Submission to the Australian Law Reform Commission Inquiry into Human Tissue Laws in Australia

I. Executive Summary

Australia stands at a critical juncture. Fragmented laws and outdated frameworks cannot meet the demands of a rapidly evolving medical and ethical landscape. Tasc urges the adoption of a nationally consistent, rights-based approach to human tissue legislation—one that upholds autonomy, safeguards against exploitation, and ensures equitable access for all. This is not only a legal imperative but a moral one: to protect dignity, honour consent, and build a system that reflects the values of a just and compassionate society.

II. Introduction

Tasc appreciates the opportunity to contribute to the Inquiry into Human Tissue Laws in Australia. As a long established not-for-profit organisation with over 42 years of experience, Tasc delivers legal, social justice, and advocacy services to over 3,000 vulnerable individuals annually across more than 400,000 square kilometres of Ipswich, Toowoomba and greater Southwest Queensland region.

This submission is from a human rights perspective, emphasising the need for a cohesive and contemporary legal framework that aligns with the fundamental principles of dignity, autonomy, and equity. Tasc advocates for a nationally consistent, principles-based approach to human tissue laws that ensures ethical integrity and equitable access to donation and transplantation services. In particular, the legal framework must be modernised to reflect advances in medical science, evolving community expectations, and the inalienable right of individuals to make informed decisions regarding their own bodies. International best practices offer valuable insights into effective regulatory models and highlight potential challenges that must be addressed to uphold the rights of all Australians.

III. Current Legal Framework

Human tissue legislation in Australia is primarily governed by state and territory laws, such as the *Human Tissue Act 1983 (NSW)* and the *Human Tissue Act 1982 (Vic)*.[1] These laws primarily regulate the donation of tissues and organs, post-mortem examinations, consent requirements and the use of human tissue for medical and scientific purposes. However, over time, amendments and differing interpretations have led to inconsistencies across jurisdictions. This has resulted in a patchwork of legislation, with varying definitions, consent requirements and regulatory processes.

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[1] Others include *Transplantation and Anatomy Act 1979 (Qld), Transplantation and Anatomy Act 1983 (SA), Human Tissue and Transplant Act 1982 (WA), Human Tissue Act 1985 (Tas), Transplantation and Anatomy Act 1978 (ACT)* and *Transplantation and Anatomy Act 1979 (NT).*

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Despite their common objectives, state and territory Acts differ significantly in scope, terminology, and procedural requirements. For instance, there is no nationally consistent definition of ‘tissue’ or ‘next of kin,’ and legislative references to consent vary widely in terms of both form and threshold. Additionally, few laws adequately address issues arising from emerging technologies or cross-border donation arrangements, and many omit enforceable provisions for donor information rights or culturally safe practices. These omissions have created challenges for healthcare providers and legal practitioners alike, particularly in jurisdictions where oversight of anatomical donations or research use is underdeveloped. The absence of an overarching national framework also hinders Australia’s capacity to meet its obligations under key international human rights instruments.[2]

IV. Key Issues and Considerations

1. Legal Inconsistencies and the Right to Equitable Healthcare[3]

The variation in human tissue laws across Australian jurisdictions creates disparities in access to donation and transplantation, thereby affecting individuals’ rights to health and fair treatment. A harmonised legal framework should ensure that donation processes are consistent, accessible, and equitable, removing arbitrary barriers based on geography or differing legislative approaches. The right to access life-saving medical treatment should not depend on one’s state of residence.

State-based human tissue laws have evolved piecemeal over several decades—often commencing at separate times and with varying scopes—resulting in a patchwork of regulations that are neither uniform nor consistent. Past experience in areas such as succession law and Voluntary Assisted Dying (VAD) has shown that such fragmentation leads to legal uncertainty, administrative inefficiencies, and inequitable outcomes.[4]

This legal fragmentation not only undermines administrative efficiency but also contravenes the principle of non-discrimination under international human rights law. The right to the highest attainable standard of health, as articulated in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), includes access to timely and appropriate health care services, irrespective of geography. A uniform legal approach would help to fulfil Australia's obligations under this treaty and ensure equal protection and access for all individuals, regardless of their state or territory of residence.

2. Consent, Autonomy, Bodily Integrity

A human rights-based approach requires that consent processes uphold individual autonomy and the right to bodily integrity.[5] A nationally standardised consent model should ensure that individuals can make informed, voluntary decisions regarding tissue and organ donation—both during their lifetime and posthumously.[6] The delegation of consent to next of kin should be circumscribed by clear legal safeguards to prevent the override of a donor’s explicitly stated wishes.[7]

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[2] Such as the *International Covenant on Economic, Social and Cultural Rights* and the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*.

[3] See discussion for example in *Human Tissue Transplants* [1977] ALRC 7 and World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

[4] Deborah Stienstra, *Australian Voluntary Assisted Dying Laws: The Case for National Uniformity* (2019) 42(4) *University of Queensland Law Journal* 1, 8.

[5] World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010) Guiding Principle 1; Council of Europe, *Convention on Human Rights and Biomedicine* (1997), Article 5.

[6] National Health and Medical Research Council (NHMRC), *Ethical Guidelines on Organ and Tissue Donation and Transplantation* (2016)

[7] World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010) and Australian Law Reform Commission, *Human Tissue Transplants* [1977] ALRC 7.

The legal framework must also provide robust protections for minors and individuals with diminished capacity. In such cases, decision-making must prioritise their best interests while respecting their evolving autonomy, in line with international human rights standards.[8]

To support genuine informed consent, legislative reform must be accompanied by clear and accessible public information and education campaigns. Without broad public understanding and trust, even the most robust legal frameworks may fail in practice. Consent must be based on comprehension, not merely a formal process. Informed consent is not only a legal prerequisite but an ethical imperative.[9] It reflects a broader societal commitment to dignity and personhood, ensuring that individuals retain agency over decisions that profoundly affect their bodies and lives.

Nationally consistent laws should enshrine the primacy of the donor's wishes, embed supported decision-making principles where appropriate, and avoid paternalistic or overly broad substitution of decision-making authority.[10]

3. *Ethical Sourcing and Regulation of Anatomical Donations*

The treatment of human bodies and tissues for medical, research, and educational purposes must be conducted with the utmost respect for donor dignity and the wishes of their families. Legislation should require that no anatomical donation takes place without explicit, informed consent.[11] Ethical sourcing principles must guide the regulation of anatomical donation programs and schools of anatomy, ensuring transparency in the handling, storage, and disposal of human remains so as to maintain public confidence and uphold donor dignity.[12]

In addition, regulatory frameworks should incorporate regular auditing and public reporting requirements to ensure accountability and public transparency. Any commercial or international exchange of human tissue must be subject to strict ethical scrutiny to prevent exploitation and trafficking.[13]

Further, guidance should be developed for culturally safe and trauma-informed practices in handling human remains, particularly when engaging with Aboriginal and Torres Strait Islander communities and culturally and linguistically diverse populations, whose beliefs about the body and death may differ significantly from Western norms.[14]

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[8] NHMRC, *Ethical Guidelines on Organ and Tissue Donation and Transplantation* (Guidelines, 2016) and United Nations, *Convention on the Rights of Persons with Disabilities*, opened for signature 30 March 2007, 2515 UNTS 3 (entered into force 3 May 2008) art 12 and United Nations, *Convention on the Rights of the Child*, opened for signature 20 November 1989, 1577 UNTS 3 (entered into force 2 September 1990) art 12.

[9] World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

[10] United Nations, *Convention on the Rights of Persons with Disabilities*, opened for signature 30 March 2007, 2515 UNTS 3 (entered into force 3 May 2008) arts 12, 25; NHMRC, *Ethical Guidelines on Organ and Tissue Donation and Transplantation* (2016) 12–14.

[11] Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (Report, April 1995); World Health Organization, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010) Principle 10.

[12] NHMRC, *Ethical Guidelines on the Use of Human Tissue in Research* (2007) 10–11; Thomas Faunce, 'The Ethical, Legal and Social Issues in Human Tissue Donation' (2011) 18(2) *Journal of Law and Medicine* 240.

[13] NHMRC, *Ethical Guidelines on the Use of Human Tissue in Research* (2007); Nuffield Council on Bioethics' Human Bodies: Donation for Medicine and Research (2011)

[14] Australian Government, *National Aboriginal and Torres Strait Islander Health Plan 2021–2031* (2021).

4. *Prohibition of Commercialisation and Exploitation*

International human rights standards strongly oppose the commercialisation of human tissues and organs due to the inherent risks of coercion, exploitation, and trafficking.[15] Australia must therefore maintain strict prohibitions against the sale of human tissue, ensuring that any cost-recovery mechanisms are transparent, fair, and free from financial incentives that could compromise ethical practices.

The underlying principle must be that the human body is not a commodity and must never be subject to commercial exploitation.[16] This position aligns with Australia's international obligations or commitments under:

- Article 12 of the *International Covenant on Economic, Social and Cultural Rights*[17] (ICESCR), which recognises the right of everyone to the highest attainable standard of physical and mental health. This includes a duty on states to regulate medical services, including organ and tissue transplantation, in a way that prevents exploitation, protects dignity, and ensures equitable access to health care. ICESCR imposes both positive obligations (to take legislative and policy steps to safeguard rights) and negative obligations (to refrain from practices that interfere with bodily autonomy and dignity).

- *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*[18], which condemns organ trafficking, transplant tourism, and commercialism in transplantation. It affirms that organs should be donated freely and without coercion, and that national systems must work toward self-sufficiency in organ donation. The Declaration urges governments to adopt laws that prevent financial incentives and ensure ethical, transparent, and equitable donation systems.

In particular, Australia's regulatory framework must ensure that individuals from vulnerable or marginalised communities—such as those experiencing poverty, incarceration, or migration—are not disproportionately targeted or exploited in donation processes. The legal framework must also guard against cost-recovery models that functionally incentivise donation or create inequities in access to transplantation.[19]

Australia's legal framework must give full effect to these obligations and commitments by reinforcing prohibitions on commercial transactions involving human tissue and embedding protections that safeguard against exploitation—particularly of vulnerable or economically disadvantaged populations.

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[15] United Nations Office on Drugs and Crime, *Assessment Toolkit on Trafficking in Persons for the Purpose of Organ Removal* (Toolkit, 2020).

[16] World Health Organisation *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

[17] International Covenant on Economic, Social and Cultural Rights, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976).

[18] 'Declaration of Istanbul on Organ Trafficking and Transplant Tourism' (Declaration, Istanbul Summit, 5 May 2008) https://www.declarationofistanbul.org/, updated 2018.

[19] WHO, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010) Principle 5.

5. *Advancing Equity in Access to Transplantation*

The right to health, as recognised under international human rights law, includes the guarantee of non-discriminatory access to organ transplantation.[20] Disparities in donor rates and access to transplant services disproportionately affect marginalised communities, including Aboriginal and Torres Strait Islander peoples, rural populations, and culturally and linguistically diverse groups.[21] Legal reforms must actively address these inequities by implementing culturally responsive policies, targeted public education initiatives, and fair allocation systems that prioritise need over socio-economic status. These reforms should be guided by the principle of equity, ensuring that systemic barriers, including geographical, cultural, and socio-economic factors, do not impede access to life-saving treatment.[22] Additionally, policies must consider the full scope of barriers faced by vulnerable populations, including financial, informational, and geographic obstacles, and include mechanisms for addressing these disparities in the allocation and distribution of transplant resources.

6. *Human Rights Implications of Emerging Technologies*

Emerging medical technologies—such as antemortem interventions and perfusion techniques[23]—present complex ethical and human rights challenges. These technologies, while offering significant potential to improve outcomes for donors and recipients, must be regulated carefully to avoid violations of individual rights.[24] Any expansion of legal frameworks to accommodate these innovations must be accompanied by rigorous ethical scrutiny, ensuring that the rights of living donors, deceased individuals, and their families are fully protected.[25]

Furthermore, informed consent processes must remain central to any advancement in these fields, particularly as these interventions may involve higher risks and unknown long-term consequences. Individuals must have the ability to make informed voluntary decisions, and any new legal framework should enshrine this right clearly. Similarly, privacy protections must be robust to guard against potential misuse of personal medical data in the context of new technologies.[26]

Moreover, Australia must remain vigilant against potential human rights violations linked to organ trafficking and unethical procurement practices by aligning its legal standards with international best practices.[27]

V. International Comparisons in Human Tissue Legislation

The following comparative models offer insights into various legal, ethical, and operational approaches to human tissue regulation across different jurisdictions. While not all are directly transferrable to Australia's legal and cultural context, each provides valuable lessons.

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[20] ICESCR Article 12.

[21] Australian Organ and Tissue Authority, *State of Organ and Tissue Donation and Transplantation in Australia 2023* (2023).

[22] World Health Organisation, *Global Transplantation: A Commitment to Equity* (2021).

[23] Organ and Tissue Authority (Australia), "Donation after Circulatory Determination of Death (DCDD), (Report, Australian Government, 2022)

[24] S Hansen and S Schicktanz (eds), *Ethical Challenges of Organ Transplantation: Current Debates and International Perspectives* (Transcript Verlag, 2021).

[25] World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

[26] Ibid.

[27] United Nations Office on Drugs and Crime, *Assessment Toolkit on Trafficking in Persons for the Purpose of Organ Removal* (2020).

1. European Union – A Human Rights-Based Approach

The European Union adopts a human rights-based approach to human tissue regulation, which places a strong emphasis on donor autonomy and informed consent. The EU's framework seeks to ensure that donations are voluntary and ethically managed, with clear, harmonised procedures across member states. This system provides robust ethical safeguards, ensuring that tissue donations align with fundamental human rights. However, the challenge lies in implementing a unified approach across the diverse legal systems of EU member states, with potential conflicts between national regulations and EU directives. Moreover, maintaining ethical oversight across such a broad jurisdiction presents an ongoing challenge.[28]

2. United Kingdom – Deemed Consent System

The UK has implemented a deemed consent system, where individuals are presumed to consent to organ and tissue donation unless they have opted out. This model aims to address the tissue shortage by increasing donation rates through presumed consent, simplifying the process and reducing administrative burdens. However, the presumed consent 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 the opt-out system can undermine its effectiveness, and there are concerns that individuals may not fully understand the implications of their presumed consent.[29]

3. Nordic Countries – National Regulation of Tissue Banks

In the Nordic countries, tissue banks are regulated under a centralised system, which allows for robust oversight and coordination. This model facilitates efficient management of tissue donations and ensures that both ethical and operational standards are met. The centralised nature of regulation fosters public trust and transparency, as government bodies oversee the entire donation and distribution process. However, this centralisation can sometimes lead to inefficiencies at the local level, with regional flexibility being limited. The complexity of the regulatory framework also imposes a significant administrative burden, which can become cumbersome as new forms of tissue use and technologies emerge.[30]

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[28] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, opened for signature 4 April 1997, ETS No 164 (entered into force 1 December 1999); Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L 102/48; European Parliamentary Research Service, *Revision of the EU Legislation on Blood, Tissues and Cells* (Briefing, July 2022).

[29] *Human Tissue Act 2004* (UK) c 30; Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research* (Report, 2011); Department of Health and Social Care (UK), *Opt-out Organ Donation: Max and Keira's Law Passed into Law* (News release, 15 March 2019) https://www.gov.uk/government/news/opt-out-organ-donation-max-and-keiras-law-passed-into-law

[30] European Directorate for the Quality of Medicines & HealthCare, *Guide to the Safety and Quality of Tissues and Cells for Human Application* (8th ed, 2022); European Directorate for the Quality of Medicines & HealthCare, *Guide to the Quality and Safety of Tissues and Cells for Human Application* (5th ed, Council of Europe, 2022)

4. Iran – A Regulated Compensation Model [31]

Iran's approach to tissue donation is distinguished by its regulated compensation model, where financial incentives are offered to encourage tissue donations. This model has proven effective in addressing tissue shortages by creating a direct financial incentive for donors. However, the ethical implications of compensating individuals for their tissues raise serious concerns, particularly regarding the commercialisation of human tissue. The model risks exploiting vulnerable populations, as economically disadvantaged individuals may be coerced into donating for financial gain. This approach also conflicts with fundamental principles of human dignity and autonomy, which are central to many international ethical frameworks.[32]

5. Council of Europe – Addressing Illicit Practices[33]

The Council of Europe has developed regulations aimed at combating illicit practices, such as trafficking and illegal trade in human tissues. This framework focuses on ensuring that tissue donation practices are conducted ethically, with strong safeguards against exploitation and trafficking. The Council's approach provides an international standard for maintaining the integrity of tissue donation systems. However, the enforcement of these regulations across diverse legal systems presents challenges, as countries with less stringent laws may struggle to comply. Additionally, the extensive oversight required to monitor these practices could lead to inefficiencies or delays in the donation process.

Drawing from the experiences of these international models, it is clear that while each offers valuable insights, certain aspects are more aligned with Australia's values and obligations. The human rights-based framework of the EU, the deemed consent system in the UK, and the Nordic countries centralised regulation of tissue banks are particularly relevant to Australia's context, focusing on respecting autonomy and ensuring ethical practices in tissue donation. While the Iranian model provides a pragmatic solution to tissue shortages, its ethical concerns make it less suitable for adoption. Similarly, the Council of Europe's regulations offer important lessons in combating illicit practices, though their practical implementation could present challenges. These international examples offer valuable lessons that can inform the development of Australia's own approach to human tissue legislation.

VI. Preferred Model: A National Human Rights-Based Framework

Australia should adopt a harmonised, national framework for human tissue and organ donation that draws on international best practice while grounding itself in a rights-based approach. This model should incorporate:

- the ethical clarity and consent safeguards of the Council of Europe and EU frameworks,
- the structured regulatory oversight and public trust foundations evident in Nordic countries, and
- cautiously adapted features of the UK's deemed consent system, contingent on robust education, transparency, and cultural safety.

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[31] See, e.g., Benjamin E. Hippen, 'Organ Sales and Moral Travails: Lessons from the Living Kidney Vendor Program in Iran' (2008) Cato Institute Policy Analysis No 614; Alireza Bagheri, 'Compensated Kidney Donation: An Ethical Review of the Iranian Model' (2006) 16(3) *Kennedy Institute of Ethics Journal* 269; *Iranian Organ Transplantation Act* (Islamic Republic of Iran, 2000).

[32] World Health Organisation, *Guiding Principles on Human Cell, Tissue and Organ Transplantation* (2010).

[33] European Committee on Organ Transplantation (CD-P-TO), *Illicit and Unethical Activities with Human Tissues and Cells: Addressing the Need for the Elaboration of an International Legal Instrument to Protect Donors and Recipients* (Report, 2018) European Directorate for the Quality of Medicines & HealthCare https://www.edqm.eu/en/d/162461; Council of Europe, *Convention on Human Rights and Biomedicine* (ETS No 164, 4 April 1997)

Australia must firmly reject any system that allows for financial incentives or commodification, such as the Iranian model, due to its incompatibility with international human rights standards. Instead, Australia's legal architecture must affirm that human tissue is not a commodity, and ensure that access, consent, and oversight are ethical, equitable, and consistent across all jurisdictions.

Key features of this preferred model should include:

- **Uniform National Legislation:** Enact a single federal law governing human tissue donation, consent, usage, and disposal, ensuring consistency across all states and territories. Current legislation is fragmented, with each state and territory having enacted different laws at different times, leading to legal inconsistency and confusion for donors, families, and healthcare providers. A national law would promote clarity, ensure equal access to treatment regardless of geography, and affirm Australia's commitment to protecting human rights.
- **Rights-Based Consent Mechanisms:** Embed informed, voluntary, and ongoing consent processes that prioritise donor autonomy. Consent should be clearly documented, with safeguards against override by third parties unless strictly justified and legally constrained.
- **Ethical Governance and Oversight:** Establish an independent, transparent regulatory body to oversee donation and transplantation processes nationally. This body should ensure compliance with human rights standards, ethical practices, and public accountability, including culturally safe and trauma-informed approaches.
- **Prohibition of Commercial Exploitation:** Codify a national ban on the commercialisation of human tissue. This must include strict limits on cost-recovery models, ensuring they do not function as covert financial incentives, particularly in interactions with vulnerable or economically disadvantaged populations.
- **Equity and Cultural Safety:** Develop policies that actively address barriers faced by marginalised populations, including Aboriginal and Torres Strait Islander peoples, rural and remote communities, and those from culturally and linguistically diverse backgrounds. These policies must support culturally appropriate engagement, improve accessibility, and embed social justice principles throughout all donation and transplantation pathways.
- **Oversight of Emerging Technologies:** Create clear legal and ethical guidelines for the use of emerging medical technologies, such as ex vivo organ perfusion or bioprinting.[34] These technologies must be subject to the same standards of consent, privacy, and ethical scrutiny as conventional transplantation procedures.
- **International Alignment and Collaboration:** Align with key international instruments, such as the Declaration of Istanbul, the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, and the Council of Europe Convention against Trafficking in Human Organs.
- **Public Education and Transparency:** Invest in accessible, culturally appropriate education campaigns to inform the public about their rights, the donation process, and the legal framework. Transparency must be a hallmark of the system, with annual public reporting on donation rates, oversight activities, and equity outcomes.

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[34] 'Advancing Healthcare Accessibility: The Role of Bio-Printing in Organ Care Technology', *Data Bridge Market Research* (Web Page, 2024) https://www.databridgemarketresearch.com/articles/transmitting-healthier-futures-pioneering-organ-care-technology-and-bio-printing-innovations

By embedding these elements into a national framework, Australia can ensure that its human tissue laws are ethical, effective, and consistent with its human rights obligations. The framework should affirm the primacy of individual dignity, provide robust safeguards against exploitation, and guarantee that advances in medical technology do not outpace the protection of personal rights.

VII. Final Observations

Reforming Australia's human tissue laws is not merely a legislative exercise—it is a moral and social imperative. The inconsistencies across jurisdictions place undue burden on individuals, families, and professionals navigating systems meant to serve the public good. A nationally unified approach that respects human rights, cultural diversity, and ethical boundaries is essential. By rejecting commodification and prioritising community trust, Australia has the opportunity to lead with integrity in this sensitive area of law. The time for principled, nationally consistent reform is now.

Tasc
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