that the person 'understands the nature and effect of the removal': *Transplantation and Anatomy Act 1983* (SA) s 9.
25 National Health and Medical Research Council (n 15) 99.

to authorise solid organ donation by people whose decision-making capacity is limited.[26] The authorisation frameworks operate inconsistently across different jurisdictions.[27]

Background to the problems

6.24 In our 1977 *Human Tissue Transplants* report, we recommended that living donation of regenerative tissue by children only be permitted if:

- the potential donor is of 'sound mind and agrees to such removal';
- a parent provides written consent; and
- independent medical advice is provided to the potential donor.[28]

6.25 For non-regenerative tissue, we said there should be additional requirements, including that:

- the intended recipient be at risk of dying without donation;
- a committee approve the donation; and
- the intended recipient be an immediate family member of the potential donor.[29]

6.26 Since that time, living tissue donation has become more common and the factors used to decide what is in a person's 'best interests' have expanded.[30] There is now case law involving children,[31] and an adult lacking capacity,[32] where courts have determined that living bone marrow donation was in the donors' best interests. The courts considered the following factors in coming to this decision, including:

- the proposed donors' psychological wellbeing;
- their views about and level of understanding of the proposed donation;
- their relationship to the recipient; and
- the risks associated with donation.[33]

6.27 Research has also emphasised the importance of providing potential donors with the opportunity to have their views heard.[34]

6.28 The NHMRC Guidelines provide that donation (other than blood) by children or adults who do not have decision-making capacity should only be considered 'in circumstances of strict necessity and where the expected benefits of donation substantially outweigh the potential risks'.[35] Because of the danger of conflicts of interest, the Guidelines note that an

> independent decision-maker (for example a court, tribunal, or independent committee) is likely to be best placed, or required by law, to make the final donation decision.[36]

6.29 Currently, the *Transplantation and Anatomy Act 1983* (SA) provides for a committee decision-making process for donation of regenerative tissue by children.[37] The *Transplantation*

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26 Ibid 100.
27 Queensland University of Technology, 'Capacity and Consent to Medical Treatment' 'Capacity and consent by state and territory' <www.end-of-life.qut.edu.au/capacity>; National Health and Medical Research Council (n 15) 90–1.
28 Australian Law Reform Commission (n 1) 51.
29 Ibid.
30 See National Health and Medical Research Council (n 15) 94, 233.
31 *Re W* (1997) 136 FLR 421; *Re Inaya* (2007) 213 FLR 278.
32 *Northern Sydney and Central Coast Area Health Service v CT* [2005] NSWSC 551.
33 *Re W* (1997) 136 FLR 421, 429; *Re Inaya* (2007) 213 FLR 278, 283–5; *Northern Sydney and Central Coast Area Health Service v CT* [2005] NSWSC 551 [26]–[28].
34 See, eg, Shih-Ning Then, 'Best Interests: The "Best" Way for Courts to Decide If Young Children Should Act as Bone Marrow Donors?' (2017) 17(1–2) *Medical Law International* 3, 31–2; Then (n 22) 194.
35 National Health and Medical Research Council (n 15) 100.
36 Ibid 103.
37 *Transplantation and Anatomy Act 1983* (SA) s 13(3).

and Anatomy Act 1978 (ACT) provides a similar process for donation of non-regenerative tissue by children.[38]

6.30 We have heard support for strong ethical standards and safeguards to make sure that people who do not have decision-making capacity are not exposed to medical risks that they might reasonably refuse if they were able to make their own decision.[39]

6.31 The NHMRC Guidelines say that for children with decision-making capacity, a refusal to act as a donor 'must always be respected'.[40] For other children and adults who do not have decision-making capacity, the Guidelines say that 'any manifest reluctance or objection' to donation 'must be taken seriously'.[41] While it is appropriate to address concerns raised by the potential donor, such as fear of going to hospital, 'where an unwillingness to donate is maintained for a period of time…[that] objection should be respected'.[42]

6.32 In the context of medical treatment, a child's decision-making capacity is assessed by reference to whether the child fully understands the particular treatment proposed.[43] This means that a child might have the capacity to consent on their own behalf to simple procedures that carry little risk but do not have the capacity to consent to more complex treatments. Legislative regulation of blood donation reflects the modern preference for treatment-specific approaches to decision-making capacity. Because blood donation poses a low level of risk for donors, and has significant social benefits, most states and territories allow people who are 16 years old or older to consent on their own behalf to donate blood.[44] However, Queensland and Western Australia still require blood donors to be 18 years old before they can consent on their own behalf to donation.[45]

6.33 In our consultations, we have heard from government and relevant institutional stakeholders that the age of consent for blood donation should be consistent across the country, and that a minimum age of 16-years-old will help encourage people to 'get involved' in blood donation from a young age.

How our reform proposal could solve the problems

6.34 **Proposal 15** provides nationally consistent definitions of an adult and a child for matters covered by new human tissue legislation by setting 18 years of age as the age for adulthood. A limitation of this approach is that a definition based on a person's age does not capture the variability in children's ability to understand the nature and effects of donation as they approach adulthood. However, **Proposals 17**, **18**, and **19** are designed to make donation of tissue possible for people who have appropriate levels of understanding by taking their wishes into account, while also protecting people who do not have decision-making capacity from coercion and exploitation, and making sure their best interests are prioritised.

6.35 Making the minimum age of consent for blood donation 16 years (**Proposal 16**) would create national consistency and align with the current approach in most jurisdictions. This approach recognises that people's decision-making capacity can be context specific, and less sophisticated understanding is required for procedures with less risk.

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38 *Transplantation and Anatomy Act 1978* (ACT) s 14(5).

39 See, eg, Australasian Biospecimen Network Association, *Submission 29*; Australian Catholic Bishops Conference, *Submission 79*.

40 National Health and Medical Research Council (n 15) 102.

41 Ibid.

42 Ibid 103.

43 Malcolm Smith and Ben Mathews, 'Children and Consent to Medical Treatment' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 195.

44 *Transplantation and Anatomy Act 1978* (ACT) s 20; *Human Tissue Act 1983* (NSW) s 19; *Transplantation and Anatomy Act 1979* (NT) s 14; *Transplantation and Anatomy Act 1983* (SA) ss 17A, 19; *Human Tissue Act 1985* (Tas) ss 17A, 19; *Human Tissue Act 1982* (Vic) ss 20A, 22.

45 *Transplantation and Anatomy Act 1979* (Qld) s 17; *Human Tissue and Transplant Act 1982* (WA) s 18.

6.36 We are seeking feedback on the appropriate composition of the Committees we are proposing (**Question 15**). For adults who do not have decision-making capacity, the role of the Committee would replace any current requirements to seek Tribunal approval, providing a streamlined and nationally consistent approach.

6.37 As it can be difficult to determine the factors that should be considered in applying a 'best interests' test to procedures that are not done for a donor's own medical benefit,[46] we are seeking feedback about whether the factors that we have proposed are appropriate (**Questions 11** and **13**).

6.38 By specifying the need to respect objections that have been maintained by adults lacking decision-making capacity or children, **Proposals 19** and **22** reflect accepted ethical standards.[47] And by providing that the proposed donors' views need to be taken into account by hearing directly from them, where appropriate, the proposals also recognise the importance of supporting children and adults without capacity to participate in decision-making processes, to the extent possible.[48]

6.39 Although safeguards are important, not all forms of tissue donation carry significant risks for donors. We are therefore seeking input about whether there are some types of donation that may not need the independent oversight of a committee. In this respect, we have made a specific proposal (**Proposal 35**) and posed a specific question (**Question 28**) regarding the use of tissue from children and adults without capacity in research.

46 Then (n 34) 24.
47 National Health and Medical Research Council (n 15) 103–4. See also Then (n 22) 194.
48 National Health and Medical Research Council (n 15) 88–9.

7. Reforms relating to deceased donation

Contents

Reforms relating to the legal authority to donate

Consent and authorisation for removal of tissue after death

Proposal 23

1. New human tissue legislation should provide that:
2. An adult may give valid consent for the removal of their tissue after their death for the purpose of transplantation or for other medical, educational or scientific purposes.
   a. If an adult is close to death and does not have decision-making capacity, or dies without having provided valid consent, the adult's authorised decision-maker may give valid consent to the removal of tissue from the adult's body for transplantation or for other medical, educational or scientific purposes.
   b. When deciding whether to give consent, the authorised decision-maker must have primary regard to the adult's known beliefs, values, and preferences regarding tissue donation, if any, and make the decision they believe the adult would have made in the circumstances.

3. If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for transplantation or for other medical, educational or scientific purposes.
4. Valid consent is:
    a. given voluntarily;
    b. given at a time when the person consenting has decision-making capacity;
    c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;
    d. given after the person consenting has been informed about the intended use of the tissue; and
    e. able to be revoked at any time before the removal of the tissue.
5. Valid consent is sufficient legal authority for the removal of the specified tissue and for the specified uses.
6. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in **Proposal 36** must be met.

Question 16

Proposal 23 removes the role of the Designated Officer, who under current legislation is required to authorise tissue removal when a person dies in a hospital. Do you agree the role of the Designated Officer is no longer necessary?

- If you agree that Designated Officers are no longer necessary, please explain why.
- If you think the Designated Officer role remains necessary, please explain why.

Question 17

Does **Proposal 23** strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach?

Question 18

Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required?

For example, Victoria's legislation allows a person to give consent to donation:

- in writing at any time before their death; or
- during their last illness, orally in the presence of two witnesses.

Proposal 24

The National Regulator (or alternative) should develop protocols or guidelines for deceased tissue donation by people accessing voluntary assisted dying, and people who have decision-making capacity and who are requesting withdrawal or cessation of life-sustaining therapy.

Authorised decision-maker

Proposal 25

New human tissue legislation should replace current HTA definitions of 'senior available next of kin' with a definition of 'authorised decision-maker' that sets out a hierarchy of decision-makers modelled on section 13 of the *Health Care Decision Making Act 2023* (NT).

Question 19

How should the hierarchy of decision-makers in **Proposal 25** be tailored to the deceased tissue donation context?

Question 20

How should new human tissue legislation address situations where authorised decision-makers with equal decision-making status in the hierarchy in **Proposal 25** disagree about whether to consent to donation?

The problems we are addressing

Inconsistencies across different states and territories

7.1 There are inconsistencies in the consent and authorisation frameworks for deceased tissue donation across different states and territories. These inconsistencies can make the law hard to access and understand.

The role of Designated Officers

7.2 All of the HTAs distinguish between deaths that occur in a hospital and deaths that occur elsewhere. This is because Designated Officers must authorise tissue removal from the bodies of people who die in hospital.[1] Having two different authorisation frameworks that depend on the location of the deceased body may not make sense in the modern context where a lot of tissue donation occurs outside of hospitals.

7.3 The intended role for the Designated Officer when the HTAs were enacted was to check whether the potential donor had indicated a willingness to donate, and if they had not, or if there was no information about their wishes, to see whether the person's senior next of kin agreed to donation. These functions are now undertaken primarily by DonateLife. As Designated Officers are no longer needed to fulfill this function, there is a question about whether legislation should continue to require a Designated Officer's authorisation for in-hospital deaths.

The role of next of kin

7.4 In addition to the role of Designated Officers, the HTAs give a person's most 'senior available' 'next of kin' a decision-making role in relation to deceased donation in specific contexts. These are when a person dies:

- somewhere other than in a hospital; and
- in a hospital and has not previously objected or consented to donation or (in some jurisdictions) made their wishes about donation known.

7.5 There is debate about whether an individual's expressed wish to donate tissue should be legally binding, or whether their next of kin should have the final decision about if donation can occur.

7.6 The current practice is to follow the wishes of a person's next of kin regardless of whether a person previously consented to donate tissue after their death.[2] There is a concern that allowing a person's family to override their expressed wish to donate does not adequately respect people's decisions about what should happen to their own bodies. On the other hand, when people sign

1 See, eg, *Transplantation and Anatomy Act 1979* (Qld) ss 22–3.
2 See, eg, New South Wales Health, *Organ and Tissue Donation, Use and Retention* (Policy Directive No PD2024_022, 26 July 2024) 11.

up to be deceased organ donors, they may not fully understand the implications of the decision and how it might affect the dying process. An approach is needed that places more weight on individual autonomy, and that can be tailored to the range of situations in which deceased donation becomes possible for individuals.

7.7 In defining 'next of kin' and the most 'senior available next of kin', the HTAs set out hierarchies of decision-makers that do not recognise:

- culturally diverse and modern understandings of family and kinship; or
- substitute decision-makers appointed through a person's advance care directive to make health care decisions on the person's behalf.

7.8 Different HTAs also provide different rules about what should happen if there is disagreement about donation among senior available next of kin who have equal decision-making authority.

The need to protect the interests of conscious and competent donors

7.9 Most people do not have decision-making capacity at the time of their death or just before it. But some people have decision-making capacity even when their death is imminent. Known as 'conscious and competent' donors,[3] this group includes people accessing voluntary assisted dying, and people dependent on life-sustaining therapy who ask for treatment to be withdrawn so they can die. As these people have decision-making capacity, human tissue legislation should enable them to make an informed decision about whether to donate tissue after death. However, there are ethical concerns that need to be considered, such as that conscious and competent donors may feel pressured:

- to hasten their death for the purpose of donating organs; or
- not to change their minds once they have agreed to donate.

Use of donated tissue in commercial contexts

7.10 As well as transplantation into the body of another person, donated tissue may be used for a range of other purposes, including for use in developing medical products. People who consent to deceased donation may not always be aware of the potential for the donated tissue to be used in commercial contexts (see **Chapter 11** discussing commercial trade in organs).

Background to the problems

The role of Designated Officers

7.11 In our 1977 report on human tissue laws, we recommended different authorisation processes for tissue donation when people die in hospital and when they die elsewhere. At the time, deceased tissue donation outside hospitals was rare.[4]

7.12 To allow for tissue retrieval in hospital settings, we recommended that there should be Designated Officers, whose role would be to:

- find out if the deceased person consented or objected before their death to donation; or
- contact the deceased person's relatives if the wishes of the deceased person were unknown, and ask the relatives for their views.[5]

3 See, eg, James Downar et al, 'Deceased Organ and Tissue Donation after Medical Assistance in Dying and Other Conscious and Competent Donors: Guidance for Policy' (2019) 191(22) *Canadian Medical Association Journal* E604.
4 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 64, 66.
5 Ibid 66, see also 117–8.

7.13 We recommended that if tissue donation was possible when a person died outside of hospital, then the deceased person's 'close relatives' should be able to authorise donation, in a way that respected any expressed wishes of the person before their death.[6]

7.14 When we recommended the creation of a Designated Officer role, there was no national agency to coordinate deceased donation or inquire about a dying or deceased person's wishes or the views of their family. Now, DonateLife is responsible for:

- Checking if a person is listed on the Australian Organ Donor Register (Donor Register).
- Providing advice to clinicians about a donor's suitability to donate.
- Planning the approach to family conversations about donation. In most cases, these conversations are led by a donation specialist nurse, who is trained and experienced in this type of communication.[7]

7.15 In addition, there are now best practice guidelines from OTA, ethical guidelines from the NHMRC, clinical guidelines from the TSANZ, and professional statements from ANZICS, which provide guidance across a wide array of donation and transplantation activities.[8]

7.16 And while solid organ donation must occur in a hospital, other types of tissue donation such as corneas, bone, skin, and tendons, can occur elsewhere: for example, in a forensic laboratory or morgue. Because tissue removal outside hospitals is now common, it would make sense to have consistent consent and authorisation frameworks, regardless of where tissue removal occurs.

7.17 Currently, the Designated Officer's role is to check if the appropriate consents have been obtained to donate tissue in a hospital setting,[9] and to provide final authorisation to donate in accordance with the provisions of the relevant HTA.[10]

7.18 Some people with knowledge of the health sector told us that the Designated Officer role is an important safeguard for the rights of potential donors and their families.[11] Others questioned the need for the role, given the robust policies and processes in our current donation system.

7.19 We have heard about practical difficulties with the Designated Officer system, including:

- difficulty recruiting people to serve as Designated Officers;
- problems in jurisdictions where a Designated Officer is required to be physically present to provide authorisation to donate, or where a Designated Officer's written consent is required, which can lead to unnecessary delays; and
- loss of usable tissue when the necessary authority to donate cannot be provided within the limited timeframes required.

7.20 **Proposal 23** does not include a role for Designated Officers. We are seeking input about if, contrary to our proposal, there is a need for Designated Officers in a modern tissue donation system.

6 Ibid 66–7.
7 Organ and Tissue Authority, DonateLife, *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* (2nd ed, 2021) 5–7.
8 DonateLife, 'Clinical Guidelines and Protocols' <https://www.donatelife.gov.au/for-healthcare-workers/clinical-guidelines-and-protocols>.
9 Organ and Tissue Authority, DonateLife, *Best Practice Guideline for Donation after Circulatory Determination of Death (DCDD) in Australia* (2021) 9.
10 See, eg, *Transplantation and Anatomy Act 1979* (NT) s 18.
11 PlusLife, *Submission 22*; H Northam, *Submission 86*.

The legal effect of a decision to donate

7.21 Consent requirements in the different HTAs are inconsistent. Inconsistencies relate to:

- When Designated Officers can authorise donation.[12]
- The role of a person's next of kin in authorising donation.[13]
- When and how a person's prior wish to donate can be treated after their death as authorisation for donation. For example, in Queensland, a person's signed and written consent to donate tissue after their death can provide authority to donate.[14] In Victoria, for deaths outside of hospital, authority to donate can come from:
    - a person's previous written consent to donate; or
    - a wish to donate expressed orally in the presence of two witnesses during a person's 'last illness'.[15]

7.22 There may also be a need to consider the form that consent should take, such as written, verbal, or digital consent. We are seeking input about whether new human tissue legislation should specify the form of valid consent.

7.23 The legal effect of joining the Donor Register may be different depending on whether an HTA requires consent to be in writing,[16] or whether a person must only express a wish to donate to enable the Designated Officer to authorise donation.[17] However, as discussed earlier, as a matter of practice, the wishes of a person's next of kin are always followed, regardless of whether the deceased person previously expressed a wish to donate.[18]

7.24 We have heard:

- There is a need to harmonise, and clarify, consent and authorisation frameworks for deceased donation.[19]
- There is a need to consider if joining the Donor Register should be given greater legal weight.[20]
- There is a need for informed decision-making, and a concern that when people join the Donor Register, they are not making an informed decision.[21]
- Some people feel that an individual's prior decision to donate (or not to donate) should be respected.[22] There is concern that a family's ability to override an individual's wishes does not sufficiently respect the autonomy and dignity of individuals.[23]

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12 For example, in some jurisdictions, if a deceased person before their death 'expressed the wish for, or consented to' the removal of their tissue after death for transplantation or other purposes, a Designated Officer can authorise the removal: *Transplantation and Anatomy Act 1978* (ACT) s 27(1); *Transplantation and Anatomy Act 1983* (SA) s 21(2); *Human Tissue Act 1985* (Tas) s 23(1); *Human Tissue and Transplant Act 1982* (WA) s 22(2). In the Northern Territory, where a deceased person before their death 'expressed a wish for, or consented to' the removal of their tissue after death, the removal is treated as having been authorised by the deceased person (not the Designated Officer), but only if their wish or consent to donate was made 'by signed writing': *Transplantation and Anatomy Act 1979* (NT) s 19B.

13 If a person's donation preferences were unknown (or in some cases, were not set out in writing), the HTAs in some jurisdictions require the person's senior available next of kin to provide consent in order to authorise donation: *Human Tissue Act 1983* (NSW) s 23(3)(b); *Transplantation and Anatomy Act 1979* (Qld) s 22(1)(c); *Human Tissue Act 1985* (Tas) s 23(2)(a); *Human Tissue Act 1982* (Vic) s 26(1)(d); *Human Tissue and Transplant Act 1982* (WA) s 22(2)(b). The HTAs in other jurisdictions require only that the senior available next of kin do not object to donation: *Transplantation and Anatomy Act 1978* (ACT) s 27(2)(c); *Transplantation and Anatomy Act 1979* (NT) s 18(1)(b); *Transplantation and Anatomy Act 1983* (SA) s 21(3)(c).

14 *Transplantation and Anatomy Act 1979* (Qld) s 22(5).

15 *Human Tissue Act 1982* (Vic) s 26(2)(c).

16 *Human Tissue Act 1983* (NSW) s 23(1).

17 *Transplantation and Anatomy Act 1983* (SA) s 21(3).

18 *Australian Donation and Transplantation Activity Report 2024* (2024) 18.

19 Transplant Australia, *Submission 24*; Law Council of Australia, *Submission 61*; Transplant Australia, *Submission 24*; University of Sydney, *Submission 60*.

20 Law Council of Australia, *Submission 61*.

21 PlusLife, *Submission 22*; Donor Families Australia, *Submission 55*; Law Council of Australia, *Submission 61*.

22 R Jenkin, *Submission 48*.

23 Health Law Group, Monash University, *Submission 67*.

- Some people are concerned about the distress families may feel if their wishes in relation to their loved one are not considered. They think families should have the final say about tissue donation after a loved family member dies. There is also concern that not giving families the final say might result in negative media attention, which could undermine public trust in the organ donation system.
- Some people have asked us to consider an approach that tries to avoid causing undue family distress while also honouring a deceased person's wishes where possible.[24] Transplant Australia proposes a model whereby families are consulted but not required to 're-consent' if a deceased person is on the Donor Register.[25]

7.25 Recent inquiries in Western Australia and Victoria recommended that governments consider:

- using advanced care planning to help people consider deceased donation before they die;[26] and
- updating legislation to allow people to appoint a substitute decision-maker to represent them after they die.[27]

7.26 We heard support for this approach in consultations and submissions.[28]

Substitute decision-makers

7.27 The HTAs do not provide a mechanism for people to appoint a person of their choice to make donation decisions on their behalf after they die, if they do not want their next of kin to play this role.

7.28 The current practice of deferring to the wishes of a deceased person's next of kin even when these wishes are contrary to a person's previously expressed wish to donate is at odds with the original intention expressed in our 1977 report. This intention was to prevent anyone from overriding a person's known wishes in relation to tissue donation.[29] The HTAs do not specifically require a person's next of kin to consent to donation if the person is known to have expressed a desire to donate when they were alive. Rather, the consent of the next of kin is needed where the person did not express either a desire to donate or an objection to donation after death.[30]

7.29 We have heard that the definition of 'senior available next kin' needs to be updated as the list is narrow. It does not include culturally diverse understandings of kinship, does not say what 'available' means in the circumstances, and does not address situations where family members are estranged.[31]

7.30 If two or more people all fall into the category of most senior available next of kin (for example, adult siblings of a deceased person), most of the HTAs provide that donation cannot proceed if any one of them objects.[32] However, the Victorian HTA provides that consent is only needed from one person, regardless of whether other senior available next of kin object.[33] We are

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24 Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand, *Submission 81*.
25 Transplant Australia, *Submission 24*.
26 Standing Committee on Public Administration, Parliament of Western Australia, *The Donation Conversation: Organ and Tissue Donation in Western Australia* (2024) 53; Legal and Social Issues References Committee, Parliament of Victoria, *Register and Talk about It: Inquiry into Increasing the Number of Registered Organ and Tissue Donors* (Summary Booklet, 2024) 202.
27 Standing Committee on Public Administration, Parliament of Western Australia (n 26) 54.
28 NSW Organ & Tissue Donation Service, *Submission 40*.
29 Australian Law Reform Commission (n 4) 65.
30 See, eg, *Transplantation and Anatomy Act 1979* (Qld) ss 22(3), 23(2)(a).
31 NSW Organ & Tissue Donation Service, *Submission 40*; R Jenkin, *Submission 48*; Shih-Ning Then and Dominique E Martin, 'Transitions in Decision-Making Authority at the End of Life: A Problem of Law, Ethics and Practice in Deceased Donation' (2022) 48(2) *Journal of Medical Ethics* 112, 112.
32 *Transplantation and Anatomy Regulation 2001* (ACT) s 27(5); *Human Tissue Act 1983* (NSW) s 23(3)(c); *Transplantation and Anatomy Act 1979* (NT) s 19(3); *Transplantation and Anatomy Act 1979* (Qld) s 22(4); *Transplantation and Anatomy Act 1983* (SA) s 21(5); *Human Tissue Act 1985* (Tas) s 23(2)(b)(iv); *Human Tissue and Transplant Act 1982* (WA) s 22(5).
33 *Human Tissue Act 1982* (Vic) s 21(6).

seeking feedback about how disagreements between decision-makers of equal status should be addressed in new human tissue legislation.

7.31 We have also heard that the role played by senior available next of kin in relation to donation decision-making can conflict with frameworks for authorising medical treatment for adults who do not have decision-making capacity.[34]

7.32 As a decision to donate may need to be made before a donor dies, and at the same time as other end-of-life decisions are being made, it may be desirable to have a single person who is authorised to consent to medical treatment as well as donation on behalf of the potential donor (see our discussion of pre-mortem interventions below).

7.33 A modern and inclusive list of substitute decision-makers that more closely aligns with substitute decision-making for medical treatment generally, is set out in s 13 of the *Health Care Decision Making Act 2023* (NT). The list creates a hierarchy, with s 14 of the Act giving decision-making priority to the first adult in the list, in decreasing order of priority from first to last. Adjusted to apply generally, without reference to other NT legislation, the list is:

a. a person with health care authority appointed by the person to whom the authority relates under an advance care directive;

b. a guardian of the person appointed under Guardianship legislation;

c. a relative of the person who is considered by Aboriginal or other customary law or tradition (of the person) to be the appropriate person to be a health care decision maker;

d. a spouse or de factor partner of the person who has a close and continuing relationship with the person;

e. a carer of the person who is not providing that care as a service on a commercial basis;

f. a child of the person who has a close and continuing relationship with the person;

g. a parent of the person who has a close and continuing relationship with the person;

h. a sibling of the person who has a close and continuing relationship with the person; or

i. a friend of the person who has a close and continuing relationship with the person.

7.34 This list may need to be tailored to the deceased donation context. Questions for us to consider include whether:

- a person's carer should have decision-making priority over some family relationships;
- an appointed guardian should have such a high priority;
- the need for culturally safe and appropriate decision-making is best achieved through this list; and
- the list is consistent with substitute decision-making frameworks in jurisdictions outside the Northern Territory.

7.35 We are seeking feedback about how the list should be tailored to the deceased donation context.

Conscious and competent donors

7.36 In the majority of situations, where a potential donor has suffered a devastating injury and does not have decision-making capacity, it is justified to consult with and give decision-making authority to the people closest to that person. It can help make sure that donation decisions reflect as much as possible what the person would have wanted. By comparison, a conscious and

34 NSW Organ & Tissue Donation Service, *Submission 40*; R Jenkin, *Submission 48*; Then and Martin (n 31) 112.

competent donor can be informed about donation and express their own preferences. Because patients in these circumstances have decision-making capacity, and access to medical advice and support, they may be in a better position than many people to make a fully informed decision about whether to donate.[35]

7.37 Presently, there are no legal barriers to tissue donation for voluntary assisted dying patients or other conscious and competent donors. Voluntary assisted dying legislation does not refer to tissue donation, and the HTAs do not refer to patients who access voluntary assisted dying. There have been cases in Australia where voluntary assisted dying patients have donated organs after their death,[36] and several states have provided policy guidance saying that voluntary assisted dying patients can donate organs.[37]

7.38 NHMRC Guidelines say that patients accessing voluntary assisted dying and patients with decision-making capacity who request the withdrawal of life-sustaining therapy are entitled to donate if they are clinically suitable.[38] OTA's best practice guidelines also contemplate situations where conscious and competent donors can donate organs after death.[39] However, deceased tissue donation in these circumstances can be controversial. There are ethical concerns that someone might seek voluntary assisted dying for the purpose of organ donation. The potential donor may feel pressured by a family member or friend in need of an organ transplant,[40] or feel unable to withdraw consent to voluntary assisted dying once they have agreed to donate organs.[41]

7.39 We have heard that there is a need to align tissue donation and voluntary assisted dying laws, and to make sure that people who choose to donate tissue and to die under voluntary assisted dying legislation are protected from coercion.[42] For example, it is important to protect the voluntariness of decision-making by separating the decision to end one's life from the decision to donate tissue.[43]

7.40 Canada and the Netherlands allow deceased tissue donation in this context and have national policy guidance to help end-of-life professionals protect voluntariness and minimise ethical risks.[44] There have been calls for similar guidance in Australia.[45] The NHMRC Guidelines cited earlier were updated recently. They provide guidance on ensuring the decision to end one's life is separated from the decision to donate tissue. They also call for:

> policies, staff training and other resources [to be put] in place so that requests for donation by people considering [voluntary assisted dying] are managed appropriately.[46]

35 Steven J Philpot, 'Organ Donation after Circulatory Death Following Voluntary Assisted Dying: Practical and Ethical Considerations for Victoria' (2018) 20(4) *Critical Care and Resuscitation* 254, 256; Downar et al (n 3) E609.

36 Jodi Gillott and Larna Woodyatt, 'Voluntary Assisted Dying and Organ Donation. A Collaborative Approach to Enable a Dying Wish' (2023) 32(2) *Transplant Journal of Australasia* 13; National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 211.

37 Government of Western Australia, WA Country Health Service, *Voluntary Assisted Dying Policy* (2025) 8; Department of Health (Tas), *Fact Sheet: Voluntary Assisted Dying and Organ and Tissue Donation After Death* (2024); donate life Victoria, *Organ Donation after Voluntary Assisted Dying (VAD) in Victoria Factsheet* 1 <https://www.donatelife.gov.au/sites/default/files/2023-09/2023-DLV-OrganDonationAfterVAD-Factsheet-FINAL.pdf>; 'End of Life Can Mean New Life', *Queensland Health* (8 February 2024) <https://www.health.qld.gov.au/newsroom/news/donate-life-vad>.

38 National Health and Medical Research Council (n 36) 210–11.

39 Organ and Tissue Authority, DonateLife (n 9) 4.

40 Australian Christian Lobby, *Submission 21*.

41 National Health and Medical Research Council (n 36) 210–12; Downar et al (n 3) E609.

42 Law Council of Australia, *Submission 61*.

43 Philpot (n 35) 256; Organ and Tissue Authority, DonateLife (n 9) 7; National Health and Medical Research Council (n 36) 210, 212.

44 Downar et al (n 3); Kim Wiebe et al, 'Deceased Organ and Tissue Donation after Medical Assistance in Dying: 2023 Updated Guidance for Policy' (2023) 195(25) *Canadian Medical Association Journal* E870; J Bollen et al, 'Organ Donation After Euthanasia: A Dutch Practical Manual' (2016) 16(7) *American Journal of Transplantation* 1967.

45 Philpot (n 35) 257. A recent inquiry in Western Australia recommended that the NHMRC and TSANZ develop ethical and clinical guidelines, followed by legislative amendments providing a legal right for people who access voluntary assisted dying to become organ and tissue donors after death: Standing Committee on Public Administration, Parliament of Western Australia (n 26) 99.

46 National Health and Medical Research Council (n 36) 211.

How our reform proposals could solve the problems

7.41 Consistent with the current HTAs, under **Proposals 23** and **25**, tissue donation can lawfully proceed if an individual consented, or if an authorised person provides valid consent on their behalf.

7.42 Our reform proposals differ from the current system in that:

- There is no requirement for authorisation by a Designated Officer. This makes consent and authorisation frameworks consistent, regardless of if a person dies in a hospital or elsewhere.
- An authorised decision-maker can be identified using a more expansive and culturally inclusive list of substitute decision-makers than the current 'senior available next of kin' hierarchy.
- The substitute decision-making process we propose should give more weight to the views of the donor than is sometimes the case with the current process. This is because an authorised decision-maker:
    - Can be someone appointed through an advance care directive as the first person in the hierarchy of substitute decision-makers, allowing people to appoint whoever they trust to uphold their wishes.
    - In the case of an adult donor, is required to make the decision they think the adult would have made in the circumstances.

7.43 **Proposal 23** provides that valid consent depends on a person having been informed about the nature and effect of tissue donation, and the intended uses of the removed tissue. This creates an informed consent threshold that does not currently exist in the HTAs. The threshold responds to concerns that donors and donor families are not always aware of the commercial nature of some types of tissue donation.

7.44 **Proposal 23** also responds to a concern that when people join the Donor Register, they may not understand the details of what deceased donation can involve.

7.45 For example:

- In some cases, withdrawal of a person's life-sustaining therapies may need to be timed so that coordinated donation and transplantation can occur. If this process is drawn out, it can be stressful and tiring for families, and delay the withdrawal of treatment.[47]
- Sometimes death needs to occur in an operating theatre with organ removal taking place almost immediately afterwards.[48] This can mean that families do not have much time to say goodbye.[49]

7.46 Most people joining the Donor Register will not be aware of these considerations. OTA has developed a detailed best practice guideline setting out the information that needs to be disclosed in particular donation contexts to make sure decision-making is informed and that donation goes smoothly.[50]

7.47 Once adults are fully informed about the implications of a decision to donate, their decision to donate their own tissue should provide the legal authority necessary for removal after their death of the specified tissue for the specified purpose(s). **Proposal 23** allows this to occur.

47 Organ and Tissue Authority, DonateLife (n 9) 7.
48 Ibid 8.
49 Ibid.
50 Ibid 8, 14.

7.48 For children and adults who do not have decision-making capacity (including adults who were not fully informed about donation at a time when they had decision-making capacity), our proposal requires that an authorised decision-maker makes an informed decision on their behalf.

7.49 The authorised decision-maker must have regard to the person's known values, beliefs, and preferences about donation (if any), and what the person would have wanted *in the circumstances*. While a person's previous decision to join the Donor Register would carry significant weight, if there is reason to think they would not have wanted donation to proceed in the circumstances that have arisen, then donation should not occur. **Proposal 23** therefore supports context-specific decision-making that protects preferences both for and against donation.

7.50 We are seeking input about whether our proposed approach strikes the right balance between respecting the dignity and autonomy of individuals, and the need to accommodate unforeseen circumstances, and respect for a deceased person's family and loved ones.

7.51 Given the importance of protecting voluntariness in decision-making by conscious and competent donors, **Proposal 23** also introduces a legal requirement that consent be made voluntarily. There are policy questions that are relevant to voluntary decision-making, such as whether donation should routinely be raised with conscious and competent people in end-of-life decision-making, and whether directed donation of an organ to a specific recipient should be allowed. **Proposal 24** therefore recommends that national protocols or guidelines be created to provide direction to end-of-life practitioners, and transparency around how donation in this context occurs.

Reforms relating to pre-mortem interventions

Pre-mortem interventions

Proposal 26

New human tissue legislation should define pre-mortem interventions to mean any activity, procedure or investigation that is performed on a living person solely for the purpose of tissue donation after death, including to assess, maintain, or improve the viability of organs for transplantation.

Question 21

Is the definition in **Proposal 26** an appropriate definition for pre-mortem interventions? Why or why not?

Proposal 27

New human tissue legislation should provide that a pre-mortem intervention is prohibited unless valid consent has been given to it. If the person to whom the intervention will be administered does not have decision-making capacity, valid consent can be provided by the person's authorised decision-maker (**Proposal 25**).

In determining whether to consent on behalf of an adult person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, and make the decision they believe the person would have made in the circumstances.

Question 22

We have heard that it is sometimes necessary to conduct a minor procedure such as a blood test to determine a person's suitability to donate tissue after their death, and that it may not be practical to obtain prior consent. Should new human tissue legislation contain an exception to the need for consent? If so, how should the exception be expressed, and what limits should there be on it?

Question 23

Should new human tissue legislation have any additional safeguards for the use of pre-mortem interventions beyond the need for valid consent? If so, what safeguards should it have?

The problems we are addressing

7.52 Pre-mortem interventions are performed to assist deceased donation. They can include imaging (such as a CT scan), blood and urine tests, or biopsies to understand if donation is possible, and medications. Pre-mortem interventions also extend to maintaining the function of a person's organs so the organs work well after being transplanted into the body of the recipient.[51]

7.53 There are different approaches to pre-mortem interventions in the HTAs. Most HTAs are silent regarding these interventions, but the Victorian and New South Wales HTAs have specific provisions defining pre-mortem interventions and imposing requirements that must be met for the interventions to be administered. The Victoria and New South Wales approaches differ in terms of definitions, consent and authorisation requirements, exceptions to the need for consent, and additional safeguards beyond consent. There is a need for consistency and clarity in the law about what constitutes an pre-mortem intervention and when it can be administered.

7.54 The invasiveness and risk for donors of pre-mortem interventions varies depending on the intervention. Because the interventions are not performed for the medical benefit of the donor, they differ from ordinary medical treatment and may require additional safeguards to protect the intended donor. Problematic issues arise as to:

- How pre-mortem interventions should be defined;
- Whether explicit consent for pre-mortem interventions should be required;
- Whether all pre-mortem interventions should require consent;
- Who should provide consent;
- The basis on which a substitute decision-maker should provide consent; and
- Whether there is a need for legislative safeguards in addition to consent to limit or provide oversight of the use of pre-mortem interventions.

Background to the problems

7.55 As pre-mortem interventions are not performed for the benefit of intended donors, there is a need to balance competing considerations. On the one hand, the system must consider risks to the donor and the danger of undermining public trust in the organ donation system; and on the other hand, consider benefits to recipients, and the need to give effect to the donation decision. We have heard that this is a high priority issue for stakeholders, who have identified a need to:

- clarify the consent process and legal permissibility of pre-mortem interventions;[52]

51 Ibid 9–10.
52 Law Council of Australia, *Submission 61*.

- harmonise consent and authorisation frameworks for medical treatment, pre-mortem interventions, and deceased donation;[53] and
- harmonise the law relating to pre-mortem interventions nationally to help make sure people have an equal opportunity to donate regardless of where they live.

7.56 Some people have advocated for an approach that facilitates the ability to administer pre-mortem interventions,[54] while others have expressed a need for caution, with concerns that it may not be in a dying person's interests to prolong their life, or subject them to additional procedures.[55]

Legal permissibility

7.57 As discussed earlier, a person who does not have decision-making capacity might have a substitute decision-maker whose role is to make health care decisions on their behalf. This may or may not be the same person who is authorised under an HTA to make donation decisions on their behalf.

7.58 Because pre-mortem interventions are not performed for the donor's medical benefit, there is doubt in some jurisdictions about whether a substitute decision-maker has the legal authority to consent to them. For example, under the *Guardianship Act 1987* (NSW), substitute decision-makers must consider if any medical treatment is 'for the purpose of promoting and maintaining [the] health and well-being' of the person for whom they are a decision-maker.[56]

7.59 New South Wales and Victoria have amended their HTAs to provide a legal basis to administer some interventions. Queensland is considering an amendment to its HTA.[57] There are concerns about how each jurisdiction has reformed human tissue laws relating to pre-mortem interventions, which we discuss below.

Definition of pre-mortem interventions

7.60 The New South Wales legislation defines pre-mortem interventions to mean a specified list of procedures performed to determine, maintain or improve the viability of tissue for a relevant purpose.[58] This approach could create confusion and doubt about the legality of procedures not on the list.

7.61 The New South Wales definition specifies that pre-mortem interventions are procedures 'other than normothermic regional perfusion' (NRP).[59] However, the logic of this provision is unclear, because NRP is performed after a person has died, while pre-mortem interventions are performed before death.

7.62 There is no universal definition of an pre-mortem intervention,[60] but we have heard that it is important to have a broad definition covering the range of actions that might be undertaken solely for the purpose of donation.

Consent as a safeguard for pre-mortem interventions

7.63 Because pre-mortem interventions do not have any therapeutic benefit for the donor, it is important that they are administered with clear legal authority and within ethical parameters. One of the purposes of **Proposals 26** and **27** is to clarify the law to enable pre-mortem interventions

53 Ibid. See also Then and Martin (n 39).
54 NSW Organ & Tissue Donation Service, *Submission 40*.
55 Department of Health for Western Australia, *Submission 23*.
56 *Guardianship Act 1987* (NSW) ss 32(b), 40(3).
57 Queensland Health, 'Health Legislation Amendment Bill (No. 3) 2025 Consultation Paper' <https://www.health.qld.gov.au/__data/assets/pdf_file/0029/1460873/2025-health-legislation-amendment-bill-3.pdf>.
58 *Human Tissue Act 1983* (NSW) s 27B.
59 Ibid.
60 Organ and Tissue Authority, DonateLife (n 9) 9.

to be administered. Part of the justification for allowing pre-mortem interventions is that they can only be administered with consent.

7.64 There are remaining questions, however, as to who should consent, how decisions should be made, whether exceptions to consent are justified, and whether safeguards beyond consent are needed. These issues are discussed below.

Substitute decision-making

7.65 Often, donors will not have decision-making capacity to consent to pre-mortem interventions themselves. It is therefore important to clarify who can act as a substitute decision-maker. As discussed above, there is presently an inconsistency between the people listed in the HTAs as 'senior available next of kin' with responsibility for deciding about donation, and the hierarchy of people who may be authorised to make medical decisions on behalf of a person who does not have decision-making capacity.

7.66 The Victorian approach to resolving this inconsistency has been to authorise the 'medical treatment decision-maker' to consent to pre-mortem interventions.[61] However, this may create an inconsistency with the person consenting to donation. The New South Wales approach has been to authorise the 'senior available next of kin' to consent to pre-mortem interventions,[62] so there is consistency between decision-making frameworks for deceased donation and pre-mortem interventions. However, this may create an inconsistency with the person who is authorised to consent to medical treatment. Ideally, there should be consistency across all three decision-making contexts.

7.67 The New South Wales legislation provides that the senior available next of kin must not provide consent to pre-mortem interventions unless they are satisfied that there is no reason to believe the potential donor expressed an objection.[63] The Victorian legislation does not have a similar provision, and there is no additional guidance in either Act about the basis on which the decision-maker should make a decision.

7.68 Options to assist substitute decision-making in this context include using:

- a 'best interests' approach, where a decision is made on the basis of what is best for the person; or
- a 'substituted judgment' approach, where a decision is made on the basis of what the person would have chosen for themselves.[64]

7.69 It is possible that a broad interpretation of 'best interests' could allow a substitute decision-maker to consent to pre-mortem interventions. For example, because it is in someone's interests to have their altruistic values realised, or their post-mortem wishes about their bodies carried out. However, this approach may be one where considerations of a person's physical wellbeing tend to outweigh other considerations.[65]

7.70 In contrast, a substituted judgment approach requires consideration of what the person would have wanted in the circumstances. This approach may be imprecise and difficult to apply given that a person's specific preferences for pre-mortem interventions may not be known. However, this approach enables consideration of a person's broader values, beliefs, and preferences to help guide the decision-making process.

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61 *Human Tissue Act 1982* (Vic) s 24B(2).
62 *Human Tissue Act 1983* (NSW) s 27C(2).
63 Ibid s 27D.
64 For a discussion of the different approaches in the pre-mortem intervention context, see Shih-Ning Then et al, 'Decision-Making about Premortem Interventions for Donation: Navigating Legal and Ethical Complexities' (2023) 107(8) *The Transplantation Society* 1655, 1659–60.
65 Ibid 1660.

Situations where it may not be practical to obtain consent

7.71 Guidelines in Australia provide that if, after consulting available medical information, tests are required to determine if a person who is near death could donate organs, the tests 'should only occur after the family (or patient) has provided consent to donate'.[66] But we have heard:

- it may not always be practical to obtain consent for pre-mortem interventions, particularly in regional areas; and
- early blood testing is important, as it can avoid significant delays that could frustrate the donation process.

Implied consent

7.72 As a general principle of medical law, consent does not need to be explicit to be valid. Consent can be implied in some circumstances.[67]

7.73 For example, best practice guidelines provide that once consent has been provided for deceased donation after a circulatory determination of death (DCDD),[68] specific consent is not required for some minimally invasive and common tests undertaken in an intensive care unit.[69] But for more invasive, risky, or unusual types of procedures, specific consent should be obtained.[70]

7.74 **Proposal 27** requires consent for pre-mortem interventions to be lawful. It does not require that consent be explicit. Generally, the validity of consent depends on whether it was given voluntarily by someone with decision-making capacity, and whether it covers the act to be performed.[71] It is possible that consent to DCDD covers consent to any minor tests needed to facilitate the donation, although this is a context-specific question. **Proposal 27** is potentially consistent with the best practice guidelines by allowing a context-specific determination of whether consent to DCDD implies consent to particular pre-mortem interventions.

7.75 Whether a person's expressed intention to donate by joining the Donor Register, as opposed to a specific consent to DCDD, would imply consent to pre-mortem interventions is more controversial. While it is possible to interpret a registered decision as implying a consent to some minor interventions,[72] the validity and scope of implied consent in this context is debateable.[73] Given the need for clarity in this area and what we have heard about there being a need to perform early blood tests on people irrespective of whether they have expressed a desire to donate, we are seeking input on whether legislation should provide an exception to the need for consent.

66 Organ and Tissue Authority, DonateLife (n 9).
67 Bernadette Richards, 'General Principles of Consent to Medical Treatment' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 142.
68 Donation after CDD requires different steps to be taken by comparison with donation after a neurological determination of death – which is often referred to as 'brain death'.
69 Organ and Tissue Authority, DonateLife (n 9) 10.
70 Ibid.
71 Richards (n 67) 143.
72 Then et al (n 64) 3.
73 Renée Taillieu et al, 'Pre-Mortem Interventions for the Purpose of Organ Donation: Legal Approaches to Consent' (2024) 52(1) *Journal of Law, Medicine & Ethics* 7, 10 ('Pre-Mortem Interventions for the Purpose of Organ Donation').

Table 5: Pre-mortem interventions — examples of models that allow for exceptions to consent, or where consent is implied

Jurisdiction	Model
Scotland	Regulations made under legislation in Scotland (which is an opt-out jurisdiction) provide two categories of interventions (Types A and B) and allow interventions specifically listed under Type A (which are low risk and not invasive) to be administered without explicit consent if the person previously consented or failed to opt-out of donation.[74]
New South Wales	A Designated Officer is required to authorise pre-mortem interventions. The relevant decision maker must provide consent to the intervention before the Designated Officer can authorise it.[75] But a Designated Officer can authorise the intervention without specific consent to the intervention if: • there are no known senior available next of kin; • the potential donor provided written consent to tissue removal for the intended purpose; • the consent has not been revoked; and • the potential donor had not objected to the carrying out of the intervention.[76]
Victoria	A Designated Officer is required to authorise pre-mortem interventions. The relevant decision-maker must provide consent to the intervention before the Designated Officer can authorise it.[77] But the Designated Officer can authorise the interventions without consent if: • the medical treatment decision-maker cannot be located; and • there is no reason to believe the potential donor would have objected to the carrying out of the procedures.[78]

7.76 We are interested to know whether any of these options would be a good choice for new human tissue legislation, appropriately adjusted to account for the removal of the Designated Officer role. For example, a medical practitioner who is not involved in the removal of tissue could fulfil the Designated Officer role.

Safeguards in addition to consent

7.77 There are a range of safeguards in addition to consent in legislation in Australia and overseas.

7.78 Both Victoria and New South Wales have requirements that the donor be close to death before administering pre-mortem interventions. In Victoria, the Designated Officer can only authorise pre-mortem interventions if two medical practitioners certify in writing that, in their

74 Ibid 12.
75 *Human Tissue Act 1983* (NSW) s 27C; *Human Tissue Act 1982* (Vic) s 24B(2).
76 Ibid.
77 *Human Tissue Act 1982* (Vic) s 24B(2).
78 Ibid s 24E.

opinion, the removal of life-sustaining therapy will result in the person's death.[79] This has caused concern amongst medical professionals, as the withdrawal of life-sustaining therapy is not generally regarded in law or ethics as causing death, but instead as allowing a person to die from their underlying medical condition.[80] In contrast, the New South Wales legislation requires that a medical practitioner certify that the death of the potential donor is imminently expected.[81]

7.79 The New South Wales legislation also provides that a Designated Officer cannot authorise any interventions unless they are reasonably satisfied that authorisation for donation will be given and the carrying out of the intervention will not hasten the person's death, cause more than minimal harm to the person, or cause undue risk to the person.[82]

7.80 In Switzerland, legislation prohibits interventions that hasten a person's death or that may cause a person to fall into a permanent vegetative state.[83] In Scotland, there is a requirement that interventions only be administered if they are necessary to determine whether the person can donate, or to optimise the chance of a successful transplant, and are 'unlikely to cause more than minimal discomfort or harm to the patient'.[84] We are seeking input on whether any of these (or other) legislative safeguards should be incorporated into new human tissue legislation.

How our reform proposal could solve the problems

7.81 **Proposal 26** defines pre-mortem interventions broadly. The definition in **Proposal 26** is generally consistent with recent commentary published in the *Medical Journal of Australia*.[85] Rather than fixing specific interventions in legislation, this approach is broad enough to capture a wide range of activities. **Proposal 27** clarifies that these interventions are lawful with consent, and it is intended that this provision would override any restrictions to the contrary in guardianship or medical treatment legislation. Collectively, these proposals will facilitate consistent access to pre-mortem interventions across Australia.

7.82 This approach is justified provided that the interventions are administered with consent. We are still exploring in **Questions 22** and **23** whether exceptions to consent should be included in the legislation and whether additional legal safeguards beyond consent are needed. These are important considerations in developing an approach to pre-mortem interventions that both functions well and maintains a high level of public trust.

7.83 **Proposal 27** also specifies the authorised decision-maker should use a substituted judgment approach, which enables a potential donor's known preferences, values, and beliefs to guide decision-making. By allowing the authorised decision-maker to consent, there will be consistency between decision-makers for pre-mortem interventions and deceased donation. And because the authorised decision-maker hierarchy (**Proposal 25**) generally aligns with hierarchies for medical decision-makers, there should be alignment in most cases between the decision-maker for pre-mortem interventions and the decision-maker for other medical decisions.

79 Ibid s 24D.
80 Steve Philpot and David Anderson, 'The Ethical and Legal Implications of the Human Tissue Amendment Act 2020 (Vic)' (2021) 23(3) *Critical Care and Resuscitation* 245.
81 *Human Tissue Act 1983* (NSW) s 27C(3)(b)(i).
82 Ibid s 27C(3).
83 Taillieu et al (n 73) 12.
84 Ibid.
85 Shih-Ning Then, Dominique E Martin and Helen I Opdam, 'Ante-mortem Interventions for Deceased Donation: Legal Barriers and Uncertainty in Australia's Decision-making Frameworks' (2025) 223(5) *Medical Journal of Australia* 236, 238 ('Ante-mortem Interventions for Deceased Donation').

Reforms relating to removal of tissue from deceased bodies

Respectful and dignified treatment of deceased body

Proposal 28

New human tissue legislation should provide that, when removing tissue from a deceased body, any person involved in the removal must treat the body with the highest level of respect and dignity that is practicable in the circumstances.

Proposal 29

New human tissue legislation should provide a mechanism enabling medical practitioners and authorised technicians to remove certain types of tissue from deceased bodies, including musculoskeletal, cardiovascular, eye and skin tissue.

The National Regulator (or alternative) should by delegated legislation specify the relevant qualifications required for technicians, and any additional type of tissue that technicians are authorised to remove.

The problems we are addressing

7.84 In current legislation, there are some provisions that require anyone removing tissue from a deceased body to be a medical practitioner. These provisions:

- are inconsistent between jurisdictions, with each HTA having its own rules about who can remove different types of tissue; and
- create barriers to donation of tissue other than solid organs because it can be very difficult to find qualified medical practitioners available for this purpose.

7.85 However, there is concern among donor families that their loved ones' bodies may not be treated with dignity and respect if people who are not medically qualified are authorised to remove tissue.

Background to the problems

7.86 Some HTAs are silent on the issue of who can remove tissue; some require that anyone who removes tissue is a qualified medical practitioner;[86] and others generally require a medical practitioner but also allow for other authorised people to remove certain types of tissue.[87] In the HTAs that allow people other than medical practitioners to remove tissue, there is inconsistency in relation to what types of tissue can be removed.[88]

7.87 We have heard support for allowing more people to be authorised to remove tissue. We have been told that the requirement to have a medical practitioner present has meant that in some cases donation cannot proceed,[89] and that the sustainability of the tissue sector requires an expansion of the people qualified to remove tissue.[90]

86 See *Transplantation and Anatomy Act 1979* (NT) s 22; *Human Tissue Act 1985* (Tas) s 26.
87 See *Human Tissue Act 1983* (NSW) s27(1A); *Transplantation and Anatomy Act 1983* (SA) s 24.
88 See Australian Law Reform Commission, *Review of Human Tissue Laws* (Issues Paper No 51, 2025) 14.
89 Department of Health for Western Australia, *Submission 23*.
90 Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand, *Submission 81*.

How our reform proposal could solve the problems

7.88 **Proposals 28** and **29** will provide a consistent national approach and facilitate tissue donation in Australia by expanding the range of people qualified to remove tissue. At the same time, **Proposal 28** requires anyone removing tissue from a deceased body to treat the body with respect and dignity. And the creation of a minimum set of qualifications under **Proposal 29** will ensure there is a baseline standard of training and experience that technicians must achieve before removing tissue from a deceased body. Training and experience will likely facilitate the capacity for technicians to carry out their functions while treating the deceased body with the respect and dignity required by **Proposal 29**.

Reforms relating to coronial consent to donation

Coronial consent to donation

Question 24

Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?

The problems we are addressing

7.89 Under the HTAs, if a death is reportable to the coroner, tissue donation can only proceed with the consent of the coroner. The coroner's decision is generally influenced by advice from a forensic pathologist about whether donation might interfere with the coroner's investigation into what caused the person's death. A coroner generally has legal expertise while a forensic pathologist has medical expertise.[91]

7.90 We have heard that sometimes forensic pathologists advise against donation, and coroners may refuse to consent to donation, or delay providing consent, even though the donation is unlikely to interfere with the coroner's investigation.[92] However, we have also heard about strong and collaborative relationships between coroners and donation teams, which can facilitate deceased donation while ensuring the work of the coroner is not compromised.

Background to the problems

7.91 According to OTA, 'approximately 50% of all organ donors have a cause of death that is reportable to the coroner and, in the vast majority, the coroner places no limitations on donation'.[93] However, we have heard that there is considerable variation in coroners' refusal rates between jurisdictions.

7.92 A study conducted in Queensland from 2009-13 found that in 6% of cases where coronial consent for donation was sought, forensic pathologists recommended that restrictions be placed on organs that could be donated.[94] The study authors noted that although refusal is infrequent, it leads to 'the loss of a small but significant number of transplantable organs'.[95]

91 Leo Nunnink et al, 'Does Organ Donation Impact on Forensic Outcomes? A Review of Coronial Outcomes and Criminal Trial Proceedings' (2019) 68 *Journal of Forensic and Legal Medicine* 101860, 5.
92 H Northam, *Submission 86*.
93 Organ and Tissue Authority, DonateLife (n 9) 9.
94 Nunnink et al (n 91) 5.
95 Ibid.

7.93 A 2024 Western Australia parliamentary report noted anecdotal evidence that coroners' refusals in Western Australia were increasing. It made recommendations to collect data on requests and refusals of coroner consent.[96]

7.94 To strengthen national consistency, some coroners and medical practitioners involved in donation have suggested that it may be useful to create an obligation for coroners to consider specific factors when making a decision about whether to consent, for example:

- the forensic needs of the investigation;
- the public benefit of organ and tissue donation; and
- the wishes of the proposed donor.

7.95 Internationally, a range of measures have been introduced to reduce rates of coronial refusal, including guidelines, protocols, legislation, and promotion of 'closer communication' between coroners and donation teams.[97]

7.96 Some in this field have noted that efforts to improve communication and collaboration may be more effective than legislation or the development of protocols.[98]

7.97 We are therefore seeking input about whether a legislative approach requiring coroners to consider listed factors is a good idea, and if so, what factors a coroner should take into account when considering deceased donation.

Reforms relating to consent for non-coronial post-mortem examinations

Authorisation for non-coronial post-mortem examination

Proposal 30

New human tissue legislation should provide that it is lawful to conduct a post-mortem examination on the body of a deceased person if the deceased person's authorised decision-maker has given valid consent to it.

In determining whether to consent on behalf of a deceased person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, about the treatment of their body after death.

Question 25

Should new human tissue legislation allow for an individual to provide their own consent while alive to a post-mortem examination?

Question 26

Should new human tissue legislation contain an exception to the need for an authorised decision-maker to provide valid consent to a post-mortem examination; for example, if the authorised decision-maker cannot be located?

96 Standing Committee on Public Administration, Parliament of Western Australia (n 26) 94–5.
97 Leo Nunnink and Chelsea Wallace-Dixon, 'The Impact of Organ Donation on Coronial Processes and Forensic Investigation: A Literature Review' (2020) 71 *Journal of Forensic and Legal Medicine* 101940, 3.
98 Ibid.

The problems we are addressing

7.98 A non-coronial post-mortem examination, also known as a 'consented' post-mortem, is an autopsy performed with the authorisation of a deceased person's next of kin or other lawful decision-maker, rather than under the direction of a coroner.[99]

7.99 These examinations require valid consent, and may be subject to conditions imposed by the family — for example, limiting the scope of the examination or excluding the removal of particular organs. The HTAs set out requirements for the conduct of non-coronial post-mortem examinations, including in relation to consent, permissible practices, and use of tissue samples. The HTAs apply the same framework for consent to non-coronial post-mortem examinations as apply to deceased tissue donation for transplantation. Our reform proposal for consent to deceased donation (**Proposal 23**) gives primacy to a deceased person's wishes, or their beliefs, values, and preferences if a decision-maker is consenting on their behalf, and requires the decision-maker to make the decision they think the deceased person would have made in the circumstances.

7.100 Unlike in tissue donation, where there is a concern about a family overriding an individual's known preference to donate tissue after death, a post-mortem examination is often requested by the family of the deceased and performed to provide the family additional information. Given the post-mortem examination is done for the family's benefit, it is appropriate for them to have a greater say about whether this type of examination should proceed.

7.101 However, a purpose of reforming current deceased donation provisions is to give greater effect to the wishes of an individual in relation to what happens to their body after death. So, if an individual has expressed an objection to a post-mortem examination or a preference about how they want their body to be treated that is inconsistent with a post-mortem examination, then their authorised decision-maker should have primary regard to these views.

Background to the problems

7.102 Non-coronial examinations are generally requested by treating doctors, hospitals, or family members to:

- clarify the cause of death where it is not legally reportable but remains uncertain;
- advance medical knowledge and education;
- provide information relevant to family members, such as possible genetic risks; or
- contribute to clinical audit and research.[100]

7.103 National ethical guidelines state that:

> A non-coronial autopsy can only be carried out with the permission of the next-of-kin…the family must be consulted and given the opportunity to be involved to whatever extent they wish to be… [and] the wishes of the deceased and the family in regard to the autopsy examination should be accommodated as far as possible.[101]

How our reform proposals could solve the problems

7.104 By giving decision-making authority to a deceased person's authorised decision-maker, **Proposal 30** recognises that the post-mortem examination is being done for the benefit of a deceased person's family. However, it is more likely that consent to the examination will then

99 See, eg, *Human Tissue Act 1982* (Vic) pt V.
100 Bianca Phillips et al, 'The Coronial System and Determining Manner of Death in Australia -An Overview' (2015) 5(3) *Academic Forensic Pathology* 436.
101 The Australian Health Ministers' Advisory Council, *The National Code of Ethical Autopsy Practice*.

not be given if conducting the examination is inconsistent with the deceased person's expressed wishes, or the beliefs, values, and preferences that they held before they died.

Consent to use tissue removed during a post-mortem examination

Use of tissue removed during a post-mortem examination

Proposal 31

New human tissue legislation should provide that tissue removed during a post-mortem examination cannot be used for any purpose other than the post-mortem examination unless valid consent under **Proposals 23** or **36** has been given to use the tissue for another purpose.

Question 27

Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?

The problems we are addressing

7.105 Current legislation differs between jurisdictions about whether consent to a post-mortem examination authorises the use of tissue removed during the examination for unrelated purposes. In some jurisdictions, specific consent to use tissue removed during a post-mortem examination for therapeutic, medical, or scientific purposes is required,[102] and in others it is not.[103] In the New South Wales and Queensland HTAs, there are specific 'small samples' and 'specimen tissue' exemptions that mean very small amounts of tissue removed during a post-mortem examination can be used for other purposes without consent.[104]

7.106 Using tissue removed during a post-mortem examination for other purposes without specific consent is problematic because information is not provided to the deceased person's family about how long the tissue may be stored, what it may be used for, and whether it can be transferred for use by others.[105] Even if consent has been provided to a post-mortem examination, using tissue removed as part of the examination for unrelated purposes, such as research, without consent undermines trust in both forensic and research institutions.[106]

7.107 On the other hand, it can be particularly useful for researchers to access large collections of human tissue samples, such as those stored by pathology laboratories (we discuss research uses of human tissue in more detail in **Chapter 8**). The New South Wales and Queensland exceptions to the need for consent for small samples apply to tissue 'retained in the form of a tissue slide or tissue block which enables microscopic examination of the tissue'.[107] However,

102 *Transplantation and Anatomy Act 1983* (SA) s 27; *Human Tissue Act 1985* (Tas) s 26C.
103 *Human Tissue Act 1982* (Vic) s 30(2); *Human Tissue and Transplant Act 1982* (WA) s 28(2).
104 *Human Tissue Act 1983* (NSW) ss 31A, 34(1)(b1); In the Queensland Act, the exemption applies to 'specimen tissue', which is defined to mean 'a small sample of tissue kept in the form of a tissue block or slide...[for] microscopic examination', or 'tissue taken from the tissue block'. It does not include 'a large proportion of the totality of an organ ... or human foetus."' *Transplantation and Anatomy Act 1979* (Qld) ss 29(2), (8).
105 Prue Vine, 'The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-Mortem Examination' (2007) 29 *Sydney Law Review* 235.
106 For discussion of controversy that has arisen in relation to the use of tissue removed during post-mortem examinations for scientific purposes: 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).
107 *Human Tissue Act 1983* (NSW) s 34(1)(b1); *Transplantation and Anatomy Act 1979* (Qld) s 29(8).

there are other methods of storing tissue, such as liquid biopsies or frozen tissue, that are not captured by these definitions.[108]

How our reform proposals could solve the problems we have identified

7.108 **Proposal 31** will provide nationally consistent regulation of the use of human tissue removed during post-mortem examinations. Our proposal makes it clear that consent to a post-mortem examination does not include consent to use tissue for any other purposes. Instead, consent must be obtained under **Proposals 23** or **36**, which require that the person consenting be informed about how the tissue is to be used. These proposals respect individual autonomy by allowing for informed decision-making and will help maintain public trust in forensic and research institutions. By including this proposal in new human tissue legislation, consistency across jurisdictions will also be achieved.

7.109 To facilitate scientific research, we are considering whether an exception should exist to the need for consent for 'small samples'. It can be very difficult for researchers to contact tissue providers to obtain their consent to access samples from pathology collections. This is even more difficult where the provider is deceased, as an authorised next of kin would need to be identified and contacted. For this reason, we are seeking feedback in **Question 27** about whether an exception to the need for consent should exist, and if so, what its scope should be. For example, rather than focussing on the method of storage (tissue blocks or slides), it may be better for it to apply to types of collections (such as pathology collections). In answering this question, you may want to also consider **Questions 31** and **32**, which ask more broadly about whether consent should be required to use stored tissue for scientific, medical or educational purposes.

108 Children's Medical Research Institute, *Submission 20*.

8. Reforms relating to tissue donation for research

Contents

Terminology: medical, educational or scientific purposes

8.1 The HTAs use different terminology to refer to the purposes for which human tissue and deceased bodies can be donated. Different parts of different Acts enable donation for anatomical examination, therapeutic purposes, medical purposes, research, and scientific purposes.

8.2 In our proposals about consent and authorisation for living donation (**Proposals 14**, **17** and **20**) and deceased donation (**Proposal 23**), we have deliberately referred broadly to a person's ability to donate for medical, educational or scientific purposes. Because the activities these terms can encompass are overlapping, we have not defined each term separately. Instead, our intention is for them to apply to a broad range of potential activities. For example, 'medical, educational or scientific purposes' would include, among other things, the:

- use of human tissue or bodies to help medical students learn about anatomy;
- removal of tissue from one person's body and the transplantation of the tissue into the body of another person;
- use of tissue in therapeutic products; and
- use of tissue for training, quality control, equipment calibration, or process validation in connection with a medical, educational or scientific purpose.

8.3 In this chapter, we specifically address research. Research is one type of medical, educational or scientific purpose that, in some contexts, requires specific legal rules. This is for a number of reasons, including that:

- traditional requirements for 'informed consent' do not always work well when donating tissue for research;
- unlike donation for clinical purposes, there is some expectation that research participants maintain ongoing control over their tissue, such as through a right to withdraw their participation in research; and
- the types of risks that living participants take on are often privacy-based rather than physical in nature.

8.4 Our proposals here relate specifically to tissue donation for research. The consent and authorisation requirements set out in this section apply to tissue donation for research only; they are separate from the consent and authorisation requirements for other living or deceased tissue donation.

Consent by living participants

Adults

Consent and authorisation for tissue removal for research – living persons

Proposal 32

New human tissue legislation should provide that:

1. An adult may give valid consent to the removal of tissue from their body for the purpose of research;
2. Valid consent is:
    a. given voluntarily;
    b. given at a time when the adult who is consenting has decision-making capacity;
    c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal;
    d. given after the adult who is consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and
    e. able to be withdrawn in accordance with **Proposal 33** or at any time before the removal of the tissue.
3. Valid consent is sufficient legal authority for the removal of the specified tissue for the intended research use(s); and for other research use(s) in accordance with **Proposal 33**.

Proposal 33

New human tissue legislation should provide that:

1. when consent is provided under **Proposal 32** in circumstances where all the specific research uses for the tissue are not yet known:
    a. the person providing their tissue has a right to access information about how their tissue is being used, if at the time of the information request the sample is identifiable or, if it has been deidentified, is re-identifiable;
    b. the person providing their tissue has a right to withdraw consent for any future research uses, if at the time of the consent withdrawal:
        i. the tissue remains usable; and
        ii. the sample is identifiable or, if it has been deidentified, is re-identifiable.
2. If consent for future research uses is withdrawn, any unused tissue must be discarded.

Proposal 34

New human tissue legislation should provide that tissue removed from a person's body for research in accordance with **Proposal 32** must be removed, and the research conducted, in a manner that is consistent with the Australian Code for the Responsible Conduct of Research[1] and the National Statement on Ethical Conduct in Human Research (the National Statement).[2]

If there are any inconsistencies between new human tissue legislation and the Australian Code for the Responsible Conduct of Research or the National Statement on Ethical Conduct in Human Research, the terms of the legislation should prevail.

The problems we are addressing

8.5 Our review of human tissue regulation almost fifty years ago did not specifically consider the donation of human tissue for research, primarily because using human tissue in laboratories was not common practice at that time.[3] Since the 1980s, the research demand for human tissue has increased dramatically,[4] and research using human tissue has helped advance our understanding of human biology, pathology, and therapeutic responses.

8.6 Human tissue is important in translational research which bridges the gap between laboratory discoveries and clinical application. Reliable research access to human tissue is therefore crucial to advances in medical science. To be ethical, this access must be reconciled with respect for individual dignity and autonomy, bodily integrity, privacy, and cultural considerations. However, excessive or poorly harmonised regulation can restrict research, delay discoveries, and waste specimens. The central regulatory challenge is therefore to design legislation that protects individuals without imposing disproportionate barriers that restrict socially and medically valuable research.

8.7 Research biobanks often collect tissue specimens from participants who broadly consent to a range of potential future research uses, or to any future research use whatsoever, rather than to a specific research study. Problems with broad or unspecified consent may include that:

- consent is treated as a static event achieved at a single point in time, as opposed to an ongoing process that should be maintained;
- participants' right to withdraw consent cannot be meaningfully exercised if participants do not know how their tissue is being used; and
- it does not accommodate a change in research participants' preferences, should they choose to alter or withdraw their consent.

8.8 For these reasons, although it has emerged as the dominant consent model in research biobanking, broad or unspecified consent is controversial.[5] There is debate about if this kind of consent is permissible and legal, even though it is frequently used.[6]

1 National Health and Medical Research Council, Australian Research Council and Universities Australia, *Australian Code for Responsible Conduct of Research* (2018).
2 National Health and Medical Research Council, Australian Research Council and Universities Australia, *The National Statement on Ethical Conduct in Human Research* (2025).
3 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977).
4 Jean-Paul Pirnay et al, 'Access to Human Tissues for Research and Product Development' (2015) 16(5) *EMBO reports* 557.
5 Søren Holm and Bjorn Reino Olsen, 'Ethics in Human and Animal Studies' in Peter Laake, Haaken Breien Benestad and Bjorn Reino Olsen (eds), *Research in Medical and Biological Sciences* (Elsevier, 2015) 53, 55.
6 Timothy Caulfield and Blake Murdoch, 'Genes, Cells, and Biobanks: Yes, There's Still a Consent Problem' (2017) 15(7) *PLOS Biology* 1.

8.9 As discussed in **Chapter 6**, current HTAs also differentiate between regenerative tissue, non-regenerative tissue, and blood, and many HTAs only allow adults to donate non-regenerative tissue or blood specifically for research. This restriction creates a barrier to research that is out of step with contemporary research uses of tissue.[7] While the restriction is designed to protect people from harm, not every removal of non-regenerative tissue is so dangerous that it should be legally prohibited. Instead, a more nuanced assessment is needed that imposes restrictions proportionate to the risk of harm faced by participants.

Background to the problems

8.10 Consent establishes a person's voluntary agreement to an action or decision that affects their rights, body, or property, making the action lawful and providing legal liability protection. Consent is important as a safeguard of individual autonomy.

8.11 **Informed consent** means that a person agrees to something after receiving clear, specific, and relevant information about what will happen, why it is being done, the risks and benefits, and any alternatives. It is typically tied to a clearly defined activity, such as a specific medical procedure or research project, and the person's decision is based on an understanding of that particular context.[8]

8.12 **Broad or unspecified consent** allows the use of a person's data, tissue, or participation for a wider range of future activities that may not be fully known at the time of consent. For example, consent for tissue samples to be stored and used in future studies that have not yet been designed. While broad consent provides more flexibility for researchers, it gives participants less detailed knowledge about exactly how their contribution will be used, which raises additional ethical and legal concerns about autonomy and the need for ongoing oversight.[9]

8.13 For donations to research biobanks, broad or unspecified consent has emerged as the status quo.[10] This means that people can consent to use of their tissue in specific categories of research (broad consent), or any future research (unspecified consent). These types of consent mean that the tissue can be stored and transferred to researchers for future research without having to contact the research participant for consent each time their sample is used. While participants are generally informed, to the extent possible, about the types of projects that might make use of their samples, it is not possible to provide specific information as it is not known at the time of tissue collection which studies will be using their samples. As a result, there has been a longstanding debate about whether broad or unspecified consent meets the legal standard required for 'informed' consent.

How our reform proposals could solve the problems we have identified

8.14 Despite the ongoing debate about the ethics and legality of broad consent, many ethical guidelines, including the National Statement, endorse specific, extended, and unspecified consent.[11]

8.15 Unlike traditional medical research, such as a clinical trial, research using stored tissue samples does not involve any ongoing physical risk to participants. For this reason, it may be justifiable to have different consent requirements for using tissue in research. However, an individual's right to be informed about and have control over how their tissue is used should be recognised to the greatest extent possible.

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7 R Balleine, *Submission 17*; Children's Medical Research Institute, *Submission 20*.
8 Peter H Schuck, 'Rethinking Informed Consent' (1994) 103(4) *The Yale Law Journal* 899.
9 John W Maloy and Pat F Bass, 'Understanding Broad Consent' (2020) 20(1) *Ochsner Journal* 81.
10 Holm and Olsen (n 5).
11 National Health and Medical Research Council, Australian Research Council and Universities Australia (n 2) 19.

8.16 Our reform proposals aim to strike an appropriate balance between enshrining ethical principles (including respect for autonomy, transparency, and voluntariness), and human rights (such as human dignity, liberty and security of the person, and privacy), while avoiding unnecessary restrictions to scientific progress.

8.17 **Proposals 32** and **33** are designed to:

- Provide clarity and certainty for researchers by legitimising broad and unspecified consent. This is the aim of **Proposal 32**, which would enable valid consent to be given after a participant is informed about how their tissue is intended to be used, insofar as the intended uses are known at the time the tissue is removed; and
- Recognise and respect the interests of research participants by enshrining their rights to withdraw from research, and to access information about how their tissue is being used, if this information is available. The right to withdraw would only apply to future research uses rather than research that might be using the tissue at the time of the request, to ensure the validity and integrity of studies relying on the initial consent.

8.18 Confirming the legal validity of broad or unspecified consent would also harmonise the law with the National Statement.[12]

8.19 **Proposal 32** would allow for the donation of tissue regardless of whether it is regenerative or not. Rather than excluding categories of tissue to which people can provide consent to removal and research use, **Proposal 32** would ensure that valid consent is informed to the greatest extent possible, and **Proposal 34** would require that the removal of tissue for research complies with national ethical standards. By requiring compliance with research ethics standards, this approach would embed flexibility. It would make sure that research studies with higher levels of participant risk are scrutinised more closely by committees with expertise to ethically evaluate whether the research should be approved.

Children and adults with limited decision-making capacity

Proposal 35

New human tissue legislation should allow tissue to be removed from children for use in research using a provision modelled on section 22B of the *Human Tissue Act 1985* (Tas).

Question 28

Should new human tissue legislation contain a similar provision to **Proposal 35** that allows tissue to be removed from adults without decision-making capacity for use in research? If so, what safeguards are appropriate to enable legitimate research while protecting participants from harm and exploitation?

The problems we are addressing

8.20 There are increasing research needs for human tissue provided by children (paediatric human tissue). Compared to the adult context, the paediatric research landscape is characterised by more limited access to tissue samples, fewer research participants, smaller sample volumes, and slower scientific progress.[13] Tissue from children that is important in scientific use include

12 Ibid.
13 Alayne Brisson et al, 'Translational Research in Pediatrics: Tissue Sampling and Biobanking' (2012) 129(1) *Pediatrics* 153.

cheek swabs, blood, biopsy material, and tumour cells. This tissue provides resources for researchers to learn about children's health and disease.[14]

8.21 How the different HTAs regulate the use of paediatric tissue varies, leading to uncertainty for researchers, paediatric participants, and parents/guardians. Some of the legislative differences for paediatric donation of tissue for research include:

- if tissue other than blood can be removed specifically for research purposes;
- the age of consent for blood donations;
- if parental authorisation is required;
- if donation of tissue for research purposes is conditional upon Human Research Ethics Committee approval of the research project; and
- the circumstances in which consent is needed in order to use tissue removed during a therapeutic procedure for research purposes.

8.22 These problems have the potential to impede paediatric research and place researchers at risk of legal liability.

8.23 We have heard that 'currently, there is a lack of clarity with respect to The National Health and Medical Research Council guideline interpretation regarding paediatric tissue being donated for research'.[15] Others argue that current laws are 'unnecessarily complicated and inconsistent'.[16]

How our reform proposals could solve the problems we have identified

8.24 We are proposing s 22B of the *Human Tissue Act 1985* (Tas) as a model provision for allowing tissue donation from children. This consent framework balances the ethical complexities involved in considering the rights of the child, the need for paediatric human tissue in research, the therapeutic benefit to the child, and the need for consent from a guardian or parent.

8.25 Section 22B provides that children can donate tissue for research if:

- the tissue removal is done for the purpose of, and in accordance with, research that has been approved by a human research ethics committee in accordance with the Australian Code for the Responsible Conduct of Research and the National Statement; and
- consent and/or assent is given in accordance with the National Statement;[17] and
- one or more of the following applies:
    - the research is for the benefit of the child;
    - the removal of the tissue occurs during a procedure that is for the benefit of the child, and a medical practitioner is satisfied that the removal is not likely to prejudice the health of the child; and
    - a medical practitioner is satisfied that the removal of the tissue will involve a negligible or low risk of harm and minimal discomfort to the child.

8.26 Rather than legislating specific categories of tissue that can be donated (such as blood or regenerative tissue), this approach shows how the underlying need to avoid exploiting and harming children can be addressed in a more nuanced way. Including a provision modelled on s 22B in new human tissue legislation would create national consistency and at the same time provide protection 'to ensure that the wellbeing and interest[s] of the child [are] sufficiently protected'.[18]

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14 Shih-Ning Then and Stephanie Jowett, 'Removal and Use of Paediatric Tissue for Research Purposes: Legal and Ethical Issues in Australia' (2020) 56(3) *Journal of Paediatrics and Child Health* 359.
15 C Stern, *Submission 12*.
16 Then and Jowett (n 14) 362.
17 National Health and Medical Research Council, Australian Research Council and Universities Australia (n 2) 64–101.
18 Macquarie University, *Submission 19*.

8.27 We are also considering whether a similar provision should be created that allows adults without decision-making capacity to donate tissue to research. In **Proposals 20–22**, we have proposed a framework enabling applications to a committee to enable adults without decision-making capacity to donate tissue for transplantation or other medical, educational or scientific purposes, where the committee can only authorise the donation if it is in the proposed donor's best interests. We are seeking feedback on whether a committee process is appropriate in the research context, or whether a mechanism similar to what we are proposing for children in **Proposal 35** is needed to enable legitimate and ethical research to be conducted. The opportunity to use tissue from adults who do not have decision-making capacity may be particularly important in the study of diseases that affect decision-making capacity, such as dementia and Alzheimer's disease. We are therefore seeking feedback in **Question 28** about whether a similar provision to **Proposal 35** should exist for adults with limited decision-making capacity, and if so, what safeguards it should contain.

Consent by or on behalf of deceased participants

Consent and authorisation to remove tissue for research after death

Proposal 36

New human tissue legislation should provide that:

1. An adult may give valid consent to the removal of tissue from their body after their death for the purpose of research;
2. If an adult is close to death and does not have decision-making capacity, or dies without having provided valid consent, the adult's authorised decision-maker may give valid consent to the removal of tissue from the adult's body for the purpose of research.
3. When deciding whether to give consent, the authorised decision-maker must have primary regard to the adult's known beliefs, values, and preferences regarding the use of their tissue in research, if any, and make the decision they believe the adult would have made in the circumstances.
4. If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for the purpose of research.
5. Valid consent is:
    a. given voluntarily;
    b. given at a time when the person consenting has decision-making capacity;
    c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;
    d. given after the person consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and
    e. able to be withdrawn in accordance with **Proposal 37** or at any time before the removal of the tissue.
    f. sufficient legal authority for the removal of the specified tissue for the intended research use(s); and for other research use(s) in accordance with **Proposal 37**.

Proposal 37

New human tissue legislation should provide that:

1. When consent is provided under **Proposal 36** by an authorised decision-maker on behalf of someone else in circumstances where the all the specific research uses for the tissue are not yet known:
    a. the person who provided consent has a right to access information about how the tissue is being used, if at the time of the information request the sample is identifiable or, if it has been deidentified, is re-identifiable;
    b. the person who provided consent has a right to withdraw consent for any future research uses, if at the time of the consent withdrawal:
        iii. the tissue remains usable; and
        iv. the sample is identifiable or, if it has been deidentified, is re-identifiable.
2. If consent for future research uses is withdrawn, any unused tissue must be discarded.

8.28 In **Proposal 23**, we set out a consent and authorisation framework for deceased donation of human tissue. This framework is largely mirrored in the above proposal dealing with the donation of tissue from deceased participants for use in research. Key differences are:

- Specifying that consent is valid even if all the future research uses for the tissue provided are not known at the time consent is given. This is consistent with the proposal for consent by living research participants above (**Proposal 32**) and aligns with how modern research is conducted.
- Clarifying that a participant can revoke consent any time before their death or, where consent is given by an authorised decision-maker on their behalf, the authorised decision-maker has an ongoing ability to access information about how the tissue is being used and withdraw consent for future research uses.

8.29 In **Proposal 31**, we have also suggested that tissue removed from a deceased body during a post-mortem examination should only be used for the purpose of the examination unless consent is obtained to other medical, educational or scientific uses. This would apply to any research that is intended to be undertaken at the time of the examination. Whether researchers should later be able to access stored pathology samples taken during the examination without consent is an issue we are seeking feedback on in **Questions 29** and **30**.

9. Reforms relating to donation and use of deceased bodies

Contents

Consent and authorisation for body donation after death

Proposal 38

New human tissue legislation should provide that an adult may give valid consent to donate their body after their death to a school of anatomy or other licensed facility for medical, educational or scientific purposes.

The requirements for valid consent should mirror the requirements set out in **Proposal 23** regarding deceased donation of tissue.

Consent and authorisation for research on the recently deceased

Proposal 39

New human tissue legislation should provide that an adult may give valid consent to the use of their body after death for research outside a school of anatomy or other licensed facility if the research:

a. adheres to the Australian Code for Responsible Conduct of Research and the National Statement, where applicable; and

b. has received approval by a human research ethics committee formed in accordance with the requirements of the National Statement.

The requirements for valid consent should mirror the requirements set out in **Proposal 23** regarding deceased donation of tissue.

The problems we are addressing

9.1 There are inconsistent provisions across the states and territories for authorising the donation of bodies for anatomical examination. In some jurisdictions, the consent and authorisation framework for deceased body donation is regulated by human tissue legislation, and in other jurisdictions reference to the relevant Anatomy Act is required.[1] Some consent requirements

1 See, eg, *Anatomy Act 1977* (NSW) ss 8–8A; *Anatomical Examinations Act 2006* (Tas) s 6; *Transplantation and Anatomy Act 1979* (Qld) ss 31–2; *Human Tissue Act 1982* (Vic) s 32.

mirror the requirements for donation of tissue after death and others have distinct requirements, some of which are outdated.[2]

9.2 The HTAs permit donation of tissue removed from deceased bodies for scientific purposes. However, the legality of donation of entire deceased bodies for scientific purposes is limited. Currently, New South Wales is the only Australian jurisdiction that allows deceased bodies to be used for scientific purposes.[3]

9.3 Research on deceased bodies can occur in different contexts. For example, in New South Wales, people can donate their bodies after death to a specific facility conducting forensic research.[4] However, for this research to occur, the research facility must be licensed as a 'school of anatomy',[5] which may not be suitable given that the purpose and needs of a forensic research facility are different from facilities using bodies primarily for educational purposes. Rules that were designed for educational uses that set out requirements for the retention of bodies and transfer of samples taken from bodies are difficult to apply to the research context. Nevertheless, it is important that legislation in other states and territories allow bodies to be donated for research so that research is not limited by the lack of human tissue available.

9.4 Sometimes researchers need to investigate a question that can only be answered by examining, observing, or intervening on a person's body while they are dying or immediately after death. In this context, the body is not being donated to a school of anatomy or other research or medical institution. But it is similarly important to have a legal mechanism to ensure this type of research can occur.

9.5 Without lawful access to deceased bodies, medical education and research could be constrained, limiting opportunities for innovation. A legal mechanism is needed in all jurisdictions to permit deceased body donation for the development of research and science programs.

9.6 The domain of deceased body donation is shaped by ethical and legal considerations, particularly with respect to consent, dignity, and cultural or religious beliefs about death and the body. Consequently, regulatory frameworks should establish a balance between the need for scientific progress and the principles of respect for individual autonomy, respect for the body of a deceased person, and public trust.

Background to the problems

Anatomical examinations

9.7 Current legislation allows bodies to be donated after death for anatomical examination, which involves dissection for educational purposes. Human cadavers allow researchers and students to study anatomy in detail, providing insights that cannot be fully replicated through models or digital simulations. In medical training, working with bodies ensures that healthcare professionals develop practical skills essential for safe and effective patient care. In most jurisdictions, the consent and authorisation process for donation of a body for this purpose mirrors the process of tissue donation for transplantation after death.

9.8 Usually, for bodies in hospital, a Designated Officer must authorise the donation and transfer of a body based on an individual's prior expressed wish, or their senior available next of kin's consent.[6]

2 See, eg, *Anatomy Act 1977* (NSW) s 8(1); *Human Tissue Act 1983* (NSW) s 23(1); *Human Tissue Act 1982* (Vic) ss 26(1)(c), 32(1)(b).
3 The definition of 'anatomical examination' in s 4(1) of the *Anatomy Act 1977* (NSW) includes 'scientific purposes'.
4 Ibid pt 2.
5 Ibid s 11.
6 See, eg, *Anatomy Act 1977* (NSW) s 8.

9.9 In Western Australia, the state can authorise the anatomical examination of deceased bodies where a person has died in prison or in a public hospital, unless the person's next of kin objects or unless the person previously expressed an objection verbally in the presence of two witnesses or in writing.[7] This provision is particularly outdated; the contemporary approach to consent focuses on voluntary decision-making by individuals or their authorised decision-maker.[8]

9.10 For bodies outside hospital, authorisation for anatomical examination is generally based on either an individual's prior expressed wish or their senior available next of kin's consent.[9] In Tasmania, there is no distinction between deaths that occur in hospital and those that occur elsewhere. Instead, consent in an approved form may be given to the Head of the Faculty of Health at the University of Tasmania. The approved form is given by a person before their death, or by their next of kin after death if the deceased person gave informal consent during their lifetime.[10] In Western Australia, an executor can authorise donation for anatomical examination unless there were objections by the deceased prior to their death, or after death if the person's next of kin objects.[11]

9.11 Several submissions in response to our *Issues Paper* say that uniform and modern consent provisions across Australia are desirable.[12]

Donation for research or other scientific purposes

9.12 The *Anatomy Act 1977* (NSW) differs from other jurisdictions by defining 'anatomical examination' to include 'use of the body for medical or scientific purposes'.[13] As a result, bodies can be donated to a school of anatomy for purposes other than educational dissection. The use of deceased bodies for medical and scientific purposes plays an important role in advancing medical knowledge and forensic science. For example, the field of forensic taphonomy, which assists the work of police and forensic investigators, uses deceased bodies to understand body decomposition.[14]

9.13 Outside of this context, an evolving area is research on the recently deceased. This type of research supports the development of new surgical techniques, medical devices, methods for donation and transplantation, and scientific understandings of death.[15] Unlike body donation to a school of anatomy, research in this context will generally occur in a hospital and will only continue for the limited time required by the specific study.

9.14 Research on the recently deceased raises many ethical issues. Navigating these ethical issues is difficult because there are no authoritative national or international ethical guidelines.[16] The National Statement, for example, addresses the use of biospecimens obtained after death, but does not address research interventions on the bodies of people who died recently.[17] The

7 *Anatomy Act 1930* (WA) s 8; Rebekah Jenkin and Kevin Keay, 'Body Donor Programs in Australia and New Zealand: Current Status and Future Opportunities' (2025) 18(3) *Anatomical Sciences Education* 301, 323.
8 Georgina Stephens, '"Because Everybody's Different": Co-designing Body Donor Program Consent Processes' [2025] *Anatomical Sciences Education* 1, 2.
9 *Human Tissue Act 1982* (Vic) s 32.
10 *Anatomical Examinations Act 2006* (Tas) s 9.
11 *Anatomy Act 1930* (WA) s 9.
12 Macquarie University, *Submission 19*; Department of Health for Western Australia, *Submission 23*; Faculty of Medicine and Health at UNSW, *Submission 25*; R Jenkin, *Submission 48*; Clinical Training and Evaluation Centre, University of Western Australia, *Submission 88*.
13 *Anatomy Act 1977* (NSW) s 4(1).
14 A Williams, CJ Rogers and JP Cassella, 'Why Does the UK Need a Human Taphonomy Facility?' (2019) 296 *Forensic Science International* 74, 74–6.
15 Dominique Martin et al, 'Addressing Ethical Confusion in Deceased Donation and Transplantation Research: The Need for Dedicated Guidance' (2021) 34(12) *Transplant International* 2459, 2461.
16 Ibid 2463.
17 National Health and Medical Research Council, Australian Research Council and Universities Australia, *National Statement on Ethical Conduct in Human Research* (E72C, 2025) 43.

absence of clear ethical rules creates confusion about whether these studies fall within established research ethics frameworks. There is a need for oversight by research ethics bodies.[18]

9.15 It is also important to ensure there is a clear source of legal authority to conduct this research.[19] In the absence of consent from an individual before death, it should be necessary to obtain consent from a substitute decision-maker. In identifying the appropriate substitute decision-maker, it is important to consider substitute decision-making frameworks on behalf of research participants before the person has died so it is the same person who is required to provide consent in both contexts. This is an issue we are continuing to examine.

How our proposal seeks to address the problem

9.16 **Proposal 38** will enable people beyond New South Wales and across Australia to donate their bodies to a school of anatomy for medical, educational or scientific purposes. By legitimising and regulating the practice of donation for all of these purposes, the law not only promotes scientific and clinical progress but also upholds public trust in the medical and legal systems that govern the treatment of human remains.

9.17 The proposal recognises the possibility of donation to a licensed research institution rather than a school of anatomy. This will address the problem of rules relating to educational uses being applied to research institutions even though the rules are a poor fit for research institutions. However, as discussed further below, there is not presently any legal framework for licensing, regulating, or overseeing research collections of human tissue. A new framework may need to be created for this purpose. We are therefore exploring in **Question 32** whether a system of regulation and oversight for research collections of human tissue should be created.

9.18 **Proposal 39** permits research on the bodies of people who have died recently to be conducted in locations other than schools of anatomy or other licensed facilities, such as hospitals. At the same time, the proposal provides safeguards to protect the autonomy of people before death, and respect for their bodies after death, ensuring that donations occur only with informed consent (see **Proposal 23**), and in accordance with emerging ethical standards.

18 Martin et al (n 15) 2467.

19 G Oniscu, K Rockell and D Martin, 'Challenges in Undertaking Research in Transplantation' (2025) 405(10480) *The Lancet* 681, 681.

10. Reforms relating to stored tissue collections

Contents

Access to stored tissue collections for purposes that differ from the original purpose of the tissue collection

10.1 Sometimes tissue is collected and stored for one purpose but later is useful for a different purpose. For example, a person's tissue might be removed for a clinical purpose such as testing for disease and stored by a pathology laboratory. These clinical tissue collections can be valuable for researchers studying different diseases. Ordinarily, consent should be obtained before using someone's tissue in research. The problem in this context is that it can be very difficult for researchers to identify, contact, and obtain consent from the people who originally provided the tissue.

10.2 Currently, many HTAs provide that as long as tissue was removed lawfully then the tissue can be used for any other purpose. This has been interpreted to mean that consent to subsequent research use is not required. In New South Wales, the ability to use tissue in these circumstances is limited to the use of 'small samples'.[1] Use of large samples would require consent.

10.3 We are considering whether new human tissue legislation should require consent to use human tissue samples for purposes that are different from what the person who provided the sample originally consented to. If a consent requirement is created, we are also considering whether there is a need for an exception to it, to enable researchers to access these samples in some circumstances. Options to consider for an exception may include:

- the size of the sample;
- the location of the sample (such as in a pathology collection);
- the intended uses for the sample (such as whether unique genetic information will be extracted); or
- whether the research project has obtained a waiver of consent from a Human Research Ethics Committee.

10.4 We recognise that there is a need for careful consideration and further consultation on this issue to avoid unnecessarily hindering scientific research while also ensuring respect for research participants and enhancing the public trust on which scientific research depends.

1 *Human Tissue Act 1983* (NSW) s 34.

Consent and authorisation for use of tissue samples

Question 29

Should there be a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes that they did not consent to?

You may want to consider **Question 27**, where we ask about secondary uses of tissue samples taken during a post-mortem examination.

Question 30

If a legal requirement for consent is imposed (**Question 29**), should there be exceptions to it? If so, what exceptions should exist?

The regulation of tissue collections for research and educational uses

10.5 Sometimes people give consent to have their tissue stored in a research biobank for future research projects. Biobanks are collections of biological materials (biospecimens). Biobanks with human biospecimens are often linked to personal and health information about the person who provided the biospecimen, such as the person's health records, family history, lifestyle, or genetic information.[2]

10.6 Unlike collections of bodies at schools of anatomy, or stored tissue samples at pathology centres or tissue banks, research collections of tissue are not currently subject to direct legal oversight or regulation. This means there are no legal rules about how tissue used in research should be stored, when it should be transferred, or disposed of.

10.7 In our previous 2003 report, *Essentially Yours*, we pointed out inconsistencies between the regulation of personal information and the physical samples containing personal information. Personal information can include things like genetic information which can be obtained from research samples which is subject to legal rules about collection, access, and disclosure. In comparison, physical samples which contain this information are not subject to a parallel set of rules, creating a potential gap in the law.[3] We are therefore seeking feedback on whether specific rules are needed to regulate human tissue samples used in research.

10.8 Research biobanking is fundamental to the modern research environment but a lack of consistent governance and oversight is a longstanding international problem faced by the biobanking sector. This is a sector that may benefit from having accountability, oversight, and nationally consistent guidelines or standards.[4] As discussed above, a regulatory framework that allows bodies to be donated to licensed research facilities, as opposed to schools of anatomy, for research purposes, would allow more tailored and research-specific rules and guidelines to be developed.

10.9 A new National Regulator (or alternative) could be involved in regulating human tissue collections for research uses. This is the approach taken in the United Kingdom, where the Human

2 Laura Annaratone et al, 'Basic Principles of Biobanking: From Biological Samples to Precision Medicine for Patients' (2021) 479(2) *Virchows Archiv* 233, 234.

3 Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Report No 96, 2003) 268–73.

4 Felix Gille, Effy Vayena and Alessandro Blasimme, 'Future-Proofing Biobanks' Governance' (2020) 28(8) *European Journal of Human Genetics* 989.

Tissue Authority (UK) regulates some collections of research tissue. We are interested to know if a similar system would be suitable in Australia.

10.10 There are also collections of human tissue used for educational purposes. These collections are often held by educational institutions and can contain skeletal remains or specimens with interesting pathologies. These collections are useful to help medical and allied health students and practitioners learn about anatomy and disease. Some of these collections are very old and contain specimens from before the HTAs were enacted. Documentation about the person from whom a specimen came and whether the person provided consent is not always available. We have heard there is a need to clarify whether these 'legacy collections' containing specimens without full documentation can be used, displayed, and transferred to other institutions.[5]

10.11 Some of these collections may contain samples taken from First Nations people without their consent. There is a long history of colonial authorities, institutions, and individuals stealing human remains of First Nations people for museum, university, and private collections in Australia and overseas.[6] The remains in these collections have been obtained through violence — by digging up burial sites and by claiming bodies of deceased First Nations people against their expressed wishes — causing significant harm to First Nations people and communities since the late 1700s.[7]

10.12 Repatriation of these remains is therefore an important part of reconciliation efforts and processes. Internationally, the Declaration on the Rights of Indigenous Peoples states that 'Indigenous peoples have…the right to the repatriation of their human remains'.[8] Domestically, the Australian Government has a policy to support repatriation of First Nations human remains to address the injustice of this harmful practice and promote healing and reconciliation for First Nations people.[9] As part of this policy, a National Resting Place is being developed for ancestral remains that cannot immediately be returned to Country, usually because of insufficient information about the origin of the remains.[10]

10.13 We have heard that a licensing system for legacy tissue collections would be useful to enable their educational value to be realised under a system of oversight and transparency designed to maintain public trust.[11] A National Regulator (or alternative) could administer and oversee a system of this nature. However, we note that it would be vitally important for any effort to regulate educational collections of human tissue to be consistent with and supportive of repatriation efforts for First Nations ancestral remains. Careful consideration of how the two frameworks would interact would be required.

Regulating stored tissue collections

Question 31

Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?

5 D Wakefield, N Hawkins, J Turchini, A Field, N Tedla, A Gill, G Velan, J Baum, S McColl, C Herbert, S Thomas and T Mackenzie *Submission 95*.

6 Department of Communications and the Arts (Cth), *Australian Government Policy on Indigenous Repatriation* (2016) 5; Heidi Norman and Anne Maree Payne, 'Nowhere Else but Home: A National Resting Place for Indigenous Australian Ancestral Remains' (2022) 65(4) *Curator: The Museum Journal* 817, 817.

7 Norman and Payne (n 6) 818–25.

8 *Declaration on the Rights of Indigenous Peoples*, GA Res 61/295, UN Doc A/RES/61/295 (2 October 2007, adopted 13 September 2007) art 12.

9 Department of Communications and the Arts (Cth) (n 6).

10 Department of Infrastructure, Transport, Regional Development, Communications, Sport and the Arts, 'National Resting Place' <www.arts.gov.au/what-we-do/cultural-heritage/indigenous-repatriation/national-resting-place>; Norman and Payne (n 6) 828.

11 D Wakefield, N Hawkins, J Turchini, A Field, N Tedla, A Gill, G Velan, J Baum, S McColl, C Herbert, S Thomas and T Mackenzie *Submission 95*.

Question 32

Would it be beneficial to have national regulation, guidance and oversight for:

a. research biobanks that store and/or distribute human tissue or human bodies; or

b. educational collections of human tissue?

Question 33

If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:

a. what aspects of tissue collection, storage, use, transfer or disposal need to be regulated?

b. what types of collections should be regulated?

c. are there types of collections that should not be regulated?

An individual's right to access stored tissue

10.14 We are also exploring whether human tissue legislation should provide a right for people to access their stored tissue samples. Freedom of information laws allow people to access personal information that has been collected about them from different entities. We have previously suggested that a similar approach may be appropriate to allow people to access stored tissue samples for certain purposes.[12] This may be important where:

- a person wants a sample tested to obtain a second opinion in a medical diagnosis;
- information in the stored tissue is relevant to a legal dispute; or
- someone wants to transfer their sample for use in research.

10.15 If a right of access is created, we will need to consider what it should entail, including:

- a right to have tissue samples tested or transferred to a research biobank or pathology laboratory; and
- to whom it should be granted. For example, whether it should apply to authorised decision-makers for samples from deceased people or living people without capacity.

10.16 We are therefore seeking input on these issues in **Question 34** below.

Accessing stored tissue

Question 34

Should new human tissue legislation provide that individuals have a right to access their stored tissue? If so, what should 'access' entail in this context and who should be granted the right?

12 Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Report No 96, 2003) 273–4.

11. Reforms relating to the prohibition of trade

Contents

Prohibiting the exchange of human tissue for reward within Australia

Proposal 40

New human tissue legislation should prohibit the offering, giving or receiving in Australia of any reward in exchange for human tissue.

A reward in relation to the supply of human tissue means:

a. any financial payment; or

b. the provision of any valuable property, good, service or advantage;

It should not include:

a. the reimbursement of any expense or cost; or

b. the recovery of any loss or damage that was reasonably and lawfully incurred or suffered in connection with the donation, procurement, storage, processing or distribution of human tissue for a purpose permitted by the legislation.

Giving extra-territorial effect to the prohibition

Question 35

Should the prohibition on exchanging human tissue for reward have extra-territorial effect? If so, what would be the best mechanism to achieve this? For example, an amendment in new human tissue legislation, or an amendment to the *Criminal Code Act 1995* (Cth)?

Agreement to be void (have no force)

Proposal 41

New human tissue legislation should provide that an agreement for the exchange of human tissue is not enforceable by any person who enters the agreement either knowing it contravenes, or being reckless about whether it contravenes, the prohibition in **Proposal 40**.

Exceptions to the prohibition on the exchange of human tissue for reward

Proposal 42

New human tissue legislation should provide that, other than human tissue donated to, or otherwise procured by, a tissue bank, the prohibition of the exchange of human tissue for reward (**Proposal 40**) does not apply to human tissue traded for a medical, educational or scientific purpose that is also:

a. a biological or medical device included in the register under the *Therapeutic Goods Act 1989* (Cth);

b. a registered good under the *Therapeutic Goods Act 1989* (Cth);

c. human tissue obtained under the 'Special Access Scheme' administered by the TGA; or

d. a blood product under the *National Blood Authority Act 2003* (Cth) that is traded by the Commonwealth or an entity mentioned in the national products price list as a supplier.

Question 36

a. Are the exceptions to the prohibition of the exchange of human tissue for reward listed in **Proposal 42** appropriate?

b. Should new human tissue legislation include additional exceptions?

c. Should new human tissue legislation include an exception to enable paid plasma donation?

Proposal 43

New human tissue legislation should include a mechanism to allow for the exemption of exchanges, or categories of exchanges, of human tissue from the prohibition of exchanges for reward in **Proposal 40**.

For example, the National Regulator (or alternative) could be empowered to grant exemptions. These exemptions would supplement the exceptions in **Proposal 42**.

In deciding whether to exempt exchanges or categories of exchanges, new human tissue legislation should require the National Regulator (or alternative) to consider certain factors, including but not limited to:

- the public interest in permitting the exchange;
- the nature or form of the material that is the subject of the exchange and the extent of the nexus to human tissue;
- the source of the human tissue; and
- the risk of exploitation, coercion, or the commodification of human tissue.

Question 37

a. Are the factors listed in **Proposal 43** that the relevant decision-maker must consider when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue appropriate?

b. Should the relevant decision-maker be required to consider any other factors when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue?

Guidance on cost recovery

Proposal 44

The National Regulator (or alternative) should be authorised to provide guidance about what expenses, costs, loss or damage can be reimbursed or recovered by persons that retrieve, process, use, and/or distribute human tissue.

Reforms relating to the prohibition of trade generally

The problems we are addressing

11.1 The HTAs prohibit trade in human tissue.[1] The prohibition of trade is designed to:

- prevent exploitation and coercion of people who might be motivated by financial need to sell their own tissue;[2]
- avoid any loss of dignity associated with commodification of the human body,[3] or with turning people into 'objects';[4] and
- maintain stringent safety standards for donated tissue.[5]

11.2 The ways in which the HTAs address these concerns are inconsistent. The content and language of, exceptions to, and penalties for breaching the prohibition of trade vary across Australian states and territories.[6]

11.3 Not all human tissue exchanges involving financial compensation are problematic. The HTAs identify some exceptions to the prohibition of trade,[7] but these exceptions are not always clear. For example, there are exceptions to the prohibition of trade in most HTAs for 'processed'

1 *Transplantation and Anatomy Act 1978* (ACT) s 44(1); *Transplantation and Anatomy Act 1979* (Qld) ss 40, 42; *Human Tissue Act 1982* (Vic) ss 38, 39; *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).

2 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 86; Roberto Andorno, 'Buying and Selling Organs: Issues of Commodification, Exploitation and Human Dignity' (2017) 1(2) *Journal of Trafficking and Human Exploitation* 119, 123.

3 Andorno (n 2) 124–6. Bruno Liga-Rucinski, 'Saviour Siblings, Commercial Organ Donation and Commercial Surrogacy: Finding the Right Balance between Acceptable Instrumental Use and Impermissible Commodification' (2021) 10 *The Oxford University Undergraduate Law Journal* 265, 275–6.

4 Andorno (n 2) 122, 124.

5 Australian Law Reform Commission (n 2) 86.

6 Queensland and Victoria prohibit the buying and selling of human tissue: *Transplantation and Anatomy Act 1979* (Qld) ss 40, 42; *Human Tissue Act 1982* (Vic) ss 38, 39. In other jurisdictions, the prohibition of trade is broader and covers offering or providing any 'valuable consideration' in exchange for human tissue: see, eg, *Human Tissue Act 1983* (NSW) s 32(1); *Transplantation and Anatomy Act 1983* (SA) s 35(1); *Human Tissue and Transplant Act 1982* (WA) s 29A(2).

7 While they vary between the different HTAs, exceptions include reimbursement of necessary costs for donors, exceptions for processed or treated tissue, cost recovery for tissue banks and schools of anatomy, and an exception for certain blood products: Australian Law Reform Commission, *Review of Human Tissue Laws* (Issues Paper No 51, 2025) 16.

or 'treated' tissue,[8] but it is not clear what 'processed' tissue means or the circumstances in which the exception should apply.

11.4 This is particularly relevant for tissue banks, which retrieve, store, process, and distribute tissue for use by clinicians in medical treatment. To be sustainable, tissue banks need to recover the financial costs of performing these activities. Under the HTAs, tissue banks can charge a fee for the tissue they distribute, to recover their costs.

11.5 To maintain public trust and an ethical system, it is important that human tissue donation and transplantation 'are not driven by financial gain',[9] and that the sector is transparent and accountable. But how the HTAs address cost-recovery:

- is inconsistent;[10]
- lacks clarity about what costs can be recovered;[11] and
- lacks oversight to ensure tissue banks are operating ethically.

11.6 We have heard that the lack of clarity and oversight can make it difficult for not-for-profit tissue banks to remain viable when operating in a sector made up of public and private organisations, some of which import tissue from overseas (we discuss tissue importation below).

11.7 Separately, there is a need for flexibility to allow ethically appropriate forms of tissue exchange. While the HTAs allow ministers to exempt some forms of exchange from the prohibition of trade,[12] seeking an exemption takes time and effort. Moreover, the HTAs do not set out the factors that ministers should consider when deciding whether to grant an exemption. This makes it hard for people to know if they are likely to be granted an exemption and creates a risk that the ministerial decision-making is arbitrary and inconsistent.

11.8 One area that relies on ministerial exemptions is the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program. This allows biologically incompatible kidney donor-recipient pairs to be matched with other willing donors and recipients. For example, the donor in one pair will donate a kidney to the recipient in the other pair in exchange for the donor in the second pair donating a kidney to the recipient in the first pair. This program does not raise concerns about exploitation or commodification and has successfully increased the number of patients receiving kidney transplants. But there is a concern that it violates the prohibition on trade and therefore requires ministerial exemptions in some jurisdictions to operate. This creates an unnecessary administrative burden.[13]

11.9 Trade in tissue can involve human rights abuses when people's tissue is forcibly removed from their bodies or removed as a result of coercion and then sold to people seeking a transplant. When victims are moved across the Australian border for this purpose, it is a trafficking offence. When Australians travel to another country to purchase an organ for transplant, this is known as 'transplant tourism'. The *Criminal Code Act 1995* (Cth) makes the former a criminal offence, but there is no similar offence for engaging in transplant tourism.

8 See, eg, *Transplantation and Anatomy Act 1979* (Qld) s 42AA; *Human Tissue and Transplant Act 1982* (WA) s 29B(3)(c).
9 National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 176.
10 Only three HTAs address cost-recovery directly: *Transplantation and Anatomy Act 1979* (Qld) s 42A; *Human Tissue Act 1982* (Vic) s 39A; *Human Tissue and Transplant Act 1982* (WA) s 29B.
11 Norton Rose Fulbright, *Submission 44*; University of Sydney, *Submission 60*.
12 See, eg, *Human Tissue Act 1983* (NSW) s 32(4); *Transplantation and Anatomy Act 1979* (Qld) s 40(2); *Human Tissue Act 1985* (Tas) s 27(4); *Human Tissue Act 1982* (Vic) s 39(2).
13 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.

Background

The prohibition of trade

11.10 The prohibition of trade in human tissue aligns with international norms. For example, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (Declaration of Istanbul),[14] and the WHO's *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, with the latter providing that 'cells, tissues and organs should only be donated freely without monetary payment or other reward of monetary value'.[15] Bioethicists suggest that commodifying human tissue conflicts with human dignity and introduces the risk of exploitation.[16]

11.11 Professionals working in the tissue sector told us there is a need for a nationally uniform prohibition, and for a set of exemptions, to allow the efficient operation of tissue banks, and programs like the ANZKX.

11.12 While there is broad agreement that human tissue should not be bought and sold,[17] policy developments challenging the prohibition of trade have emerged over time. The ANZKX is an example of an ethically sound policy that confronts regulatory barriers because of the prohibition.[18] It is important to have a prohibition that is not overly broad and is flexible enough to support ethically acceptable policy interventions such as the kidney exchange program.

Paid plasma donation

11.13 **Question 36(c)** is about paying for plasma donations. Currently, there is a debate about whether to implement a pay-for-plasma system.[19] Countries that pay plasma donors include the United States,[20] Austria, the Czech Republic, Germany, Hungary, Ukraine, and China,[21] as well as some parts of Canada.[22]

11.14 On the one hand, paying donors for plasma is contrary to WHO guidance.[23] There are concerns about vulnerable people being coerced, and people not declaring their full medical history and therefore compromising the safety of the plasma supply and undermining public trust.[24] On the other hand, some commentators argue a remuneration scheme can be

> safe, would ensure a secure supply of plasma, does not discourage non-remunerated blood donations, and would provide significant patient benefits.[25]

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14 The Transplantation Society and International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition) Principle 4.

15 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) Guiding Principle 5.

16 Herjeet Marway, Sarah-Louise Johnson and Heather Widdows, 'Commodification of Human Tissue' in Henk ten Have and Bert Gordijn (eds), *Handbook of Global Bioethics* (Springer, 2014) 581, 590–92; Andorno (n 2).

17 The Transplantation Society and International Society of Nephrology, *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (2018 Edition) Principle 4; 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) Principle 5; Marway, Johnson and Widdows (n 16) 581–2.

18 Toews et al (n 13).

19 Judd Boaz, 'The Yellow Market: With Plasma in Constant Demand in Australia, Why Aren't Donors Being Paid?', *ABC News* (6 July 2024) <www.abc.net.au/news/2024-07-07/donating-blood-plasma-money-red-cross-supply/103923554>.

20 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, 202.

21 Paul Strengers, 'Challenges for Plasma-Derived Medicinal Products' (2023) 50(2) *Transfusion Medicine and Hemotherapy* 116.

22 Government of Canada, 'Plasma Donation in Canada' <www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/activities/fact-sheets/plasma-donation-canada.html#a6>.

23 World Health Organization, *WHO Global Consultation: 100% Voluntary Non-Remunerated Donation of Blood and Blood Components* (2009).

24 Children's Medical Research Institute, *Submission 20*.

25 Peter Jaworski, *Bloody Well Pay Them: The Case for Voluntary Remunerated Plasma Collections* (The Adam Smith Institute, 2020) 6. See also Kimberly Krawiec and Alvin Roth, 'WHO Says Countries Should Be Self-Sufficient In (Unremunerated) Organs and Blood' *(Research Paper No. 2024-58, University of Virginia School of Law and Stanford University, April 2025)* 5.

11.15 While Australia does not currently pay plasma donors, we rely heavily on imported plasma from the United States, where donors are paid. Fifty-two percent of Australian plasma is imported, and the United States supplies 70% of plasma globally (as of 2020).[26] One commentator points to the hypocrisy of this:

> It's as if we're saying we don't want to take advantage of Australians, but taking advantage of Americans is okay.[27]

11.16 Allowing plasma donors to be remunerated could potentially allow Australia to be self-sufficient in plasma supply, and may even mean there is surplus that could be sent to low income countries.[28]

11.17 Some stakeholders suggest a hybrid model of remunerated and non-remunerated blood and plasma donation might be needed to increase self-sufficiency.[29] As attitudes can shift over time, a flexible approach to the prohibition of trade may be useful to accommodate future policy directions.

'Processed' tissue

11.18 The initial rationale for the processed tissue exception to the prohibition of trade was to allow 'the sale by reputable suppliers of human tissue lawfully obtained and processed or prepared for medical use if the tissue itself was obtained without payment'.[30] However, it is unclear what 'processed' or 'treated' means in this context, or how much processing is required.

11.19 Rather than have a broad exception for all processed tissue, the exemptions in **Proposal 42** are based on the wording contained in section 42AA of the *Transplantation and Anatomy Act 1979* (Qld).[31] This approach provides clarity, and ensures that the application of the prohibition will not interfere with the public health benefits that come from therapeutic goods that are already regulated or overseen by bodies such as the TGA or National Blood Authority (NBA).

11.20 **Proposals 42** and **43** envisage a system where a mechanism to provide a responsive approach to exemptions exists under new human tissue legislation. A regulator could be empowered to create future exemptions. If new types of tissue products, for example, are developed outside the scope of the listed exceptions, trade could be allowed without having to amend legislation. We have suggested that in granting an exemption, certain factors should be considered. This will help:

- provide transparency and accountability;
- avoid the risks of exploitation, coercion, and commodification; and
- allow the promotion of any public benefit of trade.

11.21 We are seeking feedback on whether these factors are appropriate.

The tissue bank sector

11.22 Tissue banks collect and store tissue such as corneas, muscle, bone, skin, heart valves, and placenta from living or deceased donors. The banks process the tissue into therapeutic

26 Jaworski (n 25) 5.
27 Boaz (n 19) quoting Professor Jaworski, Associate Teaching Professor at Georgetown University.
28 Jaworski (n 25) 6.
29 Department of Health for Western Australia, *Submission 23*.
30 Australian Law Reform Commission (n 2) 87.
31 Inserted by the *Health and Other Legislation Amendment Act 2014* (Qld).

products that are distributed to clinicians for use in the medical treatment of patients.[32] The tissue bank sector in Australia is made up of a mix of public and private actors.[33]

11.23 The Queensland provision that we have used as a model for the exemption in **Proposal 42** allows the trade of certain tissue-based products regulated by the TGA and NBA, but it does not apply to, and therefore does not allow trade of, tissue stored at tissue banks.[34]

11.24 Instead, the Queensland legislation allows a person who owns a tissue bank to charge an amount to recover reasonable costs incurred in 'removing, evaluating, processing, storing or distributing donated tissue'.[35] The legislation also allows people to pay a cost-recovery amount charged by a tissue bank.[36] The aim of this approach is to make sure tissue banks are financially viable but do not accrue unethical profits.[37]

11.25 There are concerns within the tissue bank sector about the lack of guidance and uniformity when it comes to calculating cost-recovery amounts to be charged for different tissue products.

11.26 A 2016 PricewaterhouseCoopers review (PwC review) of the tissue sector noted that different tissue banks apply different cost recovery models,[38] and more broadly, that there is an absence of 'oversight [or] regulatory or transparency arrangements … to support the current public-private sector mix' of tissue banks.[39]

11.27 We have received submissions calling for greater legal and ethical safeguards to ensure tissue is not being procured for profit,[40] consistent with **Proposal 40**. Private Healthcare Australia noted a rise in the trade of human tissue products in Australia, 'with no oversight of the commercialisation of the supply chain, where the human tissue product is coming from, and where the money is going'.[41]

11.28 The Private Health Insurance branch of the Department of Health, Disability and Ageing (Cth) oversees the Part B – Prescribed List of Medical Devices and Human Tissue Products (Prescribed List). This sets out the benefits that health insurers must pay for specific human tissue products. Tissue banks apply to have their products listed on the Prescribed List for a price reflecting a cost-recovery amount. When a clinician wants to use the product for a patient, the patient's private health insurer will pay the Prescribed List amount to the tissue bank after the tissue is implanted.[42] While the main purpose of the Prescribed List is to specify the benefits payable by private health insurance providers, as a matter of practice, it now also sets the prices that public hospitals pay for tissue provided by tissue banks.[43]

11.29 The PwC review noted that state governments are not playing a role in assessing whether the fees charged for tissue products truly reflect 'cost-recovery' amounts. Instead, the states appeared to be relying on the Prescribed List process to ensure that no profit is being earned.

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32 PricewaterhouseCoopers Australia, *Final Report: Analysis of the Australian Tissue Sector* (Australian Government Organ and Tissue Authority, November 2016) 5.
33 Ibid 6.
34 *Transplantation and Anatomy Act 1979* (Qld) s 42AA(2).
35 Ibid s 42A(1)(a).
36 Ibid s 42A(3).
37 For a discussion of the difference between ethical and unethical profits in tissue banking, see 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) 175–7.
38 PricewaterhouseCoopers Australia (n 32) 3.
39 Ibid 64.
40 NSW Organ & Tissue Donation Service, *Submission 40*.
41 Private Healthcare Australia, *Submission 64*.
42 For a discussion of how the PHI system and Prescribed List (formerly known as the Prostheses List) operates, see Department of Health and Aged Care (Cth), *Baseline Evaluation of the Prostheses List Reforms* (2024) 5.
43 Department of Health (Cth), *Protheses List Reforms: Modernisation of Part B of the Protheses List* (No Prostheses List Reforms Consultation Paper No 2(a) Modernisation of Part B of the Prostheses List, 2022) 4.

11.30 PwC concluded that this 'gatekeeper role' is not justified because the Commonwealth legislation under which the Prescribed List operates does not include monitoring the 'not-for-profit' trade in tissue, or scrutinising tissue banks to make sure they are not illegitimately 'profiteering'.[44]

11.31 Another gap relates to exported tissue. The PwC review found that some tissue banks export tissue overseas and the cost recovery mechanism used in these transactions is unknown.[45] This is because the Prescribed List process only applies to the benefits payable by Australian health insurers.

11.32 A subsequent 2023 review by PwC noted that the evidence and costings provided in support of applications to have products listed in the Prescribed List 'are highly inconsistent' and that '[c]urrent cost-recovery arrangements are not determined by a thorough study of stakeholders' financial statements or cost'.[46] This report recommended that further work be done on the methodology for pricing, and that legislative requirements that prohibit trading in tissue be reviewed.[47]

11.33 The Department of Health (Cth) agreed in principle with this recommendation and noted that the ALRC's inquiry is intended to 'determine whether legislative reform is required to harmonise laws across the nation'.[48]

Transplant tourism

11.34 Organ trafficking and transplant tourism are complex legal and policy issues that the Australian Government has focused on in recent years.

11.35 While 'organ trafficking' is often used as a catch-all term to describe different types of conduct, it is important to distinguish between trafficking in *organs* and trafficking in *persons* for the purpose of organ removal.[49] These are distinct, and raise separate but related legal issues.[50]

11.36 Currently in Australia, the *Criminal Code Act 1995* (Cth) (Criminal Code) criminalises:

- organising or facilitating someone (the victim) to come into or leave Australia,
- while being reckless about if the result will be the removal of one of the victim's organs,
- where that removal would be contrary to state or territory law, or done without the consent of either the victim or their guardian and not for a medical or therapeutic need.[51]

11.37 In the Criminal Code, the heading immediately above the provisions setting out this offence is 'organ trafficking'.[52] However, because the offence captures the movement of people for the purposes of facilitating the unlawful removal of organs, it is a 'trafficking in persons' offence, rather than a 'trafficking in organs' offence. A 2023 Targeted Review of Modern Slavery Offences (the Targeted Review), recommended renaming the offence 'trafficking in persons for the purpose of organ removal' to clarify its scope and the behaviour it targets.[53]

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44 PricewaterhouseCoopers Australia (n 32) 39.
45 Ibid 17.
46 PricewaterhouseCoopers, *Reforms to the Prostheses List Part B* (2023) 15.
47 Ibid.
48 Department of Health and Aged Care (Cth), *Reforms to the Prescribed List Part B: Analysis of Stakeholder Feedback* (2024) 14.
49 Attorney-General's Department (Cth), *Targeted Review of Modern Slavery Offences in Divisions 270 and 271 of the Criminal Code Act 1995 (Cth)* (2023) 75.
50 Law Council of Australia, *Submission 61*.
51 *Criminal Code Act 1995* (Cth) ss 271.7A, 217.7B.
52 Ibid div 271, sub-div BA.
53 Australian Government Attorney-General's Department (n 49) 78.

11.38 The Criminal Code offence does not capture an Australian leaving Australia to purchase an organ for transplantation into their body overseas, which is known as 'transplant tourism'.[54]

11.39 In some cases, organ transplants may be safely and legally undertaken in a foreign jurisdiction, for example where a friend or family member living overseas voluntarily donates an organ. For this reason, we have chosen to focus on transplant tourism which includes a commercial element of purchasing an organ. In this way, transplant tourism covers situations involving trafficking in organs.

11.40 We note that some definitions of 'transplant tourism' do not include this commercial element but encompass all 'cross-border travel of a person to facilitate an organ transplant'.[55] We have chosen not to use this broader definition, as prohibitions of transplant tourism should not apply to people travelling overseas for legitimate donations.[56]

11.41 Transplant tourism that has a commercial element (which will be our focus in what follows) may involve the exploitation of vulnerable people overseas. The risks to donors can be substantial and include 'physical, psychological, financial and social harm'.[57] It can also undermine legitimate donation programs in destination countries.[58]

11.42 There are also risks to recipients, as donor screening and matching is often not as rigorous as in legitimate systems.[59]

11.43 A 2018 parliamentary review (the 2018 review) recommended that the Australian Government amend the Criminal Code and any other relevant legislation to include an offence of 'trafficking in human organs, including the solicitation of a commercial organ transplant' which would apply 'regardless of whether the proscribed conduct occurred either within or outside of the territory of Australia'.[60] Such an offence would fill the gap in the law in relation to organ trafficking as part of transplant tourism. The review noted that:

> If an Australian citizen or resident violates the rights and dignity of a person in an identical manner in a foreign jurisdiction, that constitutes no less a violation of that person's rights than if it occurred in Australia.[61]

11.44 In 2021, the Australian Government accepted the recommendation in principle.[62]

11.45 In March 2015, the Council of Europe's *Convention against Trafficking in Human Organs* (the Convention) was opened for signature.[63] The Convention was established to address the gap in international law, which had previously focused only on trafficking in persons for the purposes of organ removal, rather than trafficking in organs.[64] The Convention requires parties to enact

54 Department of Foreign Affairs and Trade (Cth), 'Organ Transplant Tourism' (2024) <www.smartraveller.gov.au/before-you-go/health/organ-transplant-tourism>.
55 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) 3; Australian Government, *Response to the Joint Standing Committee on Foreign Affairs, Defence and Trade Report: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism* (2021) 4.
56 Commercial trade in human organs is illegal in all countries except Iran: see Fiona Pepper and Damien Carrick, 'Illegal Organ Trafficking Is Big Business, and Vulnerable People Are at Risk. Could an Ethical Organ Trade Solve This?' [2024] *Australian Broadcasting Commission*.
57 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 39.
58 Dominique Martin et al, 'Prevention of Transnational Transplant-Related Crimes-What More Can Be Done?' (2016) 100(8) *Transplantation* 1776, 1777.
59 Library of Parliament (Canada), *Trafficking in Human Organs: An Overview* (2025) 5.
60 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 87, rec 7.
61 Ibid 86.
62 Australian Government, *Response to the Joint Standing Committee on Foreign Affairs, Defence and Trade Report: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism* (n 55) 12.
63 *Council of Europe Convention against Trafficking in Human Organs*, open for signature 25 March 2015, CETS 216 (entered into force 1 March 2018).
64 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 61.

domestic legislation that specifically criminalises trafficking in human organs, and extends to 'ancillary' offences, including 'the solicitation and recruitment of organ donors and recipients, where carried out for financial gain by the person soliciting or recruiting'.[65] The Convention is open for ratification by European countries, and other countries internationally.[66] The 2018 review recommended that the Australian Government sign and ratify the Convention and work with the states and territories to make the necessary amendments to Commonwealth, state, and territory legislation.[67] The Australian Government noted the recommendation,[68] but has not signed the Convention.

11.46 The 2018 review considered the desirability and practicality of extraterritorial jurisdiction, concluding that the external affairs power in section 51 (xxix) of the *Australian Constitution* provides sufficient basis to apply extraterritorial jurisdiction to criminal offences associated with organ trafficking as a 'matter of international concern'.[69] This could be a pathway to giving extraterritorial effect to **Proposal 40**. A civil penalty regime operating extra-territorially may be less appropriate, as the external affairs power is typically associated with matters of such international concern they are appropriately met with criminal sanctions.

11.47 There have also been attempts to criminalise transplant tourism at the state level. In South Australia, a 2015 parliamentary committee report recommended that the South Australian HTA be amended to include a criminal offence for South Australians complicit in transplant abuse abroad, or in sourcing human organs of unknown or unethical origin.[70] There was also an unsuccessful attempt in 2016 in New South Wales to create an extraterritorial offence of transplant tourism.[71] It is worth considering whether organ trafficking and transplant tourism, as inherently transnational concerns, are better dealt with at the Commonwealth level. The 2018 inquiry acknowledged the challenge in organ trafficking legislation being located across both Commonwealth, state, and territory laws, and cited a submission from Australian Lawyers for Human Rights that 'the Commonwealth Criminal Code is the proper place for extraterritorial laws regarding organ trafficking'.[72]

11.48 Despite accepting many recommendations of the 2018 review, the Australian Government has not implemented criminal provisions addressing organ trafficking in the context of transplant tourism.[73] In 2024, the Migration Amendment (Overseas Organ Transplant and Other Measures) Bill 2023 (Cth) proposed introducing a requirement for overseas travellers to disclose organ transplants undertaken outside Australia in the last five years, allowing for visa cancellation for involvement in organ trafficking.

11.49 In a 2024 report on this legislation, the Senate Foreign Affairs, Defence and Trade Legislation Committee recommended that the government 'redoubles its efforts to implement the recommendations agreed to' in the 2018 inquiry.[74] The Australian Government said that the implementation of its response remained 'in progress', including through a targeted review of Australia's modern slavery offences in divisions 270 and 271 of the Criminal Code completed in

65 Ibid 62.
66 Ibid 64.
67 The review noted it had received strong support for ratification in submissions: Ibid 67–9, 71.
68 Australian Government, *Response to the Joint Standing Committee on Foreign Affairs, Defence and Trade Report: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism* (n 55) 11, rec 6.
69 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 51.
70 South Australian Government, *Report of the Joint Committee on the Operation of the Transplantation and Anatomy Act 1983* (2015) 69–70.
71 For example the Human Tissue Amendment (Trafficking in Human Organs) Bill 2016 sought to amend the *Human Tissue Act 1983* (NSW) to address extraterritorial commercial organ trafficking: Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 80.
72 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 80.
73 Law Council of Australia, *Submission 61*.
74 Senate Foreign Affairs, Defence and Trade Legislation Committee, *Report on the Migration Amendment (Overseas Organ Transplant Disclosure and Other Measures Bill) 2023* (2024) rec 2.

2023.[75] This targeted review, which was limited in scope to trafficking in persons offences, did not make specific recommendations in relation to trafficking in organs, but again referred to the recommendations from the 2018 review in relation to criminalising organ trafficking.[76]

11.50 The Australian Government responded that it had considered the findings of the review and agreed to develop potential legislative reforms.[77] It is not yet clear whether trafficking in persons offences will be extended in this way, or whether the conduct captured by an extension would cover trafficking in organs and transplant tourism.

How our reform proposals and questions could address the problems

11.51 Unifying the prohibition of trade and its exceptions will make the law more consistent, accessible, and easier to follow, encouraging compliance — particularly for organisations that operate across jurisdictions within Australia. It also ensures that the prohibition is not overly broad.

11.52 **Proposal 42** provides exceptions to the prohibition of trade to allow trade in some therapeutic products for medical or scientific purposes. **Question 37** asks about whether these exceptions are appropriate and whether additional exceptions are needed. Given the controversy about paid plasma donation, we are seeking specific input about whether paid plasma donation should be allowed.

11.53 **Proposal 43** would allow the National Regulator (or alternative) to make ongoing exceptions to the prohibition of trade that apply in addition to the exceptions listed under **Proposal 42**. The regulator could permit exchanges involving human tissue in a way that is responsive to policy developments and evolving social norms, but justified with regard to factors such as a low risk of exploitation. This will allow tailored consideration of the case for exchanges that would otherwise be prohibited.

11.54 Through **Proposal 44,** the National Regulator (or alternative) would be able to provide a clearer cost-recovery framework. This would improve transparency, help stakeholders recover the costs they are entitled to, and clarify what constitutes unethical reimbursement of expenses.

11.55 **Question 35** relates to extra-territorial effect. The aim of giving extra-territorial effect to the prohibition of trade would be to prohibit transplant tourism. While giving extra-territorial effect to Australian law is uncommon, it has been done in other contexts, such as commercial surrogacy in the Australian Capital Territory, New South Wales, and Queensland, where it is a criminal offence for Australians who live in those jurisdictions to engage in commercial surrogacy while overseas.[78] We are seeking feedback on whether extra-territorial effect for prohibitions on transplant tourism would be best accomplished through the state and territory HTAs or at the Commonwealth level through the Criminal Code.

75 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) 6.
76 Attorney-General's Department (Cth) (n 49) 76.
77 Australian Government, *Response to Targeted Review of Divisions 270 and 271 of the Criminal Code Act 1995 (Cth)* (2024).
78 Australian Law Reform Commission, *Review of Surrogacy Laws* (Issues Paper No 52, 2025) 23.

Reforms relating to advertising the trade of human tissue

Prohibiting advertising

Proposal 45

New human tissue legislation should prohibit the public dissemination of information that invites, promotes, or seeks to induce a person to engage in a prohibited exchange of human tissue (**Proposal 40**).

Question 38

Is there a need for a prohibition on advertising that is broader than the prohibition in **Proposal 45**?

Question 39

If a prohibition on advertising is imposed in accordance with **Proposal 45,** should this prohibition have extra-territorial effect?

The problems we are addressing

11.56 As well as prohibiting trade in human tissue, four jurisdictions prohibit advertisements relating to trade in human tissue. They are Queensland, South Australia, Victoria, and Western Australia.[79] In all four jurisdictions, the legislation refers to advertising related to the buying or purchase of tissue.

11.57 They also prohibit advertising about 'the right to take [or remove] tissue from the bodies of persons'. These prohibitions may be directed at misleading advertising which suggests that someone has a right to take or remove tissue, but the intent of the prohibition is unclear. We are therefore asking in **Question 38** if **Proposal 45** needs to be broadened. We are interested to know if there is a need to capture misleading claims about a right to remove tissue; or other matters beyond those set out in **Proposal 45**.

11.58 Because the HTAs in jurisdictions other than the four listed above to do not prohibit trade-related advertising, content published on a national website could be prohibited in some jurisdictions but not others.[80]

11.59 In Victoria, the prohibition of advertising is broader than in Queensland, South Australia, and Western Australia, extending to advertising related to the donation of tissue.[81] This prohibition creates problems for donation agencies running public awareness campaigns and advertisements to encourage donation.[82] It is possible that the prohibition may extend to social media posts about donation. While ministerial exceptions may be granted to enable advertisements that would otherwise be prohibited, the approval process has been a cause of delay for organ and blood donor campaigns.[83]

79 *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.
80 Norton Rose Fulbright, *Submission 44*.
81 *Human Tissue Act 1982* (Vic) s 40.
82 Victorian Institute of Forensic Medicine, *Submission 45*; Biotherapeutics Association of Australasia and the Eye Bank Association of Australia and New Zealand, *Submission 81*.
83 T Trevor, *Submission 27*.

11.60 Another issue is that some online forums use the language of gifts to disguise transactions that may breach the trade prohibition. For example, a common technique is to offer photographs of human tissue for sale, and to describe the tissue itself (for example bones) as a 'free gift' that the purchaser will receive with the photograph they purchase. This technique helps to avoid the detection of advertisements by algorithms.[84]

Background

11.61 As discussed earlier, concerns over trade in tissue relate to the potential for exploitation, coercion, and commodification of the body. A prohibition of advertising helps to address these concerns by preventing the promotion of trade in human tissue. It also means that a preliminary step on the road to unethical exchanges of tissue is prohibited, and may make it easier to identify and investigate people who are trading in tissue without having to wait for a tissue purchase to actually occur.

11.62 The *Declaration of Istanbul* against organ trafficking, transplant tourism, and transplant commercialism has widespread support from medical communities around the world. The Declaration notes that for prohibitions of trade to be effective, they

> need to include a ban on all types of advertising (including electronic and print media) or brokering for the purpose of facilitating organ trafficking or trafficking in persons for the purpose of organ removal.[85]

11.63 The 2015 South Australian parliamentary committee report recommended that South Australians involved in 'the brokerage and advertising of human organs for purchase or sale abroad' should be subject to criminal sanctions.[86] There is precedent for this type of prohibition in surrogacy laws. Some Australian jurisdictions prevent advertising of certain types of surrogacy arrangements, and give extra-territorial effect to the prohibition.[87]

11.64 Other than in Victoria, the jurisdictions that prohibit advertising limit the prohibition to the advertising of prohibited exchanges, such as advertisements to purchase or sell human tissue. That means that campaigns to promote organ donation do not face legal hurdles in these jurisdictions. It also means that the law does not prevent individuals from publicly seeking a donor, provided they do not offer a financial reward. The practice of seeking donors from the public is known as 'public solicitation'.

11.65 Public solicitation can occur through social media, traditional media, websites, and billboards. The practice is controversial because it raises concerns about unfairness in the donation system and undisclosed financial exchanges; potentially compromises donor-recipient anonymity; can stretch the capacity of donation systems when a surge of volunteers respond to high-profile cases; and sometimes attracts negative media attention, which can undermine public trust in the donation system.[88]

11.66 On the other hand, living donation is to some degree inherently unfair, as people with wide family and social networks are more likely to find a donor. Public solicitation can help people with limited family and friendship networks find a donor. Positive media attention can also raise

84 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, 122.

85 Dominique Martin et al, 'Strengthening Global Efforts to Combat Organ Trafficking and Transplant Tourism: Implications of the 2018 Edition of the Declaration of Istanbul' (2019) 5(3) *Transplant Direct* 1, 4.

86 South Australian Government (n 70) 70, rec 8.

87 *Surrogacy Act 2010* (NSW) ss 10, 11; *Parentage Act 2004* (ACT) ss 43, 45.

88 See generally Alessandro R Marcon, Timothy Caulfield and Maeghan Toews, 'Public Solicitation and the Canadian Media: Two Cases of Living Liver Donation, Two Different Stories' (2019) 5(12) *Transplantation Direct* e508; Marie-Chantal Fortin et al, 'Public Solicitation of Anonymous Organ Donors: A Position Paper by the Canadian Society of Transplantation' (2017) 101(1) *Transplantation* 17; Mihaela Frunza et al, 'Dealing With Public Solicitation of Organs From Living Donors: An ELPAT View' (2015) 99(10) *Transplantation* 2210.

awareness about the benefits of organ donation. When a public solicitation is successful, the recipient is removed from the waitlist for deceased donation, increasing the likelihood that those still on the waitlist will receive a transplant.[89]

11.67 NHMRC Guidelines recognise there are ethical concerns about, but also benefits to, public solicitation.[90] The Canadian Society of Transplantation views public solicitation as 'ethically and legally acceptable' provided there is no monetary exchange, highlighting that 'it adds an organ to the pool and removes a patient from the waitlist', thereby benefiting all transplant patients.[91] The Ethical, Legal, and Psychosocial Aspects of Transplantation (ELPAT) branch of the European Society for Organ Transplantation has taken a pragmatic view, acknowledging the reality of public solicitation and making recommendations on how transplant programs can mitigate ethical concerns.[92]

How our reform proposal and questions could address the problems

11.68 **Proposal 45** will provide a consistent approach across Australia that extends to any forms of public communication that may relate to a prohibited exchange. This would expand the prohibition of advertising beyond the four jurisdictions that currently have one, as well as clarifying the operation of the prohibition. **Proposal 45** supports the prohibition of trade (**Proposal 40**), with the *Declaration of Istanbul* emphasising the link between trade and advertising. However, legitimate public awareness campaigns and communications would not be captured by the prohibition of advertising in **Proposal 45,** as it only applies to advertisements of prohibited exchanges.

11.69 Except for in Victoria, **Proposal 45** will maintain the current legal approach, which allows public solicitation. It would change the approach in Victoria to make public solicitation lawful, provided it does not involve offers of reward in exchange for donation.

11.70 **Question 38** seeks feedback on whether **Proposal 45** is sufficiently broad or not, and is specifically seeking input on whether the wording in existing legislation in Queensland, South Australia, Victoria, and Western Australia, referring to advertising of 'the right to take/remove tissue from the bodies of persons' needs to be maintained as a component of the proposed national prohibition.

11.71 In **Question 39**, we are seeking feedback on whether the prohibition of advertising should have extra-territorial effect, to help address organ trafficking and transplant tourism.

Reforms relating to tissue importation ethics and oversight

Question 40

Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced?

If so, should the mechanism be:

a. A prohibition of the importation into Australia of human tissue that was originally obtained without the consent of the donor, or in exchange for reward or profit? or

b. A reporting mechanism similar to that contained in the *Modern Slavery Act 2018* (Cth)?

89 National Health and Medical Research Council (n 9) 217.
90 Ibid 217–8.
91 Fortin et al (n 88) 18.
92 Frunza et al (n 88) 2213.

Question 41

If a prohibition is legislated of the kind described in **Question 40(a)**, or reporting requirements introduced of the kind described in **Question 40(b),** should new human tissue legislation include a mechanism to exempt importations of human tissue from the prohibition or reporting requirements, and if so, what factors should be considered as a basis for justifying an exemption?

For example, relevant factors could include but not be limited to:

- the health needs of Australians;
- if it is possible to meet the health needs of Australians through domestic supply of the relevant tissue; and
- the risk that the people from whom the tissue was originally obtained were coerced or exploited.

The problems we are addressing

11.72 The Australian demand for tissue products is not being met by tissue donated to tissue banks domestically. Instead, tissue is increasingly being imported from overseas.[93]

11.73 Some jurisdictions allow tissue to be imported from overseas to train surgeons at licensed schools of anatomy, which sometimes occurs through commercially sponsored events. We have heard concerns about whether this tissue is ethically sourced. The two main concerns are:

- whether the tissue has been paid for (which carries risk of exploitation, as discussed in relation to the prohibition of domestic trade in human tissue); and
- whether the tissue was obtained with informed and free consent.

11.74 There are no provisions in the HTAs regarding imported tissue. This means there are no legal requirements for imported tissue to be sourced from consenting donors who have not been coerced or paid for their tissue. The TGA evaluates the safety of therapeutic products and biosecurity regulations are designed to minimise the biosecurity risks of imported tissue. However, no regulatory body has responsibility for ensuring that imported tissue was sourced ethically.

11.75 Some states have policy requirements that apply to schools of anatomy that import tissue from overseas. Schools are required to verify and keep records of information regarding how the tissue was sourced. However, these requirements are not reflected in law. It is not clear whether all states and territories have policies of this nature and the policy requirements only apply to tissue imported by schools of anatomy, not tissue imported for therapeutic purposes. As a result, there appear to be legal gaps in the regulation of imported tissue.

Background

11.76 Submissions to our *Issues Paper* raise concerns about inadequate oversight of the circumstances in which imported tissue was donated.[94] We have heard support for national regulation of the tissue sector given the high volume of tissue being transferred within Australia and imported from overseas,[95] which supports the exploration of the possible mechanisms outlined in **Question 40**.

93 PricewaterhouseCoopers Australia (n 32) vi–vii.
94 Private Healthcare Australia, *Submission 64*.
95 PlusLife, *Submission 22*.

11.77 Tissue banks are licensed through the TGA and must comply with standards for manufacturing, donor screening and tissue testing, and the safety of the therapeutic goods being produced.[96]

11.78 The TGA maintains the Australian Register of Therapeutic Goods (the register). Before listing a product on the register, the TGA reviews evidence to ensure the product meets required standards for quality, safety, efficacy, and performance. The TGA licenses domestic manufacturers and reviews the international manufacture of products to ensure that they meet the same standards required in Australia.

11.79 This process allows therapeutic goods on the register made from human tissue, called 'biologicals', to be imported provided the TGA's requirements are met. In addition, there is a Special Access Scheme that enables clinicians to access products from overseas that are not listed on the register in exceptional circumstances.[97] Clinicians can apply to access products through the Special Access Scheme, but must explain why products listed on the register are not suitable.[98] The TGA assesses these applications on case-by-case basis.

11.80 An allograft is tissue — such as bone, ligaments, or heart valves — that has been removed from a human donor for transplantation into another person. The 2016 PwC report discussed earlier found that approximately 9,000 allografts had been imported to Australia under licence from the TGA over a three-year period.[99] The report showed that applications to the Special Access Scheme to import tissue were growing, with thousands of allografts imported through this mechanism each year.[100]

11.81 The PwC report noted that, although stakeholders believed that the TGA's assessments of tissue products considered the source of the tissue and whether it was ethically procured, 'ethical procurement is only within the TGA's scope if it influences the tissues' quality, safety and efficacy'.[101]

11.82 Because imported tissue has not been sourced under Australian law, it is important to ensure that it was obtained ethically from consenting donors. The 2018 review discussed earlier recommended that the Australian Government work with the states and territories to make sure that anyone importing tissue for commercial purposes be required to produce 'verifiable documentation of the consent of the donor … or their next of kin'.[102]

11.83 Tissue importers must comply with the *Biosecurity Act 2015* (Cth). However, the Australian Government has indicated that, under the Biosecurity Act,

> ethical considerations around the sourcing of goods are only relevant to the extent that those considerations inform an assessment of the biosecurity risk associated with those goods.[103]

11.84 Because of this, the *Biosecurity Act 2015* (Cth) 'is not the appropriate legislative instrument to give effect' to the 2018 review recommendation that commercial tissue importers provide documentation to verify that tissue was obtained with consent of the donor or their next of kin.[104]

11.85 Tissue is also imported for use for anatomical examination at schools of anatomy. While the HTAs do not directly regulate tissue importation, there are relevant policies at the state and territory level. For example, in New South Wales, there is a policy requirement that licensed

96 PricewaterhouseCoopers Australia (n 32) 78.
97 Ibid 79–80.
98 Ibid 80.
99 Ibid 19.
100 Ibid 19–20.
101 Ibid 42.
102 Joint Standing Committee on Foreign Affairs, Defence and Trade, Parliament of Australia (n 55) 103, rec 12.
103 Australian Government (n 75) 12.
104 Ibid.

anatomy schools importing tissue from overseas ensure the consent requirements and provisions in the *Anatomy Act 1977* (NSW) are complied with, as well as ensuring there is consent about disposal.[105] Similar requirements exist in South Australian and Victorian policies.[106] As schools of anatomy are subject to licensing and inspection, there is also a mechanism for oversight of this policy requirement.

11.86 In **Question 40,** we are seeking feedback on whether new human tissue legislation should include either:

- a prohibition on importing tissue that was originally obtained in a manner that would violate domestic law relating to consent and authorisation to donate tissue, or trade; or
- a reporting mechanism along the lines of that contained in the *Modern Slavery Act 2018* (Cth).

Modern Slavery Act reporting

11.87 The record keeping and reporting requirements in the *Modern Slavery Act 2018* (Cth) comprise a scheme designed to extend Australia's commitment to avoiding exploitation beyond Australian borders. The Act uses reporting obligations to require some corporate entities to address modern slavery risks.[107] Entities covered by the Act must provide the Minister with modern slavery statements, which describe:

- the entity's structure and supply chains, and slavery risks within these;
- the actions taken by the entity to mitigate slavery risks; and
- how effective mitigating actions are likely to be.[108]

11.88 Currently the only consequence of failing to provide a modern slavery statement is potential reputational harm from being listed on a public register.[109]

11.89 Two submissions to our *Issues Paper* suggest that human tissue laws should be aligned with the *Modern Slavery Act 2018* (Cth).[110]

How our reform proposals and questions could address the problems

11.90 If a tissue importation prohibition or reporting mechanism is created, a legal gap would be filled that would either require importers of tissue to verify that the tissue was provided consensually and in a way that would not violate the domestic prohibition of trade or report on their plan to mitigate these risks. The prohibition or reporting mechanism would apply nationally, providing consistency across the country.

11.91 In **Question 41**, we are seeking feedback on whether a mechanism should exist to exempt importations of tissue that has not been ethically sourced. This may be important for the importation of plasma products. As discussed above, Australia imports a large proportion of our plasma products from the United States. In the United States, donors are paid for the time and discomfort involved in donating. If payments for plasma donation are not allowed under new

105 NSW Health, 'Anatomical Examinations and Anatomy Licensing Policy Directive' 15 (2023) <www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_044>.
106 Department of Health (Vic), *Guidelines for the Governance of Schools of Anatomy in Victoria* (October 2014) 2; Government of South Australia, SA Health, *Standard for the Operation, Management and Oversight of Schools of Anatomy in South Australia* (No 2017.01) 8.
107 *Modern Slavery Act 2018* (Cth) ss 5–6.
108 Ibid ss 14, 16.
109 Ibid s16A(4). In 2023 a review recommended some amendments to the mandatory reporting criteria in the *Modern Slavery Act 2018* (Cth): John McMillan, *Report of the Statutory Review of the Modern Slavery Act 2018 (Cth): The First Three Years* (2023) 66.
110 Australian Christian Lobby, *Submission 21*; Lions Eye Donation Service, *Submission 28*.

human tissue legislation in Australia, then the importation of United States plasma products may violate the prohibition envisaged in **Question 40(a)**.

11.92 If exemptions should be facilitated, we are considering the grounds on which exemptions should be granted. In **Question 41**, we are seeking feedback on what factors should be considered in granting an exemption.

11.93 Oversight of how imported tissue has been sourced will help maintain public trust in our tissue sectors and ensure Australians are not participating in or benefiting from exploitative, coercive, or other harmful practices occurring overseas.

Reforms relating to data transparency

Improving access to data

Question 42

We have heard there is a need for data from donation agencies, tissue banks and other tissue product manufacturers, distributors, and sponsors to better understand the demand for tissue and inform future policy development.

If you agree there is a need for data, what type of data is needed?

Question 43

In relation to **Question 42**, how should the data be reported?

For example, should there be:

a. voluntary reporting?

b. mandatory reporting?

Question 44

In relation to **Question 43**, if you support mandatory reporting, should the National Regulator (or alternative) have the power to conduct mandatory inspections of records?

The problems we are addressing

11.94 Inadequate data about the tissue sector makes it difficult to gauge the demand for donated tissue (other than organs or blood products) in Australia, or to asses with clarity how the sector is operating.[111] Other than for eye tissue, there is no reporting mechanism to provide clinical insights into how tissue is used.[112] The lack of national oversight also makes it difficult to determine the true demand for specific types of tissue products.[113] This can make it difficult to develop targeted and useful policy recommendations to improve the functioning of the sector.[114]

11.95 We have received submissions to our *Issues Paper*, advocating for:

- improved transparency around the importation and use of tissue in Australia;[115]

111 We heard this in consultations with people who work in the tissue sector. See also PricewaterhouseCoopers Australia (n 32) 42.
112 Ibid 43.
113 Ibid 42.
114 Ibid.
115 R Jenkin, *Submission 48*.

- laws to make sure eye and tissue banks are 'required to report their activities transparently', and to restrict profiteering from donors;[116] and
- transparent national reporting and 'movement towards more centralised systems of regulation and management', given the high volume of interjurisdictional and international tissue supply.[117]

11.96 These submissions have been taken into account in the development of **Questions 42–44**.

Background

11.97 The WHO's Guiding Principles encourage transparency and call for 'transplantation activities' to be 'open to scrutiny'.[118] This is enshrined in the NHMRC's guiding principles.[119] The NHMRC has also encouraged the ethical collection and reporting of data, including that data be collected and reported to help estimate the need for transplantation and to evaluate donation and transplantation performance.[120]

11.98 In the tissue sector, the PwC report noted several areas where standardised data reporting would be useful, including information about the financial operations of actors in the tissue sector, the transfer of tissue across national and state and territory borders, and clinical outcomes of patients who receive tissue products.

11.99 With respect to financial reporting, PwC found that 'the ability of government to monitor the financial accountability and viability of the sector as a whole' is compromised by the absence of national reporting obligations.[121] PwC also found that the sector's ability to adapt and respond to changing clinical needs is undermined by the lack of national oversight of the clinical need for and use of tissue.[122]

11.100 While the TGA requires that tissue banks keep records to ensure the traceability of tissue, 'the way in which this information is collected across tissue banks is inconsistent, and is not collected and reported nationally'.[123] PwC identified barriers to increased standardisation of reporting, including 'a lack of requirement to do so', reporting burdens, privacy concerns, a lack of clinical follow-up to report outcomes of tissue use, and the lack of a professional body prioritising this issue.[124]

11.101 Since the PwC report, the National Eye and Tissue Sector Framework has been published to set objectives for the sector and help guide future directions. The Framework acknowledges that there is a need for improvements to national data collection and reporting, and that the 'current lack of data relating to imported tissue, or any product containing human tissue, is recognised as a particular challenge'.[125]

How our reform proposal and questions could address the problems

11.102 **Question 42** is designed to elicit information about the types of data required to:

- help inform future policy development; and

116 Lions Eye Donation Service, *Submission 28*.
117 PlusLife, *Submission 22*.
118 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) 9.
119 National Health and Medical Research Council (n 9) 46.
120 Ibid 148–9.
121 PricewaterhouseCoopers Australia (n 32) 44.
122 Ibid 42.
123 Ibid 43.
124 Ibid.
125 Department of Health and Aged Care (Cth), *National Eye and Tissue Sector Framework* (2022) 12.

- facilitate oversight and compliance with the prohibition of trade and the potential prohibition on importing tissue that has not been ethically sourced.

11.103 **Question 43** seeks feedback on the appropriate mechanism for reporting this data. Together, **Questions 42–44** aim to ensure that a national picture is available to fill the current data gaps and facilitate policy development.

12. Reforms relating to how information can be disclosed and shared

Contents

Reforms to non-disclosure provisions

Prohibiting non-consensual public disclosures of a tissue donor's or tissue recipient's personal information

Proposal 46

New human tissue legislation should prohibit the public disclosure of a human tissue donor's or human tissue recipient's 'personal information', unless consent to disclosure has been provided in accordance with **Proposal 48**.

'Personal information' is information that identifies an individual, or that makes an individual reasonably identifiable.

Permission for health practitioners to disclose a tissue donor's personal information in limited circumstances

Proposal 47

New human tissue legislation should provide that it is permissible for medical practitioners to disclose a human tissue donor's personal information to a potential human tissue recipient provided:

a. the information is clinically relevant to the potential tissue recipient's decision about whether to accept tissue for transplant; and

b. the information is disclosed in a manner that mitigates the risk of the donor being identified to the greatest extent possible without compromising the ability of the potential recipient to make an informed decision.

Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information

Proposal 48

New human tissue legislation should provide that consent to the disclosure of a human tissue donor's or human tissue recipient's personal information may be given by:

a. the human tissue donor or the human tissue recipient themselves; or

b. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is deceased; or

c. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is a child or an adult who does not have decision-making capacity.

The problems we are addressing

12.1 The HTAs have provisions that prohibit the disclosure of information that may lead to the identity of a donor or recipient becoming publicly known.[1] These provisions were originally designed to protect people's privacy by preventing public disclosures and media reporting that could identify human tissue donors or recipients without their consent.[2] The prohibitions against publicly disclosing identifying donor or recipient information also protect the anonymity of participants in non-directed donations. These are donations made to the person at the top of the transplant waitlist, rather than to a specific recipient.

12.2 As we explain in more detail below, the HTA prohibitions create a complicated framework of privacy protections that is inconsistent across different jurisdictions,[3] and difficult to follow and apply.

The class of information the prohibitions capture may be too broad

12.3 Because they refer to the disclosure of information that 'may' identify a person, the prohibitions may be too broad. Given the amount of information that is now available through the internet and social media, a prohibition on disclosing information that 'may' publicly identify a human tissue donor or recipient could include extensive information. Current privacy legislation only requires protection of 'personal information', defined as information about an individual who is identified or is 'reasonably identifiable'.[4]

The class of people the prohibitions apply to may be too narrow

12.4 In all states and territories except the Northern Territory and Western Australia, the prohibitions only apply to people professionally involved in or associated with the relevant human tissue donation or transplantation. This means that anyone who has identifying information about a human tissue donor or recipient, such as friends and acquaintances, can publicly disclose that information without the consent of the person to whom it relates. This could allow the use of social

1 *Transplantation and Anatomy Act 1978* (ACT) s 49; *Human Tissue Act 1983* (NSW) s 37; *Transplantation and Anatomy Act 1979* (NT) s 28; *Transplantation and Anatomy Act 1979* (Qld) s 49; *Transplantation and Anatomy Act 1983* (SA) s 39; *Human Tissue Act 1985* (Tas) s 31; *Human Tissue Act 1982* (Vic) s 45; *Human Tissue and Transplant Act 1982* (WA) s 34.

2 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, 1977) 101.

3 Anthony Cignarella et al, 'Identity Disclosure Between Donor Family Members and Organ Transplant Recipients: A Description and Synthesis of Australian Laws and Guidelines' (2024) 21(2) *Bioethical Inquiry* 309, 325.

4 For example, s 6 of the *Privacy Act 1988* (Cth) defines 'personal information' to mean 'information or an opinion about an identified individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not; and (b) whether the information or opinion is recorded in a material form or not.'

media to breach the anonymity of human tissue donations. It could provide a way for a tissue donor to contact the recipient of their tissue, or for a tissue recipient to contact their donor, without the other person's consent and where the contact may be unwelcome.[5]

In the Northern Territory and Western Australia, there may be a need for additional exceptions to the prohibition

12.5 In the Northern Territory and Western Australia, the prohibitions apply to everyone and include only limited exceptions. In all jurisdictions, including the Northern Territory and Western Australia, an exception to the disclosure of information prohibition applies if the person to whom the information relates consents to the disclosure.[6] However, in the Northern Territory and Western Australia, the HTAs do not include an exception to allow the families of deceased tissue donors or recipients to disclose identifying information.[7] This means that the families of deceased donors in these jurisdictions are legally prohibited from publicly telling their loved ones' stories. A limited exception is provided in Commonwealth legislation, to allow family members to share their loved ones' stories for the purposes of OTA and DonateLife activities.[8]

Complying with the prohibitions may be difficult for health practitioners

12.6 We have heard that medical practitioners may be unclear about how to reconcile legal duties to respect the privacy of human tissue donors while also meeting their duties of disclosure to potential recipients. Potential recipients are entitled to receive clinically relevant information about donated tissue to inform their decision about whether to accept it.

Background

12.7 Aside from the prohibitions of disclosure of information in the HTAs, a range of laws protect patients' privacy, and the confidentiality of their information. These include:

- common law obligations based in the law of contract and equity;[9]
- professional codes of conduct;[10] and
- a combination of state and territory health record legislation,[11] and Commonwealth privacy laws.[12]

12.8 Privacy rights are about giving individuals control over the collection, use, and disclosure of their personal information. This is important in the context of human tissue donation and transplantation, where:

- sensitive health information, such as a donor's risk of transmitting an infection, needs to be obtained, and sometimes shared for clinical or other legitimate purposes;

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5 Cignarella et al (n 3) 326; Name withheld, *Submission 71*.

6 *Transplantation and Anatomy Act 1978* (ACT) s 49(4)(d); *Human Tissue Act 1983* (NSW) s 37(3); *Transplantation and Anatomy Act 1979* (NT) s 28(2)(c); *Transplantation and Anatomy Act 1979* (Qld) s 49(3)(c); *Transplantation and Anatomy Act 1983* (SA) s 39(2)(c); *Human Tissue Act 1985* (Tas) s 31(4)(c); *Human Tissue Act 1982* (Vic) s 45(3)(c); *Human Tissue and Transplant Act 1982* (WA) s 34(2)(c).

7 *Transplantation and Anatomy Act 1979* (NT) s 28; *Human Tissue and Transplant Act 1982* (WA) s 34.

8 *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) s 58A.

9 GE Dal Pont, *Law of Confidentiality* (Lexis Nexis Butterworths, 2015) 172–3.

10 See, eg, Australian Health Practitioner Regulation Agency, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (2020) 9; Australian Medical Association, *Code of Ethics* (rev ed, 2016) 2. Breach of some codes may constitute unprofessional conduct.

11 See, eg, *Health Records (Privacy and Access) Act 1997* (ACT) s 17; *South Australian Public Health Act 2011* (SA) ss 99, 100; *Health Records Act 2001* (Vic) s 27. There are also obligations contained in mental health legislation: see, eg, *Mental Health and Related Services Act 1998* (NT) s 117; *Mental Health Act 2013* (Tas) s 134.

12 The Office of the Information Commissioner has released a guide on Commonwealth privacy laws for health providers: Office of the Australian Information Commissioner (Cth), *Guide to Health Privacy* (2025).

- maintaining the anonymity of non-directed donation prevents biased or discriminatory decision-making, which could occur if the identity of a potential recipient is revealed to a potential donor; and
- human tissue donors and human tissue recipients are entitled to privacy, and to have their wishes respected if they do not want the other person involved (the donor or recipient) or the families of either party, to know their identity.

12.9 The protection of donors' and recipients' privacy, and maintaining the confidentiality of personal information, are regarded as fundamentally important in national and international ethical instruments.[13]

12.10 We have not yet established the extent to which common law obligations, professional codes of conduct, and state, territory, and Commonwealth privacy laws protect the privacy of human tissue donors and recipients, and prevent their personal information being shared without their consent. In our Final Report, we will provide more detail about these laws.

12.11 Currently, the HTAs allow living donors and recipients to exercise control over their information by allowing them to consent to disclosures of their information that may lead to their identity becoming known.

12.12 However, the ability for the families of deceased donors or deceased recipients to consent to the disclosure of their loved ones' information varies. Commonwealth legislation was recently amended to allow OTA and DonateLife to publicly identify deceased donors and recipients, with the consent of authorised family members, for educational, promotional, or commemorative purposes. The legislation also allows family members to share their loved ones' stories for the purpose OTA or DonateLife activities.[14]

12.13 Outside this context, in all jurisdictions except for the Northern Territory and Western Australia, families can share their loved ones' stories because the HTAs only prohibit disclosure of relevant information by people professionally involved in or associated with tissue donation or transplantation. In the Australian Capital Territory, New South Wales, South Australia, and Tasmania, authorised family members can also provide consent to allow disclosure by a person to whom the prohibition on disclosure applies — that is, a person professionally involved in or associated with the donation or transplantation.[15] There is no provision for this in the HTAs in Victoria and Queensland.

12.14 A program exists to assist consenting bone marrow donors and recipients to contact one another after the transplant.[16] There are no legal impediments in the HTAs to this program operating because living donors and recipients can consent to public or private disclosures of their own information. In the deceased donation context, the legality of developing a similar program is more complex for the reasons outlined above.

13 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) 9; National Health and Medical Research Council, *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (NH208, 2025) 46.

14 *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) s 58A.

15 These exceptions to the prohibition on disclosure of information are very recent in South Australia. The SA legislation was amended in 2024 by the *Transplantation and Anatomy (Disclosure of Information and Delegation) Amendment Act 2024*.

16 National Health and Medical Research Council (n 13) 141.

12.15 We heard from Donor Families Australia that the scope of the prohibitions on disclosure of information in the HTAs, especially in the Northern Territory and Western Australia, is a cause of significant distress. Donor Families Australia Chairperson McDowell told us:

> We want to be able to use [our deceased family member's] information unconditionally – we as the family own their information. My daughter's information belongs to us. It should not matter what environment I'm in, I should be free to speak about my daughter with no conditions attached.[17]

12.16 We heard from several people who work in the tissue donation sector that it is important for donor families to be able to publicly identify that their deceased loved one was a donor. We were told that it may be especially important for First Nations people to be able to share their deceased kin's donation stories with other First Nations people as a way of de-mystifying organ donation.

12.17 More generally, we heard from submissions which support allowing consenting recipients and deceased donor families to obtain information about and meet one another.[18] In the stem cell context, Stem Cell Donors Australia, and Australia and New Zealand Transplant and Cellular Therapies described consensual contact between donors and recipients as 'of critical importance'.[19]

12.18 The importance of preserving the anonymity of human tissue donors and recipients was also highlighted in submissions to our *Issues Paper*. Transplant Australia told us that '[m]any recipients struggle with survivor guilt amongst a range of other physical and mental conditions in recovery and they do not need the added burden or expectation that they should make direct contact with their donor's family'.[20]

12.19 The right to privacy can sometimes be in tension with other rights or obligations. For example, doctors have a duty to disclose material information to their patients, including disclosing information a reasonable person in the patient's position would want to know.[21] For doctors treating a potential organ recipient, this may mean disclosing information about the donor, such as an age range the donor belonged to or whether the donor engaged in behaviours that mean their organs have a higher risk of transmitting infections.[22]

12.20 Doctors need to be able to fulfil their disclosure obligations without fear of violating a prohibition on disclosing a donor's personal information. As more information and data enters the public domain, it becomes easier to identify people using fewer individual data points. This is known as 'triangulation' or 'data linkage'.[23] It means that a donor's age range, viral risk status, or other clinically relevant details could, in some circumstances, like a highly publicised accident, be information by which the donor's identity may become publicly known. As technology and the availability of data is making it easier to identify people over time, it is important to provide clarity for medical practitioners into the future that their disclosure obligations are paramount.

17 Donor Families Australia, *Consultation 1*.
18 See, eg, K Appleby, S*ubmission 16*; W Duncan, *Submission 69*; L Campbell, *Submission 76*; G Harrison, *Submission 85*; H Northam, *Submission 86*.
19 Stem Cell Donors Australia and ANZTCT, *Submission 42*.
20 Transplant Australia, *Submission 24*.
21 *Rogers v Whittaker* (1992) 175 CLR 479. See also discussion in Tina Cockburn and Bill Madden, 'Negligence' in Ben White et al (eds), *Health Law in Australia* (Thomson Reuters, 4th ed, 2024) 335.
22 Ethical guidance on what is 'clinically relevant information' is provided by the NHMRC: National Health and Medical Research Council (n 13) 132.
23 James Cook University, 'Triangulation, Data Linkage and Integrating Authorities' <www.jcu.edu.au/rdim/step-2-manage/organise-data/triangulation>.

How our reform proposals could solve the problems

12.21 **Proposal 46** for a prohibition in new human tissue legislation of public disclosures of personal information without consent will provide consistency across jurisdictions.

12.22 The prohibition in **Proposal 46** is designed to prevent non-consensual disclosures that could reasonably lead to an individual donor or recipient being publicly identified. This aims to protect the privacy of donors and recipients regardless of who has access to their information, so it is not limited to health practitioners or people working in the human tissue sector.

12.23 The prohibition in **Proposal 46** only applies to public disclosures. As discussed earlier, a range of other laws protect patients' privacy and the confidentiality of their information, and prevent health care practitioners and some other people with access to this information from sharing it without the consent of the person to whom the information relates, or for illegitimate purposes. New human tissue legislation should not include additional privacy protections if they are unnecessary. Our Final Report will consider in detail the coverage of general privacy protections for patients and if there are any gaps that new human tissue legislation should fill.

12.24 Our proposals align with Commonwealth privacy law principles that prohibit the disclosure of information that identifies or could reasonably identify an individual.[24] This provides a clearer standard for practitioners.

12.25 By allowing consensual public disclosures in **Proposal 48** we are supporting donor and recipient control over their own information. And by allowing deceased donors' or recipients' authorised decision-makers to disclose the donor's or recipient's personal information, or to consent to the information being disclosed by others, we are making it possible for families to share their loved ones' stories regardless of where they live.

12.26 We acknowledge that there are benefits and risks of donors, recipients, and families identifying and contacting one another following a transplant, and that risks of unwanted contact may be higher when a person publicly identifies themselves as a donor or recipient.

12.27 However, given that in most jurisdictions there is nothing presently in the HTAs that prohibits any of these people from publicly identifying themselves, we do not think our proposals will exacerbate a risk of harm. If anything, by extending the prohibition to apply to everyone (rather than just to health care workers or those professionally involved in the donation or transplantation), donors and recipients will be better protected from being publicly identified without consent.

12.28 **Proposal 47** aims to provide clarity for medical practitioners who may have competing obligations to provide risk information to potential recipients while maintaining a donor's privacy. This proposal makes it clear that it is not a violation of the law to disclose clinically relevant information about a donor provided the information is disclosed in a way that tries to avoid the donor being identified to the greatest extent possible.

24 For example, s 6(1) of the *Privacy Act 1988* (Cth) defines 'personal information' to include 'information or an opinion about an identified individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not; and (b) whether the information or opinion is recorded in a material form or not'. 'Reasonably identifiable' refers to information that is not necessarily public: Office of the Australian Information Commissioner, 'Australian Privacy Principles Guidelines. Chapter B: Key Concepts' (2022) <www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-guidelines/chapter-b-key-concepts>.

Reforms relating to screening and information sharing

Allowing certain people to access and share information for identification and screening purposes

Proposal 49

New human tissue legislation should use sections 45(4)–(6) of the *Human Tissue Act 1982* (Vic) as a model to ensure that medical practitioners, health authorities, and DonateLife staff can access and share with each other relevant information for donor identification and screening.

The problems we are addressing

12.29 Before deceased tissue donation is raised with a potential donor's family, some initial investigations need to occur to see if donation is possible. This means that some information needs to be collected and disclosed by and between medical practitioners, health agencies, donation organisations, and the Australian Organ Donor Register without the prior consent of the deceased person's family. Legal uncertainty about the sharing of health information in this context means that these steps can take longer to complete than they otherwise would, or that the initial donation conversation with families is not as informed as it could be.

Background

12.30 While privacy laws generally allow members of a treating team to share patient information between each other for the purpose of providing medical treatment,[25] it is not clear that the provisions apply to potential donor referral and screening, as these activities are not undertaken for the purpose of improving the donor's health. For example, we have heard a concern that current Commonwealth legislation may prohibit DonateLife staff accessing My Health Records without a donor's prior consent.[26] Most states and territories also have their own privacy laws that apply to different entities and contexts.

12.31 Information access and sharing is important for identification of organ and tissue donors, checking to see if the potential donor registered an intention to donate, and for screening to help determine if organs and tissues are suitable for donation. And it is important that some of these steps be undertaken before obtaining consent from a person's next of kin.

12.32 For example, if there are clear medical reasons why a person will not be able to donate organs or tissues, identifying these issues before donation is raised as a possibility with families will avoid unnecessarily adding to the family's distress. Conversely, if a person is potentially suitable to donate and they registered an intention to donate by joining the Donation Register, this is important information for the person's family to consider. As we are recommending in **Proposal 23** that a person's authorised decision-maker is obliged to make the decision they think the person would have made in the circumstances, knowing that a person registered their intention to donate will be important in making this decision.

12.33 Subsection 45(4) of the *Human Tissue Act 1982* (Vic) authorises the collection and disclosure of information by people and entities such as medical practitioners and organ donation services, for the purposes of determining if tissue is suitable for a permitted use (transplantation,

25 Office of the Information Commissioner, 'Chapter 3: Using or Disclosing Health Information' (2019) <www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy/chapter-3-using-or-disclosing-health-information>.

26 Australian Centre for Transplantation Excellence and Research, *Submission 65*.

research, etc) as well as to locate the senior available next of kin.[27] Subsection 45(6) further provides that these provisions prevail over 'any other Act or law'. We have heard that the Victorian provisions provide a useful model for reform.

How our reform proposals could solve the problem

12.34 Providing lawful access to and sharing of information without prior consent for the limited purposes in **Proposal 49** could provide clarity for health care practitioners, donation agencies, and information custodians that the steps needed to identify, refer, and screen potential deceased donors are lawful. Access to earlier and better information will also help initial donation discussions with families to be as informed as up to date as possible.

27 Section 45(5) of the *Human Tissue Act 1982* (Vic) lists the actors and entities that sub-s 45(4) applies to.

13. Compliance

13.1 Many of the proposals in this *Discussion Paper* recommend that human tissue legislation should impose obligations on various persons, including prohibiting certain conduct. We have also discussed the role of a new National Regulator (or alternative) in encouraging or enforcing compliance in some cases.

13.2 In the next phase of our Inquiry, we will consider what, if any, reforms are necessary to promote or encourage compliance with the obligations and prohibitions imposed. As well as criminal and civil sanctions, a range of regulatory tools are available to promote compliance, including, for example, enforceable undertakings.

Compliance mechanisms

Question 45

Do you have views about the best mechanisms to encourage or enforce compliance with the obligations and prohibitions that we are proposing should be included in new human tissue laws, regulations or standards?

In your answer, you may wish to focus on particular obligations or prohibitions that we are proposing, and the best way of encouraging or enforcing compliance with these.

14. The timeframe for implementing our reform proposals

14.1 Our Terms of Reference ask us to consider whether, and how, implementation of any reforms we recommend should be staged or prioritised.

14.2 We are seeking feedback on:

- whether some reforms are more urgent than others, and if so, which reforms are most urgent and which reforms are less pressing;
- any other views you have on how the reforms we are considering should be staged or prioritised; or
- any views you have on the most appropriate timeframe for particular reforms.

The timeframe for implementing our reform proposals

Question 46

Do you have views on the timeframe/s within which the reforms set out in this *Discussion Paper* should be implemented, or on how the implementation of these reforms could be staged or prioritised?

15. Reforms we are unlikely to propose

Contents

Regulation of schools of anatomy

15.1 Schools of anatomy are specialised institutions, often located within universities or medical faculties, that are dedicated to the study and teaching of human anatomy using donated deceased bodies. They provide students, researchers, and healthcare professionals with the opportunity to explore the structure and function of the human body in detail. These schools deliver foundational training in anatomy for medical, dental, and allied health students. They also support postgraduate education, surgical skills training, and research into medical techniques and technologies.

15.2 Schools of anatomy manage the acquisition, care, and eventual disposal of human remains. These schools ensure that body donation and handling is conducted with dignity and in accordance with the wishes of donors and their families. By bridging scientific inquiry with ethical stewardship, schools of anatomy play a critical role in advancing both medical knowledge and clinical practice.

15.3 Current regulation of schools of anatomy mostly occurs at the state and territory level.[1] In New South Wales, Western Australia, and Tasmania, dedicated Anatomy Acts deal with schools of anatomy.[2] In other jurisdictions, schools of anatomy are regulated through a combination of the HTAs, regulations, and policy.

What we have heard about schools of anatomy

15.4 Several submissions we received in response to our *Issues Paper* suggested there is a need for consistent consent provisions across body donor programs. For example, Jenkin suggests that:

> all body donor programs should be required to use a common consent form which contains a set of consensus derived clauses … Additional clauses could be otherwise added to fulfil individual program needs (provided they did not override the core clauses).[3]

15.5 We discuss consent and authorisation frameworks for body donation in **Chapter 9**.

1 Except for New South Wales, where schools of anatomy are regulated by Local Health Districts.
2 *Anatomy Act 1977* (NSW); *Anatomical Examinations Act 2006* (Tas); *Anatomy Act 1930* (WA).
3 R Jenkin, *Submission 48*.

15.6 We also received submissions saying that legislative provisions dealing with schools of anatomy need to be modernised, and that schools of anatomy should be regulated with national consistency.[4] There is support for the national regulation of schools of anatomy in academic literature.[5] Academic commentators also suggest that current legislative provisions do not align with best practice.[6]

Why we are not considering the regulation of schools of anatomy

15.7 The focus of our Inquiry is on harmonising and modernising the legislative framework for human tissue donation, transplantation, and use, using the current HTAs as our starting point.

15.8 With respect to schools of anatomy and bodies donated for anatomical examination, we have addressed the most significant issues that require harmonisation and modernisation by:

- making proposals to modernise and harmonise the consent and authorisation process for donation of bodies;
- proposing that bodies can be donated to schools of anatomy for a wider set of purposes (medical, educational or scientific purposes) beyond 'anatomical examination', to capture the types of activities undertaken in a contemporary school of anatomy;
- proposing how to harmonise and modernise the prohibition of trade in tissue, which includes human bodies; and
- asking questions about how imported tissue (including tissue imported to schools of anatomy for surgical skills workshops) should be addressed in new human tissue legislation.

15.9 There are jurisdictional differences in terms of how schools of anatomy are regulated — such as how long bodies can be retained, the process for the appointment of inspectors, and the inspection process.[7] By comparison with this regulatory framework, collections of research tissue have no licensing, regulation, or oversight at all. We have chosen to address the most pressing issues requiring modernisation and harmonisation and rather than more granular issues in the sector.

15.10 It may be appropriate to review the regulatory framework for schools of anatomy in the future. Given the range of issues requiring more urgent attention in the HTAs that we are considering, we have decided not to consider this topic further.

Statutory defences in relation to blood collection

15.11 Before donating blood or plasma, potential donors are required to complete a donor questionnaire and declaration. This is designed to assess their eligibility to donate, including the risk of their donation transmitting infections through the blood supply. As blood donation is coordinated nationally through Australian Red Cross LifeBlood, the same questionnaire is used throughout Australia. The questionnaire and declaration are updated regularly to reflect changing risk factors to the blood supply. Any proposed changes are reviewed by the TGA to assess the risk and impact that changes might have on Australia's blood supply.[8] Changes to the donor questionnaire must also be approved by the relevant authorities in each of the states and territories.

4 Department of Health for Western Australia, *Submission 23*.
5 Erin Hutchinson et al, 'The Law, Ethics and Body Donation: A Tale of Two Bequeathal Programs' (2020) 13(4) *Anatomical Sciences Education* 512, 514.
6 Ibid 513.
7 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; Macquarie University, *Submission 19*; Norton Rose Fulbright, *Submission 44*; Department of Anatomy and Physiology, University of Melbourne, *Submission 82*.
8 See, eg, Therapeutic Goods Administration, 'Lifeblood Sexual Activity and PrEP Deferrals' <www.tga.gov.au/news/news/lifeblood-sexual-activity-and-prep-deferrals>.

15.12 In all states and territories except Queensland, there are statutory provisions that provide service providers in the blood sector with a defence to legal actions if blood recipients contract specific infections from the blood supply.[9] Donor questionnaires and declarations are an important element of these statutory defences. The purpose of the statutory defence provisions is to reduce the risk of blood service providers being exposed to civil litigation relating to the transmission of blood borne diseases where the provider has complied with prescribed donor screening and testing.

15.13 Originally introduced in the context of the HIV/AIDS epidemic to address difficulties with insurance and risk management for supplier organisations, the statutory defence provisions also provide clarity for potential litigants regarding when a claim can be made.[10] One requirement of the defence is that the service provider responsible for collecting infected blood must have ensured the donor of the infected blood completed the questionnaire and declaration. Different state and territory Acts define and identify the relevant questionnaire differently. For example:

- in Victoria, it must be in an approved form that is published in the Victorian Government Gazette;[11]
- in the Australian Capital Territory, it takes the form of a 'disallowable instrument', which must be notified and presented to the Australian Capital Territory Legislative Assembly;[12] and
- in the Northern Territory, it must be approved by the Chief Health Officer and then posted on the Department of Health's website.[13]

15.14 There are also differences between jurisdictions related to the types of infections that are covered by the defence, who the defence applies to, and the conditions that must exist for the defence to apply.

Problems with current statutory defences

15.15 People with knowledge of the sector have told us that the different procedures in the states and territories for approving the blood donor questionnaire can cause delays when the questionnaire is updated.

15.16 More broadly, jurisdictional differences between statutory defences for infections acquired through donated blood are in tension with the national coordination of blood collection. The differences create inequalities. Depending on where people live, their rights to receive compensation for transmission of blood borne diseases may be limited by comparison with people in other jurisdictions.

15.17 Given that blood donation occurs through a national program where donated blood in one jurisdiction might end up being transfused to a patient in another jurisdiction, it may make sense to have a uniform approach to statutory defences for the blood sector.

15.18 In 2001, as part of a broader review of the Australian blood supply sector, a report to the Commonwealth Minister for Health and Aged Care called for uniform statutory defence laws 'as a matter of urgency'.[14]

9 *Blood Donation (Transmittable Diseases) Act 1985* (ACT); *Human Tissue Act 1983* (NSW) s 20F; *Notifiable Diseases Act 1981* (NT) pt 3A; *Blood Contaminants Act 1985* (SA); *Blood Transfusion (Limitation of Liability) Act 1986* (Tas); *Public Health and Wellbeing Act 2008* (Vic) s 151; *Blood Donation (Limitation of Liability) Act 1985* (WA).

10 Minister for Health and Aged Care (Cth), *Review of the Blood Banking and Plasma Product Sector* (2001) 49.

11 *Public Health and Wellbeing Act 2008* (Vic) sch.

12 *Blood Donation (Transmittable Diseases) Act 1985* (ACT) s 10(3).

13 *Notifiable Diseases Act 1981* (NT) ss 26A(3)–(4).

14 Minister for Health and Aged Care (Cth) (n 10) 51.

15.19 In 2003, a report prepared for the Australian Health Ministers Advisory Committee provided recommendations on what the statutory defence should contain and the need for it to be uniform across Australia. In 2013, an independent review commissioned by the National Blood Authority comprehensively examined the statutory defence laws, making recommendations for legislative models to achieve harmonisation, and endorsing many recommendations from the 2003 report regarding the substance of what the defence should contain.[15]

Why we are not considering statutory defences

15.20 Our focus is on strengthening and harmonising the legislative framework for human tissue donation, transplantation, and use, using the current HTAs as a starting point. Other than in New South Wales, the issue of liability for transmissible infections in the blood supply is dealt with either in dedicated legislation, or as part of broader public health legislation, rather than in human tissue legislation. As such, issues of blood safety or civil liability for actionable wrongs in the supply of blood are not directly raised by our Terms of Reference.

15.21 To the extent that these issues are indirectly raised by our Terms of Reference, we do not consider them a central focus of this Inquiry. The problems with the statutory defence laws are longstanding, and previous reports and inquiries have already documented the key issues (including delays in approving donor questionnaires, and disparities across jurisdictions). In light of the wide range of complex matters we are addressing, and given the significant body of work that has already examined the issue of inconsistent statutory defences, we do not propose to consider or recommend additional reforms in this area.

Opt-out consent to deceased organ donation

15.22 The HTAs provide for an 'opt-in' consent model for organ donation. This means that to be a living tissue donor, a person needs to expressly communicate their consent to donate. To donate organs after a person dies, the consent of the person or their family is usually required.[16]

15.23 Some countries have adopted 'opt-out' consent frameworks for deceased organ donation. In these countries, everyone is treated as a willing organ donor unless they have expressly communicated that they do not want to be a donor (for example, by joining an opt-out register).[17]

15.24 Previous inquiries have considered if Australia should adopt a model of opt-out consent for deceased donation.

15.25 The most recent inquiries either expressed doubt about the effectiveness of opt-out policies compared with other policies to increase organ donation rates,[18] or highlighted the need for additional evidence about if Australians support a national change in this direction.[19]

15 Ernst & Young, *National Blood Authority Review of Risk Management in the Blood Sector: Review of the Statutory Defence Laws* (2013). The 2003 report has not been made public and was provided to the ALRC in confidence.

16 In some jurisdictions, a Designated Officer or a family member may authorise consent if there is no indication that the deceased person would have objected to the donation: see, eg, *Transplantation and Anatomy Act 1979* (Qld) s 22(3).

17 Phil Walton et al, 'Organ and Tissue Donation Consent Model and Intent to Donate Registries: Recommendations from an International Consensus Forum' (2023) 9 *Transplantation Direct* 1, 5.

18 Legal and Social Issues References Committee, Parliament of Victoria, *Register and Talk about It: Inquiry into Increasing the Number of Registered Organ and Tissue Donors* (2024) 58–63.

19 Standing Committee on Public Administration, Parliament of Western Australia, *The Donation Conversation: Organ and Tissue Donation in Western Australia* (2024) 68–79.

Overview of previous inquiries

15.26 A 2024 Western Australian inquiry chose not to recommend an opt-out model but suggested the government in that state should conduct another review of organ and tissue donation in five years' time.[20] Also last year, a Victorian parliamentary inquiry concluded:

> Evidence from international jurisdictions suggests that higher organ donation rates can be better achieved through: improvements to organ and tissue donation hospital systems and donor identification; investment in professional training and clinical staff who talk to families to obtain family consent; and better community awareness about donation—rather than by introducing an opt-out system.[21]

15.27 The Victorian inquiry referred to the Australian Government's conclusion in 2018 that 'systemic approaches' to increasing donation rates are likely to be more effective than opt out models:

> Experience in other countries shows that systems which compel organ donation, such as 'opt out' models, are not necessarily the reason for increased donation rates. Research shows that better long-term results are achieved through systemic approaches that educate and involve hospitals, clinicians, donor families and the general public.[22]

15.28 In 2012, another Victorian parliamentary inquiry endorsed the state's 'informed consent' or opt in model for organ donation.[23] In 2008, a Tasmanian Legislative Council committee recommended that the 'current "opt in" system for registration of consent to donate be maintained'.[24] In the same year, a Queensland review similarly recommended against the adoption of a 'presumed consent' or opt out model, saying the review had failed to find any 'convincing evidence that introduction of a system of presumed consent would have a positive effect on organ and tissue donation rates'.[25]

What we have heard about opt-out models

Support for opt-out models, or suggestions that we should consider these models

15.29 Some submissions to our *Issues Paper* said Australia should adopt an opt-out consent model for deceased organ donation. The advocacy organisation, Resilience Rising, suggested that ethical concerns about the absence of express consent to donate in opt-out systems, and the risk of undermining public trust in the donation system, could be addressed through 'comprehensive public education campaigns'.[26]

15.30 The Law Council of Australia called on us to consider if the framework for organ donation in Australia should be opt-in or opt-out.[27] The Council noted 'initiatives by a number of overseas governments to increase the rate of organ donation', including the adoption of an opt-out system in Ireland.[28]

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20 Ibid rec 12.
21 Legal and Social Issues References Committee, Parliament of Victoria (n 18) Finding 7, 63.
22 Australian Government, *Response to the Joint Standing Committee on Foreign Affairs, Defence and Trade Report: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism* (2021) 20–1.
23 Legal and Social Issues References Committee, Parliament of Victoria, *Inquiry into Organ Donation in Victoria: Report* (2012) rec 6.
24 Legislative Council Select Committee, Parliament of Tasmania, *Organ Donation* (2008) recs 1, 4.
25 Legislative Assembly of Queensland, Parliament of Queensland, *Report of the Review of Organ and Tissue Donation Procedures Select Committee* (2008) 43.
26 Resilience Rising, *Submission 2*.
27 Law Council of Australia, *Submission 61*.
28 Ibid.

Opposition to or concerns about opt-out models

15.31 We also heard concerns about opt-out models, and opposition to Australia adopting an opt-out donation model. A Community Legal Centre, the Advocacy and Support Centre (TASC) noted that an opt-out model:

> raises ethical concerns about individual autonomy, as it may infringe upon a person's right to make an informed, voluntary decision. Additionally, public confusion about [an] opt-out system can undermine its effectiveness, and there are concerns that individuals may not fully understand the implications of their presumed consent.[29]

15.32 In our consultations, we spoke with some medical professionals who said they were not in favour of opt-out models because they had not seen evidence demonstrating that these models reliably improve organ donation rates.

15.33 Other people we spoke to who work in the organ donation system were concerned that opt-out models are likely to undermine public trust, especially for groups like First Nations people. We heard that because there have been historical cases of First Nations' people's body parts being taken without their consent, any proposal for an opt-out system is likely to be met with concern and distrust.

Why we are not considering opt-out models

15.34 We have chosen not to focus on opt-out models for deceased organ donation in this inquiry because:

- other inquiries have considered the advantages and disadvantages of these models and based on current research and comparisons with international jurisdictions, have not supported adoption of an opt-out model in Australia;
- there does not appear to be strong evidence to indicate that opt-out models improve organ donation rates overall;
- there is a danger that opt-out models will undermine public trust in the health and organ donation system; and
- effectively educating the public about opt-out models and their right to expressly opt-out of organ donation would be complex and resource intensive.

29 TASC Legal and Social Justice Services, *Submission 1*. These concerns are raised in light of the United Kingdom's adoption of an opt-out model.

16. Is there an urgent need for other reforms?

16.1 Our Terms of Reference are broad. Our focus has been on identifying issues with the core human tissue laws (the HTAs), and the reforms necessary to harmonise and modernise these laws.

16.2 We have been guided by the following aims and principles:

- improving access to human tissue in Australia;
- providing respect for persons and the human body;
- ensuring equitable participation in and access to donation and transplantation systems; and
- promoting and upholding public trust.

16.3 We are interested to know if there are aspects of human tissue law that urgently require reform but that we have not addressed, or have not addressed adequately, in this *Discussion Paper*.

Are other reforms urgent?

Question 47

Is there an urgent need for reform of human tissue laws that we have not addressed in this *Discussion Paper*?