

HEALTH LAW GROUP, MONASH LAW SCHOOL

SUBMISSION TO THE ALRC
REVIEW OF HUMAN TISSUE
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Marc Trabsky, Karinne Ludlow and Calvin Ho
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INTRODUCTION

The Health Law Group (HLG) is a research group within the Faculty of Law, Monash University, focusing on the legal and ethical aspects of health and healthcare. It encompasses a broad range of research areas including the ethical and legal aspects of accident, workplace and health insurance, healthcare practice, environmental health, gender and health, end-of-life law, emerging technologies, data and cybersecurity, public health, global health, intellectual property and trade, and research governance. The HLG also offers academic opportunities for students interested in health law, including specific units and postgraduate supervision. Information about the HLG, its people and activities are available here: <https://www.monash.edu/law/research/centres-and-groups/law-health-wellbeing>

In February 2025, the Commonwealth Attorney-General requested that the Australian Law Reform Commission (ALRC) conduct a review of human tissue laws in Australia. In May 2025, the ALRC called for input into its Issues Paper on its review of human tissue laws. In this submission we discuss the objectives of human tissue laws in Australia, the principles that should guide legislative reform and what should be included in the Priority Reform Areas in the Inquiry. We also propose additional issues that we suggest should be addressed in the Inquiry as well as issues with the current regulatory landscape, particularly around effective and consistent oversight of human tissue use across Australia. Our submission is limited to addressing what could be addressed in the Inquiry and what objectives and principles should drive reform.

This submission has been written by Associate Professor Marc Trabsky, Associate Professor Karinne Ludlow and Associate Professor Calvin Ho from the Health Law Group, Faculty of Law, Monash University.

OBJECTIVES

WHAT ARE GOOD AIMS OR OBJECTIVES FOR THESE LAWS?

1.1 History of Human Tissue Acts in Australia

Human Tissue Acts (HTAs) in Australia evolved from attempts since at least the sixteenth century to regulate the supply of human cadavers for purposes of pedagogical anatomy in England.¹ The eighteenth and nineteenth centuries witnessed an acute rise in the trafficking of dead bodies to medical schools in England and Scotland.² The enactment of the *Anatomy Act 1832* in England, and similar legislation in the Australian colonies in the nineteenth century, made an effort to halt the trade for body snatching, grave robbing and generally, trafficking of corpses to medical schools. These acts regulated the study of anatomy in the British Empire, and provided lawful avenues for medical schools to obtain cadavers for learning and training, however, as Marc Trabsky has written “[t]he subjects of dissection were still overwhelmingly collected from public institutions, such as workhouses, prisons and hospitals, and were disproportionately represented by convicted criminals, paupers and indigenous people”.³

The Anatomy Acts of the nineteenth century remained largely unchanged in Australia until the ALRC’s report on *Human Tissue Transplants* in 1977 and its recommendation that each State and Territory enacts legislation to define death and regulate organ and tissue transplantation.⁴ There

¹ Marc Trabsky, *Law and the Dead: Technology, Relations and Institutions* (Routledge, 2019) 42.

² For a history of human dissection in England, Australia and America see Tim Marshall, *Murdering to Dissect: Grave-robbing, Frankenstein and the Anatomy Literature* (Manchester University Press, 1995); Ruth Richardson, *Death Dissection and the Destitute* (University of Chicago Press, 2001); Michael Sappol, *A Traffic of Dead Bodies: Anatomy and Embodied Social Identity in Nineteenth-Century America* (Princeton University Press, 2004); Helen MacDonald, *Human Remains: Dissection and Its Histories* (Yale University Press, 2006); Helen MacDonald, *Possessing the Dead: The Artful Science of Anatomy* (Melbourne University Press, 2010); Elizabeth T Hurren, *Dissecting the Criminal Corpse: Staging Post-Execution Punishment in Early Modern England* (Palgrave Macmillan, 2016); Richard E Bennett, *Capital Punishment and the Criminal Corpse in Scotland, 1740–1834* (Palgrave Macmillan, 2018).

³ Trabsky, *Law and the Dead*, 43.

⁴ Australian Law Reform Commission, *Human Tissue Transplants: Report No. 7* (Australian Government Printing Service, 1977).

were two factors that proceeded and catalysed the ALRC's report: first, medical innovations in the second half of the twentieth century extended life to the point that a 'near-dead patient' could be kept alive, and second, the Ad Hoc Committee of Harvard Medical School recommended, due to the effect of medical innovations on the extension of life, the creation of a new legal definition of death.⁵ The former involved new medication, machinery, and surgical methods and treatments – such as the modern ventilator, cardiac pacemakers, defibrillators, immunosuppressive drugs and transplantation techniques – which prolonged life and troubled definitions of death in the 1950s and 1960s.⁶ The latter entailed an influential group of clinicians, ethicists and lawyers who set out in 1968 a new legal definition of 'brain death' – the 'irreversible cessation of neurological function' – which they argued would provide clarity in law as to when hospitals could withdraw life-support technology for a patient in an irreversible coma, and when organs and tissue could be extracted for such patients for potential transplantation. The Committee led to the enshrinement of the 'dead donor' rule, which was enacted in the *Uniform Anatomical Gift Act 1968* (US) – meaning that organs and tissue can only be legally removed from patients who consented to their donation in their life and who are deemed dead by medical practitioners – and then the *Uniform Declaration of Death Act 1981* (US), which enacted the Committee's two-pronged definition of death as either cardiopulmonary or neurological.⁷ In the late 1970s and early 1980s, every Australian State and Territory enacted a HTA that enshrined the new legal definition of death and regulated the donation, retrieval and transplantation of organs and tissue.

1.2 Objectives of Human Tissue Acts in Australia

The aims of HTAs in Australia have been to set out a legal definition of death; regulate the donations of tissue by living persons and donations of tissue after death; regulate the operation of anatomy schools and donations of whole bodies and body parts to anatomy schools; and prohibit trade in human blood and tissue.

Guiding these aims have been the *implicit* objectives to increase the supply of and equitable access to human tissue in Australia while at the same time respecting the wishes, rights, dignity and autonomy of donors, ensuring the safety of donation and transplantation systems, and upholding public trust in medical institutions.

We believe that the guiding objective of HTAs remains to increase the supply of and equitable access to human tissue in Australia due to the substantial gap between supply and demand for blood, organs and other tissue for life-saving and other medical, research and other socially valuable uses. In addition, we assert that maintaining tissue donation as purely altruistic as an objective of the legislative framework should be subject to exceptions. While the prohibition of trade in tissue from donors after death may be ethically and legal justified, allowing for monetary compensation to be offered to living blood donors or gamete donors may be more consistent with the requirements of justice and equity. The provision of fair compensation may help to advance the policy goal of increasing the supply of and equitable access to human tissue in Australia, which should be balanced by the objectives to (a) obtain informed consent from donors during their lifetime about donation and the use of their tissue in the future; (b) respect the wishes, rights, dignity and autonomy of donors, even if the senior next of kin does not agree with the choice of the donor; (c) build a "transparent and easy to navigate tissue donation system"⁸; and (d) ensure the safety of the donation and transplantation systems. We caution any objective that would constrain the ability for the HTAs to decrease the gap between the supply and demand for human tissue in Australia, and prohibit the use of donated tissue for life-saving and/or medical research purposes because it is not "consistent with respect for persons and the human body".⁹ The advances in medical technologies, medication, and surgical methods and treatments, particularly in the context of increasing digitalisation, have

⁵ Marc Trabsky, *Death: New Trajectories of Law* (Routledge, 2024) 19. See further, Ad Hoc Committee of the Harvard Medical School, 'A Definition of Irreversible Coma: Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death' (1968) 205(6) *Journal of the American Medical Association* 337.

⁶ Trabsky, *Death*, 17-18.

⁷ Trabsky, *Death*, 17-18.

⁸ Australian Law Reform Commission, *Human Tissue Laws, Issue Paper No. 51* (Australian Government Printing Service, 2025) 9.

⁹ Australian Law Reform Commission, *Human Tissue Laws, Issue Paper No. 51* (Australian Government Printing Service, 2025) 9.

underscored the need for regulatory regimes – including those that relate to human tissue – to be more participatory and responsive to the expectations and needs of donors, users and the general public. Such an approach is more likely to promote public trust and support for socially valuable applications (like research) over time. It is also consistent with human rights goals and requirements (see for instance: <https://www.ohchr.org/en/calls-for-input/report-guidelines-right-participate-public-affairs>).

PRINCIPLES

WHAT PRINCIPLES SHOULD DRIVE REFORM?

1.3 Principles of Human Tissue Acts in Australia

We support the principles identified in the Issues Paper. We add that the following principles should drive reform of HTAs:

- Respect for wishes, rights, dignity and autonomy of donors
- Substantive and procedural ethical principles that could be applied in tissue governance
- Consistency across Australia
- Flexibility with adapting to new and emerging technology
- Justice and equity, including responsiveness, inclusiveness and participation (we note that equitable access to tissue is already highlighted as an important issue for consideration, which we are supportive of)

In the context of research involving human tissue, it is important that the principles and associated arrangements are consistent and coherent across all Australian jurisdictions, and consistent with international requirements and standards, in order to better support scientific research, international collaboration and public participation. The normative and regulatory landscape that applies to research and medical innovation is complex and difficult to navigate. The NHMRC's *National Statement on Ethical Conduct in Human Research* (2025) speaks to some of the normative requirements, but there are significant gaps between this ethical framework and regulatory/legal requirements. For instance, statutory provisions and/or mechanisms could help to address concerns relating to commercial use and benefit-sharing, and return of results.

PRIORITY REFORM AREAS

WHAT SHOULD BE A FOCUS FOR OUR INQUIRY?

We support the Priority Reform Areas identified in the Issues Paper. We make further suggestions below to assist the Inquiry.

1.4 Issues around the definition of 'tissue'

1.4.1 *Whether the definition of tissue should include gametes*

The Issues Paper identifies the question of whether it is more appropriate to rely on assisted reproductive treatment laws (ARTs) to regulate the donation of gametes as one likely to be considered in the review.

Gametes are regulated by HTAs only where gametes are sourced from deceased persons. In such cases, HTAs regulate the retrieval / collection of gametes from such persons but not the subsequent use of such gametes. Two immediate concerns raised here are:

- a. If gametes are excluded from the HTAs' definition of tissue, differences in state ART laws around the use of gametes in reproduction from people who are deceased may have important implications for the current rights of people to have gametes retrieved from their deceased partners.

For example, in NSW a person can agree to sperm being retrieved from their now deceased partner but is unable to use that sperm to create an embryo for reproductive purposes. Nevertheless (subject to state laws on export and import of gametes) that person can travel with the retrieved sperm to another state where reproductive use is permitted. Removing retrieval rights from the NSW HTA and instead relying on the NSW ART Act would (unless the latter is amended), take that choice from people in NSW.

- b. Current state ART laws around gamete use for *scientific* research beyond ART, are inadequate in some cases and HTA reform could be used to improve this.

More generally, there is lack of clarity over regulatory pathways that apply to different stages of tissue engineering, beyond what may fall under the purview of the Therapeutic Goods Administration. We are of the view that this concern could be addressed within a statutory framework on tissue governance.

1.4.2 *Whether the definition of tissue causes problems for research*

We strongly support consideration of the fitness of the tissue definition for emerging fields.

Neither the *Research Involving Human Embryos Acts* or state ART Acts regulate somatic stem cells or pluripotent stem cells, other than initial derivation from an embryo. Nor do they regulate the subsequent use of stem cell lines. This may be appropriate. However, such lines are being developed to create, for example, organoids (three dimensional structures derived from stem cells that mimic the functions of organs). Those organoids may then be used in tissue transplants. Bioprinted tissues, which use other cells beyond stem cells, are similarly being developed with the goal of being used as donor tissue.

Whether such materials should be included in the definition of tissue will depend upon the agreed reformed aims of the amended HTAs. Current responses to the commercialisation and trade in tissue and products derived from such tissue discussed later in the Issues Paper require significant reform. For example, divides between blood and plasma products, and differences in the regulation of biobanks around Australia raise these issues. A relevant boundary here is whether HTA reform should address control rights over tissue and/or income rights of donors?

1.5 **Issues related to the donation of tissue by living persons**

1.5.1 *What tissue should be used in research?*

Clarification is needed around the regulation of the donation of gametes in storage with an ART clinic, where the gamete provider has since died, but has left (written) consent for the gametes to be redirected to research outside the clinic.

1.6 **Issues related to the donation of tissue after death**

1.6.1 *How should 'death' be defined?*

We agree that the current definition of death needs to be updated for the reasons stated in the Issues Paper. However, the Inquiry would need to probe what would be the intended and unintended effects of a new legal definition of death for a range of bureaucratic processes and institutional practices, such as state-based registration systems, coronial investigations, decisions on claims for life insurance, funerary insurance and superannuation benefits, the disposal of human remains, and the management of estates and the inheritance of debt. Additionally, if clinical practice is subject to change, ensuring consistency between the legal definition of death and clinical definitions of death require justification in and of itself. We caution that changing the definition of death can result in inadvertent effects in medical, financial, legal and social systems, and erode public trust in the stability and consistency of medical, financial and legal advice.

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

This should be one of the most important priority areas for reform in order to increase the supply of and equitable access to human tissue in Australia. The so-called ‘family veto’ in HTAs (e.g. section 26 in HTA 1982 (Vic)) runs counter to respecting the wishes, rights, dignity and autonomy of donors who have consented to tissue donation during their lifetime.

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

This is an important priority area, and it should be investigated in consultation with forensic institutes and the coroners courts of each state and territory. Since the introduction of postmortem medical imaging in 2005, the rate of postmortem dissections has decreased in each state and territory, however, the issue of how tissue is removed, retained and/or returned requires examination by the Inquiry.

1.7 Advertising and trade in human tissue

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

The Inquiry should consider how tissue and bodies from deceased donors have been increasingly plastinated and exhibited privately or publicly for commercial gains since the first *Bodyworlds* exhibition in Japan in 1995. Since 1995, Dr Gunther von Hagen, the founder of *Bodyworlds* has openly called for donations and assured the public that all donors have consented to donate their bodies to his exhibitions prior to their deaths. However, in the early 2000s investigative reporters raised questions about how bodies were donated from Serbia and China to Germany, which raised the question of whether informed consent was obtained from donors prior to their deaths. Given that *Bodyworlds* has been exhibited in Australia in the 2000s, and the exhibitions have become a lucrative use of deceased bodies, we suggest that HTAs should define the legality or illegality of such exhibitions, which will promote public trust in both legal and medical institutions on the use of human tissue and bodies from dead donors.

OTHER ISSUES

ISSUES TO FOCUS ON IN THIS INQUIRY

We believe that HTAs should explicitly include the objectives and principles of the Acts in legislation. This would be similar to the *Coroners Act 2008* (Vic), which has clarified the objectives and principles that guide the interpretation of the Act.

ISSUES WE ARE UNLIKELY TO FOCUS ON IN THIS INQUIRY

As we discussed in 1.4, we believe the Inquiry should focus on “the regulation of human gametes (sperm and egg cells) and embryos”, because they intersect with HTAs.

Further information

Monash University
Wellington Road
Clayton, Victoria 3800
Australia

monash.edu.au