Government of **Western Australia**
Department of **Health**

Review of Human Tissue Laws 2025 – Discussion Paper 90

The Department of Health Western Australia Submission

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Overview

The Department of Health, Western Australia (Department) is pleased to provide a submission to the Australian Law Reform Commission (Commission) for its input into the Review of Human Tissue Laws Discussion Paper 90 (Discussion Paper).

In Western Australia (WA), the Department is the agency responsible for *the Human Tissue and Transplant Act 1982*, the *Anatomy Act 1930*, the *Human Reproductive Technology Act 1991* and the *Assisted Reproductive Technology and Surrogacy Act 2025.*

Policy Officers and Medical Advisors with extensive experience in both the recent legislative amendments and the ongoing regulatory work of the various Acts have been involved in developing this submission, with input sought from a range of Western Australian stakeholders.

The Department commends the Commission for its comprehensive review of human tissue laws and for the breadth of proposals presented in the Discussion Paper. A national review of this kind is much needed, given the significant advances in medical knowledge and technology over the past 50 years. While WA has been able to review and update some aspects of its human tissue legislation to reflect contemporary practice, many issues remain unresolved, including the absence of consistent regulatory frameworks across jurisdictions.

Legislation and regulatory frameworks must be grounded in sound policy. In Australia, numerous respected expert bodies have developed well-considered guidelines on the use of human tissue, and the Department encourages the Commission to draw on this substantial body of work when developing policy and defining policy objectives.

In discussing the definition of human tissue, the Commission refers to an “it’s in, unless it’s out” approach to avoid regulatory gaps. The Department suggests that an “it’s out, unless it’s in” approach may also warrant consideration when developing new human tissue laws. Prohibiting the possession or use of another person’s tissue unless it is for purposes specified under human tissue or other Australian laws may help to reduce or eliminate some of the existing regulatory gaps.

1. A nationally harmonised regulatory framework

Proposal 1

The Department supports regulating the retrieval, storage, and use of human tissue in Australia for medical, educational, or scientific purposes through a coordinated and harmonised framework across all states, territories and the Commonwealth.

This approach would ensure that States and Territories remain key partners and decision-makers in regulating human tissue practices, rather than being treated as stakeholders.

Proposal 2

The Department supports structuring the regulatory framework using a combination of legislation, delegated legislation, codes of practice, standards and guidelines, as outlined in the paper.

Proposal 3

Proposal 3 requires further consideration. While establishing a National Regulator for all types of human tissue may appear to offer a simplified solution to the current complex and overlapping governance systems, the caution expressed in Gall's Law is relevant. Gall's Law states that effective complex systems typically evolve from simpler systems that already work; complex systems designed from scratch rarely function effectively and cannot easily be fixed once established.

Australia's oversight systems for solid organ donation and transplantation, donated blood, and reproductive tissue have evolved over many years and are now relatively robust. However, significant gaps remain in the governance of the eye and tissue sector. These include limited oversight of manufacturing and financial practices of private tissue product agencies, incomplete data on the export of human tissue products, and a lack of mechanisms to ensure the safe and ethical sourcing of imported tissue and tissue products.

Strengthened regulatory oversight of the eye and tissue sector is needed. A National Tissue Sector Regulatory Body could provide consistent national regulation of tissue banking and help address current governance gaps. However, it is unclear whether there is support or funding to establish such a body.

Further detailed consideration and consultation would be required to clarify how a National Tissue Sector Regulator would interact with existing national regulatory agencies and State and Territory regulatory frameworks, as well as to define its powers and functions.

Setting national policy on human tissue, and developing clinical guidelines, standards and codes of practice, are not considered appropriate roles for a National Tissue Sector Regulator. These functions are better suited to expert advisory groups and, where necessary, endorsement by a ministerial council as described in section 1.18, rather than being vested in a regulator.

Proposal 4

As stated in the Department's submission to the Issues Paper 51, the preferred structure for achieving national uniform legislation is an applied legislation model.

2. The objects of human tissue laws

Proposal 5

New human tissue legislation should include an opening section stating that its objects are to:

a) Modernise and ensure adaptability and consistency in the laws and regulatory frameworks governing the donation 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.
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?

While acknowledging the merit of the proposed objects, it may be valuable to consider whether these are achievable legislative objects or whether they are better suited as guiding principles. Some matters currently proposed as legislative objects may be more appropriately framed as objectives of the national legislative framework rather than of the human tissue legislation itself.

The objects of new legislation could be considered to:

- Regulate the ethical removal and use of human tissue for medical, educational and scientific purposes; and
- Establish the National Regulator (if approved).

Guiding principles should then be incorporated to assist interpretation and administration of the Act and to guide how regulated activities are to be undertaken.

Comments on specific objects:

- **5(a)** may be better suited as an objective of the national legislative framework or a role of the National Regulator (if supported).
- **5(b)** may be more appropriately framed as a function of the National Regulator or other regulatory bodies. Improving access depends largely on health service delivery. Access must also never override an individual's self-determination and bodily autonomy.
- **5(c)–5(f)** may be more suitable as guiding principles rather than objects.
- **5(g)** could be an objective of the national legislative framework or the National Regulator (if supported) or included as a guiding principle.

Question 2: Should new human tissue legislation include other objects?

WA Health stakeholders suggested additional or alternative objects, including:

- Regulating the ethical removal and use of human tissue for medical, educational and scientific purposes by establishing processes for informed consent to donation.
- Establishing the National Regulator (if supported).
- Regulating the ethical trade of human tissue and human tissue products by establishing processes that consider the provenance of tissue and tissue products.
- Regulating access to information to ensure privacy is protected while allowing appropriate information access for those entitled to it.
- Promoting a sustainable supply of ethically sourced human tissue.
- Preventing the commercialisation of human tissue by prohibiting trade, sale or other financial gain from the donation, removal, storage or use of human tissue, while permitting reasonable cost recovery in accordance with the law.
- Ensuring transparency, traceability and accountability in the governance of human tissue through nationally consistent record-keeping oversight and audit mechanisms across the tissue lifecycle.
- Protecting public health and safety by ensuring the quality, safety and integrity of human tissue and promoting practices that minimise risks associated with the removal, storage, transport and use of human tissue.

Suggested guiding principles include:

- The health, wellbeing and safety of donors and recipients is paramount.
- The human body is not to be treated as a commodity.
- Exploitation of donors must be prevented.
- Donations of tissue are undertaken with a human-centred approach.
- Informed, voluntary consent is essential for the removal of donated tissue.
- The emotional and mental health of decision-makers at the time of a person's death should be protected.
- Donated tissue must be treated with the utmost respect and not wasted.
- Donated tissue must only be used for valid therapeutic, scientific or educational purposes.
- Access to human tissue and tissue products must be equitable.
- Allocation of donated tissue must be based on clinical need and consistent with ethical standards.

The Department also recommends that the ALRC consider any additional objects proposed by the Australian Alliance for Indigenous Genomics and other Aboriginal health sector services that support Aboriginal people in this field.

Proposal 6

If a National Regulator (or alternative model) is established, it must have regard to the objects of the new human tissue legislation. The objects and any guiding principles should be applied by all persons or entities exercising a function under the Act.

3. Removing barriers and promoting equitable access to human tissue

Removing barriers and promoting equitable access for Aboriginal people aligns with the *WA Aboriginal Health and Wellbeing Framework 2015–2030* and the *National Agreement on Closing the Gap.*

The Department supports the views presented in the Discussion Paper under 'Barriers for First Nations groups' (sections 3.7–3.10), while noting that human tissue legislation alone may provide limited opportunities to directly promote equitable access.

4. Reforms relating to the definition of tissue

The Department supports adopting a broad definition that captures all human material within scope unless it is expressly excluded. This "in unless out" approach reduces the risk of inadvertently leaving any tissue unregulated.

The Department does not hold a unified position on a preferred term or definition but supports using the term "derived from" rather than "extracted from." The term "derived from" more accurately reflects the origin of certain types of tissue.

The Department also supports establishing a mechanism that allows the scope of the definition - or the application of particular schemes or Parts of the legislation - to be adjusted or to exclude specific tissues where appropriate. As noted in the Discussion Paper, there is significant variation in the types of tissues collected, processed and used, and any future framework should provide flexibility in how tissue is regulated.

Guidance on the definition and scope of "tissue" (or any alternative label) would be beneficial. Similar attention will be required for definitions and interpretations of other key terms, including "purposes."

Consideration of excluding certain materials from human tissue laws, or from their application for particular purposes, circumstances or provisions:

Human milk - should *not* be excluded

Human milk significantly reduces the risk of conditions such as necrotising enterocolitis in very premature infants in neonatal intensive care units. When a parent cannot provide their own milk, donor human milk (DHM) is used.

Because DHM is stored and transported for use in vulnerable neonates, it must be processed to remove potentially harmful microbial contamination. Pasteurisation is currently the preferred method, but describing DHM as "processed" rather than "pasteurised" allows for alternative safe processing methods in future.

Regulation of processed donor human milk (PDHM) for medical purposes is essential to ensure its safe, sustainable and ethical supply; Additionally

- The Therapeutic Goods Administration's (TGA's) therapeutic goods framework does not include PDHM.
- Food Standards Australia New Zealand (FSANZ) regulates food, not therapeutic goods.
- FSANZ food standards cannot be applied directly to human milk because the risks associated with milk from animals differ significantly from those associated with human milk.

Donated human milk used informally as food could be excluded through delegated legislation.

Delegated legislation, similar to the Supply of Processed Donor Human Milk in Western Australia Code of Practice 2024, could prescribe medical and scientific purposes and other requirements for the safe and ethical supply of donated human milk, including consent processes.

Faecal tissue - should be excluded

Faecal matter and faecal microbiota transplant (FMT) products should not fall within the broad definition. Microbes constitute a significant portion of faecal matter and, although therapeutically valuable in FMT, they are distinct non-human organisms. The metabolic waste products and dead cells present in faeces are generally considered waste and do not require regulation under human tissue legislation.

The TGA already regulates FMT products.

Gametes from deceased donors - should *not* be excluded

Reproductive tissue, including gametes, gonadal tissue and embryos, should be included within the broad definition, with exclusions for specific purposes, circumstances or provisions where other legislation applies (e.g., donation of reproductive tissue by living donors, trade of reproductive tissue, the person's own use such as In-Vitro Fertilisation).

There should be no exclusion for the post-mortem removal of gametes for reproductive purposes, as this is not regulated under Western Australian reproductive technology or surrogacy legislation.

Foetal tissue - should *not* be excluded

Foetal tissue may be used for research and has been previous attempts to use it for medical purposes.

Foetal tissue is not included in the definition of human reproductive material under Western Australia's human reproductive technology laws. Excluding foetal tissue from the broad definition of human tissue would therefore create a regulatory gap.

5. Reforms relating to the determination of death

Proposal 10

The Department is supportive of updating provisions for determining death in line with international consensus favouring a unified definition of death based on cessation of brain function.

Updating these provisions will remove a substantial barrier to the use of normothermic regional perfusion, allowing for increases in quality and viability of transplanted organs.

This is in line with the recommendations of the Western Australian Parliamentary Report 41: *The donation conversation: Organ and tissue donation in Western Australia.*

The Department does not, however, support the deliberate omission of the following phrase from the definition of death as proposed by the Australian and New Zealand Intensive Care Society Death and Organ Donation Committee (ANZICS):

> *'This can result from devastating brain injury or from cessation of blood circulation in the brain after circulatory arrest'*

The complete omission of any mention of cessation of circulation from the wording of the proposed statutory provisions in Proposal 10 led to initial confusion and uncertainty amongst experienced senior medical professionals in WA. It is likely to cause even greater uncertainty and anxiety amongst the general public.

The Department strongly recommends the ALRC retain all components of the definition of death proposed by ANZICS for the reasons provided in their submission in response to the Issues Paper.

Moving reference to cessation of circulation out of the legislation to a supporting note or explanatory memorandum creates will not provide sufficient clarity for members of the medical community or the general public who have limited experience in navigating legislative instruments.

Consideration should be given as to the requirements of Section Y(3) with respect to the qualifications of the medical practitioners and if this would need to be specified further in the legislation or in regulations.

New statutory location for the determination of death provisions

At 5.75 the Commission asks for feedback on whether the proposed determination of death provision should apply for all purposes of the law as is the current position for States and Territories other than Queensland.

The Department is unable to advise as to whether there would be adverse and unintended consequences in other areas with any certainty, given the large number of Acts and subsidiary legislation in WA that mention death or dying. Further consideration by legislative experts would be required. Again, the Department advises that the full ANZICS wording be used in lieu of the ALRC's abridged version to reduce potential confusion.

The Department notes the submission by ANZICS that public confidence in organ and tissue donation and transplantation could be undermined if there are different determination of death provisions for different purposes.

The Department is supportive of the proposal that all Commonwealth, State and Territory legislation contain a consistent legal standard for determining death.

The Department's preference is for the provisions to be updated in the most expeditious manner possible in order to remove this barrier to the use of NRP by our organ retrieval teams in order to improve the quality and viability of donated organs.

If this is achieved by each State and Territory deciding where to locate uniform determination of death provisions may be an optimal way of updating provisions without untoward delays, then it would be important to ensure that any delays in amending legislation in one jurisdiction would not interfere with the use of NRP in another.

Proposal 12

Postmortem interventions

It is the Department's preference to consider Proposal 39 (Consent and authorisation for research on the recently deceased) alongside Proposal 12 (Postmortem interventions).

For Proposal 12, clarity must be provided as to whether research into post-mortem interventions is considered as a form of 'accepted medical practice'.

Research into postmortem interventions should be permitted, with safeguards to ensure research is conducted with the same high ethical standards required in other forms of research, and for other aspects of organ and tissue donation, including approval by a suitable ethics committee and provisions for valid consent.

Research into postmortem interventions should only take place in the same hospital where death was determined. The proposal that research may be conducted 'outside a licensed facility' is not supported, as hospitals are required to be licensed.

The inclusion of Proposal 39 in a section relating to Schools of Anatomy and body donation programs may have inadvertently prevented busy clinicians who are involved in postmortem interventions from being aware of this proposal, and we would advise separate targeted consultation with be undertaken to assist in understanding how pre- and postmortem interventions are conducted, and how ethical approval for research is obtained.

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

Consent and authorisation for removal of tissue from living persons

For consent to be valid, the information provided should include any potential for the donated tissue to be exported, as well as whether profit may be generated from its use.

The proposed definitions of 'adult' and 'child' are supported. Evidence shows that blood donation by younger adults carries a higher risk of adverse events, and lowering the minimum donor age to 16 could expose 16 and 17 year olds to greater risk of harm. Providing targeted education about the importance of blood donation may be a safer and more appropriate way to encourage future participation without increasing the risk to potential donors.

Donation of tissue by children and adults deemed to lack context-specific decision-making capacity

Clarification is required to ensure that the proposed provisions related only to the removal of tissue for the purposes specified in legislation – medical, educational, scientific and research. Tissue removed from a child or adult deemed to lack decision-making capacity for valid clinical reasons should not require oversight by an independent committee.

7. Reforms relating to deceased donation

Consent and authorisation for removal of tissue after death

Proposal 23

Valid consent as sufficient authorisation for removal of tissue

Proposal 23 is partially supported.

Valid consent by an individual or authorised decision-maker must be provided for the removal of tissue after death for the specified purposes. Removal of tissue for research is addressed separately in Proposal 36 rather than as a scientific purpose under Proposal 23. It is unclear why a separate proposal for the removal of tissue for research is needed, given that Proposal 37 outlines provisions for the use of tissue removed from a deceased donor for research.

Information provided for consent to be valid should include any potential for the tissue to be exported, or where profit may be generated from use of the tissue.

Further detail is needed regarding how valid consent is facilitated, who is authorised to obtain it, and whether additional verification of consent validity is required.

Designated Officer role

Designated Officers play an important role in promoting public trust in tissue donation by providing independent oversight of valid consent prior to authorising tissue removal.

While independent oversight of DonateLife's facilitation of consent for tissue donation may not be necessary in WA, Designated Officers have other critical responsibilities, including:

- Authorising non-coronial post-mortem examinations.
- Authorising the removal of gametes from deceased individuals for reproductive purposes.
- Confirming that a prospective donor's death is not reportable to the coroner.

Differences in authorisation frameworks across settings should be addressed by increasing oversight of consent and authorisation in community settings, rather than reducing oversight within hospitals.

Without adequate oversight beyond hospitals - such as in funeral homes - there is a risk of unethical practices similar to those documented in the United States, where musculoskeletal tissue has been obtained without valid consent or adequate disease screening and sold to tissue banks and educational institutions.

The Department's preference is for a role equivalent to a Designated Officer to be extended to all non-hospital locations where tissue retrieval may occur, including funeral parlours and nursing homes, to ensure rigorous oversight of consent.

Legislation could specify who may facilitate valid consent, for example:

- DonateLife officers for tissue removed for the purposes specified under the Act.
- Designated Officers for the removal of gametes for reproduction, non-coronial post-mortem examinations, or where DonateLife has not facilitated consent.
- Coroners for deaths reportable under coronial legislation.

Proposal 24

Guidelines regarding donation after VAD or voluntary withdrawal of life-sustaining therapy

The Department supports the development of protocols or guidelines for deceased donation by people accessing voluntary assisted dying (VAD), noting that this work may not need to be led by a National Regulator.

Significant progress has already been made following the release of the WA Parliamentary Standing Committee's 2024 report on organ and tissue donation. National ethical guidelines affirming the rights of people accessing VAD to donate tissue have been endorsed by the National Health and Medical Research Council. WA has also developed clinical protocols and care pathways for donation after VAD, and other jurisdictions are likely to have undertaken similar work aligned with their local legislation.

Proposal 25

Definition and hierarchy of 'authorised decision maker'

Tailoring of the authorised decision-maker hierarchy is required for posthumous removal of gametes for reproductive purposes.

- The *surviving spouse or partner* should be recognised as the authorised decision-maker for posthumous gamete collection intended for reproduction.
- If the surviving partner is unavailable or unable to provide consent, another authorised decision-maker may consent on their behalf for the removal of posthumous gametes, but only for use of the material for reproductive purposes by the surviving partner.
- Consent for posthumous removal of gametes for use by anyone other than the surviving partner should not be considered valid.

Proposals 26 and 27

Pre-mortem interventions

The Department supports including in legislation a definition or description of pre-mortem interventions for posthumous tissue donation, and a requirement that valid consent be obtained, with authorised decision-makers guided by the individual's known beliefs, values and preferences.

Consent for pre-mortem interventions should be consistent with standard clinical consent requirements, including information on the need for interventions such as blood tests, screening for blood-borne viruses, biopsies and bronchoscopies.

The Department does not support any exceptions to the requirement for consent for pre-mortem interventions - including early blood tests conducted before establishing donation intent or consent, as referenced in section 7.75. Assessing suitability prior to intent and consent would undermine public trust in donation systems.

Proposals 28 and 29

Respectful and dignified treatment of the deceased body

The Department strongly supports Proposal 28, noting previous reports of disrespectful handling of deceased donors overseas. The Department has proposed that respectful handling of donated tissue be included as a guiding principle to ensure respect for donors throughout the donation lifecycle.

Proposal 29 is also supported and aligns with current WA legislation. WA has permitted corneal retrieval by authorised technicians and doctors since 1987. Amendments in 2022 now allow trained and qualified individuals to retrieve ocular, skin and musculoskeletal tissue without a medical practitioner physically present.

The technical skills required for tissue retrieval are not unique to medical practitioners and often require specialised training beyond standard medical education. A wide range of training pathways exist for retrieval technicians, including university eye-banking programs and international tissue banking training.

Nationally consistent training and credentialling guidance would be welcome, and the Biotherapeutics Association of Australasia may be well placed to oversee these requirements.

Question 24 – Factors for coroners to consider when deciding whether to consent to donation

The Department supports including factors for coroners to consider when consenting to donation and in determining whether internal post-mortem examination is appropriate.

WA context:

- Increased use of less invasive post-mortem procedures has reduced internal post-mortems, which are important for assessing donor safety.
- The WA Law Reform Commission's 2012 report recommended principles supporting least-invasive methods (Rec. 102) and listed factors for ordering internal post-mortems, including community health benefits (Rec. 103).

- WA Parliamentary Report 41 (2024) recommended allowing coroners to authorise internal post-mortems to enable tissue and bone donation, though the State Coroner did not support amending coronial legislation for this purpose.

Including relevant factors within human tissue legislation - rather than coronial law - may allow coroners to consider the public health benefits of tissue donation without altering the scope of coronial functions.

Suggested factors include:

- The known wishes of the deceased and/or family regarding donation.
- The public benefit of organ and tissue donation.
- The healthcare benefits of an internal post-mortem examination undertaken for tissue or bone donation.

Proposals 30 and 31

Non-coronial post-mortem examinations

The Department supports Proposal 30, requiring consent from the authorised decision-maker for post-mortem examination, with decisions guided by the deceased person's known wishes. This aligns with the proposed objects and principles of human tissue laws and national ethical guidance.

New legislation could recognise consent provided by an individual before death where no authorised decision-maker can be located after reasonable efforts.

Any other exception to the consent requirement should require special consideration and authorisation - such as a public health-related need for a post-mortem examination, which should require approval by a Minister or delegate, based on Chief Health Officer advice.

Proposal 31 is supported. Valid consent should be required for any tissue removed during post-mortem examination to be used for any additional purpose. Exceptions are not supported, consistent with the *National Code of Ethical Autopsy Practice*, which requires families to be informed about sample retention and to choose whether retained tissue may be used for research, education or quality control.

8. Reforms relating to tissue donation for research

The Department's preference is that all legislative provisions relating to the use of human tissue in research be aligned with the *National Statement on Ethical Conduct in Human Research* (National Statement).

The goal described at 8.16 *"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"* is commendable. However, the Department considers that the National Statement already provides a more comprehensive and nuanced treatment of the complex ethical considerations inherent in human research.

Proposals 32 and 33 are not consistent with the consent requirements set out in the National Statement, which allows for specific, extended, or unspecified consent. Proposal 33 could be interpreted as placing responsibility for withdrawing consent on the donor, whereas the

National Statement places responsibility on researchers and Human Research Ethics Committees (HRECs) to determine when further consent is required.

Proposal 35 suggests adopting a provision modelled on section 22B of the *Human Tissue Act* (Tas), which requires consent to be obtained in accordance with the National Statement. This is supported, as would a similar provision to allow adults without decision-making capacity to donate to research.

Proposal 34 requires that research involving human tissue comply with both the *Australian Code for the Responsible Conduct of Research* and the National Statement, and this is supported.

However, the second element of Proposal 34 - providing that the legislation prevails over the Code or the National Statement in the event of inconsistency - highlights the need for exceptional care in drafting, to reduce confusion and avoid unnecessary barriers to research.

It is also unclear why the removal of tissue for research is addressed separately in Proposal 36, rather than included in Proposal 23 given that provisions for the use of tissue removed from a deceased donor for the purpose of research are outlined in Proposal 37.

9. Reforms relating to donation and use of deceased bodies

Proposal 38

The Department supports the proposal that an adult may give valid consent to donate their body after death to a school of anatomy or other licensed facility for specified purposes.

In Western Australia, the Body Donation Program only allows body donation where the consent has been provided by the deceased themselves. Allowing an authorised decision-maker to provide valid consent on behalf of the deceased would require careful consideration.

Historically, Anatomy Acts were developed to prevent grave robbing as a means of supplying bodies for anatomical education. These Acts ensured a lawful supply of bodies - predominantly from the poor and vulnerable - so that the bodies of the wealthy were protected. Modern body donation programs arrange for the subsequent burial or cremation of the deceased at no cost to families, and in some parts of the world this has created a financial incentive for donation among impoverished families. Extending consent to authorised decision-makers would therefore require robust safeguards to ensure that donation reflects the actual wishes of the deceased.

Clarity is needed regarding the definition of specified purposes. It is unlikely that a deceased body could be used for any valid medical purpose, and therefore the purposes should be limited to educational and scientific uses.

Proposal 39

This proposal relates to research into postmortem interventions and has been addressed in Section 5 alongside Proposal 12.

10. Reforms relating to stored tissue collections

Valid consent should be obtained for the use of stored tissue for research, consistent with the requirements outlined in Section 7 (use of tissue removed during post-mortem examination) and Section 8 (tissue donation for research).

The Department does not support a broad exemption from consent requirements for research using entire stored pathology collections. Such an exemption could significantly increase the workload for public pathology laboratories in responding to third-party access requests and appears inconsistent with the statement in Section 8 that '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'.

Stored reproductive tissue collections are subject to the requirements of assisted reproductive legislation and should therefore be exempt from the consent requirements of human tissue laws.

The Department supports strengthened oversight and governance for research biobanks and for legacy collections of human remains, noting the complexity involved in developing regulatory frameworks for such disparate areas.

Regulation is also required for collections of more recently preserved human bodies and body parts. Some of these collections may be used for public exhibition by private organisations for profit rather than for purposes consistent with human tissue legislation. It may be prudent for legislation to prohibit the possession of recently preserved human bodies and body parts outside specific settings such as medical museums, schools or anatomy or other educational facilities and to ensure that public exhibitions are subject to prohibition of trade provisions.

11. Reforms relating to the prohibition of trade

General prohibition of trade

The World Health Organisation (WHO) Guiding Principles allow for the reimbursement of reasonable and verifiable expenses associated with the recovery, processing, preservation and supply of human tissue. In Australia, some private for-profit organisations provide processing, manufacturing and distribution services to tissue banks, with tissue banks then receiving payment for the final tissue product. Oversight of the costs charged to tissue banks is currently limited, creating a risk that profit may be generated at multiple points along the pathway between donor and recipient.

The Department's preference is that legislation ensure all organisations involved at any stage of the supply chain for human tissue are restricted to **cost recovery only**, preventing both legitimate and illegitimate profiteering. As currently drafted, Proposals 40 to 44 are unlikely to meet this objective.

It is essential that any guidance developed under Proposal 44 clearly encompasses cost recovery for processing, distribution and related services provided by for-profit organisations.

Proposal 40

Proposal 40 is supported in principle. While clarity around the definition of "reward" is welcome, further guidance is needed regarding the interpretation of "valuable."

The inclusion of the phrase *"the recovery of any loss or damage that was reasonably and lawfully incurred or suffered"* is unclear. Although this may aim to address income loss for living donors taking time off work, the wording could be interpreted broadly, enabling tissue banks or other organisations to claim a wide range of losses or damages.

The proposal appears intended to ensure that human tissue can be exchanged at cost-recovery prices, but the reference to recovering losses or damages raises concerns about how broadly this principle would apply.

Question 35 - Extraterritorial prohibition

A prohibition on the extraterritorial exchange of human tissue for reward is supported in principle but must be carefully considered. The Discussion Paper focuses on organs, but broader implications for access to human tissue overseas must be assessed.

For example, an Australian undergoing surgery abroad may be charged for blood products, with the payment resulting in profit for the supplier. This could place the Australian at risk of breaching the prohibition despite the transaction being lawful in that country.

Proposal 42 provides exceptions for certain tissue products traded by the Commonwealth or other authorised suppliers, but these do not extend to overseas suppliers authorised under foreign law.

Proposal 42

Proposal 42 appears to permit profit-making for some tissue products while limiting others to cost recovery. It is unclear whether this is intended to apply to all human tissues donated to or procured by tissue banks, including processed products that are subsequently sold to private companies.

For example, a tissue bank may sell a processed TGA-registered biological at cost-recovery pricing to a commercial organisation. Proposal 42 appears to allow that organisation to on-sell the product for profit, though it is unclear whether this was the intended outcome.

It is also unclear why non-tissue-bank organisations may sell human tissue for profit (for permitted purposes) when tissue banks may not. The intention may be to prevent financial reward for donation, procurement and processing, but the drafting results in broader consequences.

There may also be an intention to ensure Australia can purchase overseas tissue products - such as plasma from the United States - where cost-recovery pricing is not available. However, the broader impacts of this proposal require further consideration.

Question 36 asks:

a) Are the exceptions listed appropriate?

b) Should human tissue laws include additional exceptions?

c) Should human tissue laws include an exception to enable paid plasma donation?

The Department is supportive of the categories of human tissue listed in Proposal 42 being exempted from a prohibition of trade, however, has concerns about allowing valuable consideration for some exchanges of human tissue but not others, with no obvious mechanism to prevent excessive profits being made.

Additional exceptions should include:

- Human tissue products that may be accessed under the TGA's Clinical Trials Scheme or emergency supply arrangements.
- Bodies donated to Schools of Anatomy.
- Small tissue samples used for quality assurance and training in pathology.

Paid plasma donation

The Department acknowledges there is a need for the current hybrid model involving the importation of plasma and products from paid donors overseas via for-profit organisations combined with local manufacture of products from non-remunerated Australian donors however does not support an exception to the prohibition on trade to enable paid plasma donation in Australia.

Paying donors for tissue is not in keeping with the objects and principles of human tissue laws as described in Section 2.

There is insufficient evidence that paid plasma donations would increase donations without risking the health of potential donors, the safety and quality of the plasma supply, or potentially discouraging the existing pool of donors. Paying donors for the supply of one sort of tissue might also threaten public trust in all tissue donation systems.

Greater consideration of the potential impact of paid donation on non-remunerated blood donors, the potential health impact on donors who are incentivised financially to donate, and on public confidence in the Australian blood sector is required before introducing financial incentives for donation.

Paying for plasma donations would result in an increase in the cost of producing plasma derived medicines which is likely to be passed on to Australian Governments. A move to paid plasma donation could result in commercial gain to pharmaceutical manufactures if the practice was not closely regulated.

Paid plasma donation is often cited as the reason why the United States has an apparent surplus of donated plasma that can be exported. It may also be useful to consider if there is unmet latent demand arising from barriers to accessing healthcare that exist in the United States and potential inequities in access to human tissue products.

Proposal 43

Mechanisms to allow additional exemptions are essential. Types of tissue not clearly addressed in Proposals 40 or 42 include:

- Small tissue samples used for pathology training and quality assurance.
- Cadaveric material used at Schools of Anatomy.
- Tissue used under the TGA Clinical Trials Scheme.

Question 37 - Factors to consider when exempting exchanges

Factors should include:

- Purpose of the tissue and public benefit.
- Risk of exploitation or coercion.
- Risk of profiteering.

- The duration of exemption and need for scheduled review.

Proposal 44

A national pricing and/or costing framework for the retrieval, processing, use and distribution of human tissues would ensure that cost recovery is properly reflected in pricing and consistently applied by tissue banks and other organisations.

The guidance referred to in Proposal 44 appears to be for cost recovery as described in Proposal 40, with no reference to the provision of guidance for the exempted tissue exchanges listed in Proposal 42.

It is not clear how the of pricing for therapeutic goods exempted under Proposal 42 would be determined. The TGA does not provide any regulatory oversight of how prices for therapeutic goods are determined.

Question 40 - Ethical sourcing of imported tissue

Legislation must include mechanisms to strengthen oversight of imported tissue. The Department supports Option (a):

Prohibit the importation of human tissue that was:

- Obtained without donor consent consistent with Australian standards.
- Obtained in exchange for reward or profit

Additional context highlights risks associated with imported untreated tissue, including musculoskeletal tissue not clearly regulated under TGA mechanisms. Requiring ethical sourcing standards would help protect against internationally documented unethical practices.

A reporting mechanism alone is insufficient due to reliance on self-reporting.

Question 41 - Exemption mechanisms

A mechanism to grant and revoke exemptions is essential. Consideration should include:

- Purpose and public benefit.
- Risks of exploitation or coercion.
- Remuneration models and potential for profiteering.
- Conflicts of interest.
- Oversight of imported tissue, including traceability and trackability.
- Duration of exemption and review requirements.

Improving access to data – eye and tissue sector

Transparency and accountability are essential for public trust. Data is required to improve understanding of supply, demand and cost recovery.

Supply data may include:

- Source of donated tissue (domestic/imported, living/deceased).
- Domestic donation activity and location of retrieval.
- Onshore processing and manufacturing activity.
- Traceability of processed tissue.

- Imported tissue: type, volume, source, supplier, TGA pathway.
- Exported tissue: type, volume, destination.
- Evidence of valid consent (retrieval, purpose, export).

Demand data may include:

- Procurement volumes by licensed facilities.
- Volume used and discarded.
- Volume exported.

As noted in the Discussion Paper, demand for human tissue – other than organs and blood – remains poorly understood. Increases in demand may reflect higher clinical activity, increased waste or a combination of both. Significant work over recent decades to reduce the overuse of donated blood and blood products has supported the National Blood Authority's efforts to ensure a sustainable national supply.

Currently, there is no reliable way to determine whether bone allograft is being wasted. Private Healthcare Australia observed in its submission to the Issues Paper 51 that the use of bone allograft has increased considerably over the past decade, at a rate disproportionate to changes in surgical activity. It remains unclear how much of this increase may be attributable to unused bone allograft being discarded.

Further analysis of data collected by the Australian and New Zealand Eye and Tissue Donation Registry (ANZETD) would be valuable in identifying potential waste of donated musculoskeletal tissue and supporting sustainable national supply. Currently, the ANZTED reports tissue graft implantation by the jurisdiction of the retrieving bank, but not by the location where implantation occurs.

Linking ANZTED data with surgical activity at regional and hospital levels would provide greater insight into variations in tissue graft implantation rates across jurisdictions and support efforts to ensure that donated human tissue is used in line with best practice, in line with Action 1.28 of the National Safety and Quality Health Service Standards.

Mandatory reporting of the supply and transplantation of imported tissue should also be introduced to improve transparency and accountability across the sector and assist in better understanding of supply and demand.

Cost recovery

The WHO Guiding Principles support reimbursement of reasonable, verifiable costs across the tissue pathway. Current variability in visibility of activities and costs may undermine public trust and complicate assessment of cost-recovery compliance.

All agencies handling donated human tissue should report sufficient data to provide transparency around operating costs and revenue, including funds from Commonwealth programs and private health insurance.

Questions 43 and 44

Human tissue legislation may not be the most effective mechanism for voluntary data reporting. Further consultation is required to understand how mandatory reporting systems could operate, including governance models, data custodian arrangements, types of data to be reported and necessary inspection powers.

12. Reforms relating to how information can be disclosed and shared

The Department has no comment on this section.

13. Compliance

The Department has no comment on this section.

14. The timeframe for implementing our reform proposals

The outdated definition of death in Australia's legislation must be addressed as a priority and should not be delayed by other proposed legislative reforms. Updating this definition would allow the introduction of NRP, improving outcomes for transplant recipients and aligning with the recommendations of the WA Parliamentary Standing Committee on Public Administration's report on organ and tissue donation in WA.

15. Reforms we are unlikely to propose

The Department has no comment on this section.

16. Is there an urgent need for other reforms

The Department has no comment on this section.

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