Australian Law Reform Commission Review of Human Tissue Laws

Thank you for the opportunity to make this submission. I am a Research Affiliate at the University of Sydney. Since 2017 I have been researching the history of body donation at the University of Sydney, current body donation in Australia, and attitudes to organ and body donation amongst health and medical sciences students at the University of Sydney. I have briefly addressed the questions posed in the Issues Paper below, but the focus of this submission is on four issues:

1. The importation of human tissue, in particular bodies and body parts from the United States for use (primarily) in post-graduate and professional training.
2. The lack of consensus and gold standard criteria for body donation and absence of a common consent form across, and within, Australian jurisdictions.
3. The practice of permitting posthumous next-of-kin donation of a body post-without the deceased having elected to do so, pre-death and, the practice of permitting next-of-kin to override the pre-death election of the deceased and thus to refuse to honour a donation; and,
4. The lack of national compilation of information and public reporting on body donation.

I have set out the background and key matters arising in relation to each of these issues below. My research into body donation across Australia and New Zealand has established that body donor programs place great emphasis on respecting local donors and their families. They manifest this respect in the care they afford the individual from reception to disposition, and in their regard for family and their loved one. There are areas, however, where current practice is less than ideal, often a reflection of the disparate practices evident in a federation where each jurisdiction acts individually. It is anomalous that there are no national guidelines or operating procedures for body donation. There is also an unfortunate sense that universities are focused on revenue streams, such as income earned through contracted workshops, with the tight funding environment driving decisions which perhaps merit closer ethical review. The ALRC review provides a timely and important opportunity to address these shortcomings and anomalies, and to reinforce the position of Australia as a leader in the ethical conduct of body donation.

But first in relation to the questions posed by the Issues paper:

1. *What is your personal experience of how human tissue is obtained or used in Australia.*

I have been involved in research examining the history and current practice of body donation in Australia and New Zealand and have also surveyed students about their attitudes to organ donation. These programs primarily operate for the purposes of supporting education and training, although some research is also conducted, for example imaging research. All body donor programs in Australia and New Zealand use locally consented donors. I have made some observations about the importation of human bodies and body parts from the USA below, and about the consent processes for donation. I also have some familiarity with legacy remains that are preserved in museums associated with universities across Australia. Recent international guidelines on legacy remains should be incorporated into local policy and practice (Cornwell et al., 2024).

2. What is your personal experience of how human tissue laws work in Australia?

The ethical and legal framework for the use of human tissue in Australia is internationally lauded for its focus on consenting donors and respect for the autonomy and dignity of the donors. In many ways this acclaim is deserved. However, our research has found that in practice the application of the laws varies across and within jurisdictions and there are some substantial inconsistencies with international best practice. This review is an opportunity to establish a national standard of consent, and to implement consistency in practices. The legal framework has some significant loopholes, particularly in relation to next-of-kin veto of consent, and importation of human bodies and body parts.

3. What are good aims or objectives for laws governing how human tissue is obtained and used?

- Ensuring ethical conduct and compliance with international best practice.
- Transparency of reporting – currently there is none on body donation nor on the importation of human tissue, nor more broadly on use of human tissue in Australia for therapeutic, education and research purposes..
- Flexibility to enable adjustment to reflect new technology and innovation in how human tissue is used, but only within a strong framework of independent governance and ethical review.
- Recognition of the important contribution of human tissue donation to education, training and research as well as to life saving transplantation.

4. What principles should guide reform of human tissue laws?

- International best practice
- Respect for the autonomy and right of the deceased to determine how their body is used.
- Avoidance of commodification of the human body.
- Transparency and accountability – reporting of all human tissue use available publicly.
- Recognition of the value of human tissue donation in education, training, research and to the overall Australian community.
- Consistency across all jurisdictions.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry?
Broadly yes. However, there should be close scrutiny of the commercialisation of human tissue, the importation of bodies and body parts for what amount to commercial purposes, and the lack of uniformity across and within jurisdictions in relation to consent practices.

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

I have detailed below four issues of particular concern because of their deviation from core ethical principles and their potential to adversely affect public trust in the use of human tissue for education, training and research.

1. *The importation of human tissue, in particular bodies and body parts from the United States.*

Background:
The findings summarised here have been published in Anatomical Sciences Education (Jenkin and Keay, 2025). They were collected as part of a survey of body donation programs in Australia and New Zealand.

Australia currently has seventeen body donor programs, with some 1000 – 1500 hundred bodies donated each year. All programs are located within a university. The number of programs varies across each jurisdiction with some, for example, Victoria, Western Australia and South Australia, having central mortuaries which accept donors on behalf of all licensed anatomy schools. Others, in particular NSW and Queensland (QLD), have multiple programs – NSW has eight, and QLD has four. The ACT and Tasmania each have one program, based at the ANU and University of Tasmania respectively. The size of the programs varies considerably, with some accepting only a couple of donors each year and other taking more than 150. The majority of donor programs are over-subscribed with many more potential donors than programs have the capacity to accept. In consequence, most programs have considerably narrowed their acceptance areas such that many potential donors are unable to register as donates. This is particularly the case for rural donors who do not live proximate to programs in rural NSW (Wollongong/Armidale/Newcastle) or QLD (Gold Coast/Tweed region, Townsville/Cairns). Some programs will direct the family of deceased to other programs if they cannot accept the body at the time of death. However, many potential donors are turned away, both at registration and at the time of their passing. **There is thus a mismatch between potential donors, actual donors who are registered and whose bodies cannot be accepted at the time of their death, and programs which would prefer to receive more donors.**

Donated bodies are usually embalmed or frozen. All programs in Australia except the one at Macquarie University have embalming facilities and use embalmed bodies and embalmed prosected body parts and specimens for the education of undergraduate, graduate and post-graduate students, mostly in the Science, Medical and Health Sciences faculties. Macquarie uses both frozen and embalmed (obtained from other programs) for such education. Some 10,000 students, clinicians, educators and researchers use the donated tissue each year.

The freezing of bodies for use in post-graduate and professional education including surgical training, emergency medicine, and other health specialties is relatively new (in contrast to the history of teaching with embalmed bodies which dates to the 19th century). There has been a proliferation of licensed anatomy facilities seeking to acquire frozen tissue for a range of purposes. The majority of these facilities are not connected with a body donor program and thus are not embedded in the same ethical framework which places care for the donor at the forefront of their operations. The three main activities offered by these facilities using frozen tissue are surgical training, professional training and medical device testing and training.

Surgical trainees are effectively required to undertake postgraduate training to obtain their specialty registration, and other health workers including paramedics, nurses and medical practitioners attend professional workshops for upskilling in tasks such as intubation, transfer of patients, scoping etc. The public health sector often contracts with university anatomy facilities to provide this training on a reimbursement of cost basis.

The advent of contracted workshops, for example for testing of, and training in medical devices, offered by universities on a fee for workshop basis, is also a relatively recent development. In contrast to professional upskilling, the fee for workshop arrangement is a very lucrative source of revenue for the universities; surgical trainees and commercial organisations will pay thousands of dollars for short workshops to revise key anatomical structures; learn new techniques; test out new devices, particularly prosthetics; and train specialists in the use of these devices. Professional Colleges also offer courses to upskill in techniques, for example in microsurgery, cosmetic surgery and orthopaedic surgery. Given the charitable status of the institutions which host these workshops, the proceeds are labelled as non-commercia, despite their contribution to revenue flows.

Not all body donation programs have the capacity to freeze bodies, and some have extremely limited capacity - for example, the University of Sydney main campus anatomy laboratory has very limited capacity. In contrast, some programs, notably the UTS, University of Adelaide and the Queensland University of Technology, have established dedicated facilities and **specific consent pathways** within their existing programs for local body donors whose bodies will be frozen and used for such training. However, others have established stand-alone surgical training units which operate solely for the purpose of hosting workshops and which predominantly source their human tissue by importing bodies or body parts from the United States. There are also multiple small units with anatomy licenses importing human tissue for education and research.

There is a clear need for such training and upskilling, and for the testing of medical devices and other interventions. **However, given the excess of potential body donors, it is not apparent why frozen tissue procured from overseas is used rather than that of locally consent donors.** Surgical programs argue that the greater variety – in particular age and condition – of bodies available through importation is superior to that available through local donor programs. However, there is no empirical evidence to support the contention that education and training are inhibited by exposure of students and trainees to the bodies of older people. Expanding acceptance areas for body donation might also increase the diversity of individuals who register as donors. This importation raises significant ethical issues and is possibly in breach of the requirements set out under the relevant jurisdictional laws.

Ethical Issues:

The majority of bodies and body parts imported into Australia are sourced from Science Care. Science Care is a for-profit "Body Broker" based in the United States. Body brokers operate in a legal 'grey' zone, accepting body donations to on-sell.

The *Uniform Anatomical Gift Act* (UAGA) was passed in the United States in 1968 to regulate the donation of human tissue including donated bodies, body parts and organs. The UAGA was amended in 1987 to specifically prohibit the sale of bodies and body parts. However, the legislation does not prohibit payment for 'processing' costs including those relating to preservation, transportation and disposal. Additionally, although US legislation prohibits the sale by individuals of their body, it does not prohibit the **on-selling** of donated bodies (only of donated organs), **nor limit** the fees that can be charged for the shipping, handling and processing of donated bodies. Testimony from those involved in for-profit body brokerage has established that such costs are inflated to ensure that the companies are able to secure a substantial profit, and such inflation continues to increase until the buyer is no longer willing to pay (Reuters, 2017; Rinaldo, 2019). Thus, companies elevate their fees to make a profit without breaching the law and on-sell or rent the donated body or body parts (Champney, 2016; Reuters, 2017; Champney et al., 2019; Rinaldo, 2019).

There are well-documented concerns about the practices of Science Care (Dickenson, 2017; Reuters, 2017; Rinaldo, 2019), particularly in:

- its targeting of vulnerable populations,
- payment of 'scouts' to identify likely donors/families, and,
- lack of transparency in consent processes including the poor understanding of those who consent to the donation (often a family member) that the body will most likely be sectioned into seven pieces, each of which may be on-sold or rented to institutions both within and outside of the US.
- Families also fail to appreciate that the ashes returned to them (if they elect for this to occur) are not the whole body and may in fact be just residual tissue left after sectioning. There is also evidence that many such donors do not realise

that Science Care is a for-profit organisation (Champney, 2016; Champney et al., 2019; Dickenson, 2017; Reuters, 2017; Rinaldo, 2019).

The quantum of tissue imported in Australia via Science Care is unknown, but it is not small. Every state has facilities associated with universities which import bodies and body parts, often on a monthly – quarterly basis. Programs report selecting appropriate tissue from a "shopping catalogue" of options, including the capacity to specify the age, sex, medical history and ethnicity of donors. Programs were unwilling to divulge the extent of these arrangements and the costs, citing "commercial in confidence dealings".

It is apparent that the importation of bodies and body parts is conducted to meet a commercial purpose; the conduct of income generating workshops. There is no ethical prohibition on the use of human tissue for training, but there should not be a commercial gain arising from the activity, and it should not rely upon the exploitation of vulnerable populations. In permitting this practice to occur, Australia is operating outside the gold standards of ethical practice for body donation (Jones, 2016; IFAA, 2017; Champney et al., 2019; Cornwall et al., 2024).

Furthermore, the human tissue imported into Australia is not treated with the same level of dignity and respect afforded local donors:

- Once tissue is received in Australia, Science Care does not require detailed tracking and accountability in the use of the tissue and its compliance with the contract. Although users sign a contract which specifies the intended use, there is no review or inspection to ensure use and care of the tissue complies with those conditions. This contrasts with the regulatory framework and routine inspections that monitor facilities and the use of local donors.
- Imported tissue is disposed of as a collection of up to 100kgs which is cremated. Science Care are not routinely advised of the disposition and there is no tracking and reuniting of individual bodies or body parts as occurs with local donors.

- There is no recognition of these individuals in commemoration or thanksgiving services as occurs with local donors, notwithstanding that information about them is provided to the importers.
- The family members are not given the opportunity for return of the ashes which is standard practice for local donors.
- The bodies and body parts are treated as commodities, used to generate revenue.

Local donors are thus afforded much higher ethical, legal and regulatory protection *and* institutional priority, in contrast to the deceased whose bodies are sourced internationally. As one senior anatomist stated when interviewed as part of our research:

> "*it may be legal to import bodies and body parts, but is it ethical? Why do we consider local donors and their families to be more deserving of dignity and respect [in the procedures and protections we have in place to guide our use of their bodies] than the donors and families from other countries?" (Jenkin, 2023).*

The international gold standards for body donation embed recognition of the donor as a human, and the respectful treatment of them and their bodies from reception through to disposition (IFAA, 2017 and AAA (Balta et al., 2024)). These standards also outline the requirements for informed consent and recommend against commercial use of donated tissue. Despite Australia leading the anatomy world in its ethical and legal procurement and care of local donors, it does not afford the same care to international donors. This is in effect it an ethical double standard.

This activity calls into question the integrity of our institutions and is a reputational risk. It is likely that the broader community which is very supportive of body donation would feel uncomfortable to discover that the bodies of individuals imported into the country are dealt with as a disposable commodity, not as a human.

The shift in Australia towards commodification of the donated body and its potential to generate income is one which appears to have developed in isolation from full consideration of the ethical issues it raises. Aside from the need to ensure donors are completely and accurately informed about the potential uses of their body, commercial exploitation of the donated body may erode the respect, autonomy, and control donors expect when they consent to donation (Richardson and Hurwitz, 1995; Champney, 2016; Winkelmann, 2016; Dickenson, 2017; Wallace, 2018; Champney, 2019; Farsides and Smith, 2020; Hildebrandt and Champney, 2020; Farsides and Smith, 2023). Bioethicists suggest that in considering human tissue as a commodity, to be deployed for maximum profit and utility, the dignity and "personhood" of the donor is undermined, and their human rights may be violated (Marway et al., 2014; Wallace, 2018; Comer, 2022). Contemporary anatomy facilities need to be mindful of their responsibilities to uphold the highest ethical standards and to make considered decisions about their policies and practices where there may be reasonable questions about their ethical foundations. The prevailing law should mandates these obligations.

This shift also has strong parallels with the historic use of unclaimed bodies (Sharp, 2000; Winkelmann, 2016; Wallace, 2018; Champney, 2019; Champney et al., 2019; Ghosh, 2020; Comer, 2022). In both cases, there is a pejorative assumption that the "needs" of the institution and the provision of education/training (a community good) are sufficient justification to ignore or override the rights of individuals (Goodman, 1944; Keith and Keys, 1957; Richardson, 2006; MacDonald, 2011; Champney, 2016).

Legal issues:

The human tissue legislation in every jurisdiction in Australia prohibits trade (commercial dealings) in human tissue, although the recovery of reasonable costs associated with the procurement and handling of the tissue may be levied. The legislation also requires that all bodies are donated by informed and consented donors. However, there is some ambiguity regarding what constitutes a body and/or a body part

The NSW *Anatomy Act 1977* defines "body" to mean a dead human body, but the Act is silent on the issue of payment for bodies and body parts, an omission which was noted upon by commentators on the impact of the implementation of the ALRC Report (1977) (Scott, 1977).

The NSW *Human Tissue Act 1983* which provides the companion framework in which commercial trade in human tissue is regulated in NSW defines "tissue" in s4:

> *"includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body."*

It does not appear to include whole bodies. The wording used in the NSW *Human Tissue Act 1983* is very similar to that used in the Western Australian, South Australian, Tasmanian, Victorian, and Queensland legislation regulating the use of human tissue.

The ACT *Transplantation and Anatomy Act 1978* also uses this definition of "tissue" but has an explicit provision (s44) relating to the commercial trade in human bodies for anatomical examination alongside its definition of body. Similarly, the New Zealand *Human Tissue Act 2008* has, in s7, a very detailed definition of human tissue which includes the whole body and which, arguably, clarifies without ambiguity that the provisions of the Act apply to anatomical examination using bodies and body parts, especially in relation to the commercial trade provisions (discussed in more detail below). **It would be of great benefit for all Australian human tissue legislation to include a more detailed definition of human tissue to remove all ambiguity about what constitutes a body or body part.**

Most jurisdictions have operating procedures which govern the importation of human tissue from interstate or overseas. For example, Section 5.3 of the NSW Conduct of Anatomical Examinations and Anatomy Licensing in NSW: Procedures and Guidelines provides. These procedures require those importing the tissue to obtain documentation and evidence that "*demonstrate that the acquired tissue complies with the consent and other provisions of the Act. It is incumbent upon the facility to ensure that any agreements with interstate/international suppliers of imported tissue clarify the requirements of the original consent regarding the disposal of the tissue."*

The institutions and units that import bodies and body parts into Australia from Science Care do so using Science Care provided paper-work and contract with a separately established not-for-profit arm of the company. The paperwork certifies that the charges levied are only for costs associated with processing and handling the bodies. Several reports have documented that these costs are substantially inflated (Reuters, 2017; Rinaldo, 2019). Science Care was purchased by private equity firm American Capital Equity in 2016 and has been documented to bank large profits from its activities which it has publicly stated includes the exportation of bodies and body parts (Reuters, 2017). The Science Care paperwork provided to importers also states that the tissue has been obtained from consented donors, although the consent forms are not provided. Each set of tissue comes with information which details a limited medical history and donor characteristics but has the name and other personal information removed.

The paperwork therefore meets the requirements under the applicable legislation. However, in permitting institutions to satisfy legal requirements using Science Care issued paper-work, Australia is willfully turning a blind eye to the questionable validity of the documentation, and to the well-document status of Science Care as a for-profit company. This poses both legal and reputational risks.

The American Association for Anatomy has publicly criticised the unethical procurement practices of body brokers and is actively canvassing for greater legal and ethical regulation of body donation and associated practices. It strongly recommends that schools of anatomy and associated institutions do not purchase or accept bodies from body brokers (Cornwall et al., 2025).

The Uniform Law Commission in the US has drafted a revision to the Uniform Anatomical Gift Act, which would address the issues of fraudulent acts in dealings with donated bodies and body parts such as highlighted in the Reuters and CTN investigations (Uniform Law Commission, 2009). These changes (s16-s17) have yet to be enacted (Uniform Law Commission, 2009). More recently, the Uniform Law Commission has established a Study Committee on Post-Mortem Retrieval of Gametes, Safeguards for the Acquisition and Use of Anatomical Material by Non-Transplant Anatomical Organizations, and Protections for Unrepresented Donors.

The Study Committee will "study the need for and feasibility of a model act, or uniform legislation on the matters described below", including but not limited to consideration of whether the highly successful Uniform Anatomical Gift Act (UAGA) should be amended. The Committee will examine the following three areas, the last two of which (highlighted below) relate directly to the issue of importation of human tissue by Australian facilities from the US (information provided by the Uniform Law Reform Commission and shared with permission):

1. Postmortem Gamete Recovery. Gametes can be recovered postmortem and preserved for the possibility of posthumous reproduction. There are potential reasons to consider treating gametes differently than transplantable organs and tissues, including their use for reproduction and not medically urgent treatment, and reasons to consider whether, alternatively, they should be covered by UAGA.
2. Whole body donation. The supply of human cadavers for education and research is severely limited and largely controlled by organizations that acquire bodies for free and sell them at significant cost to medical institutions. The National Organ Transplant Act (NOTA) prohibits buying and selling transplantable organs but does not prohibit body sales. While the UAGA provides general guidance as to who may receive anatomical gifts (including bodies), it provides limited guidance as to what constitutes legitimate education or research, and no guidance as to what authorizing families must be told about what could happen to their loved one's body. While the Organ Procurement and Transplant Network (OPTN) governs gifts made for transplant, no parallel organization exists to oversee whole body gifts, sales, research and educational activities, or disposition of the remains.
3. Unrepresented donation. The UAGA provides a hierarchy for establishing the authorized decision maker for organ donation according to relationship with the decedent. After "anyone who showed special care or concern for the decedent," the final category for decision-maker is "anyone with the authority to dispose of

> the body." These individuals are often hospital administrators, with no knowledge of the decedent's wishes. (ULC, 2025)

There is a concerted push amongst senior anatomists and bioethicists in the US to implement a regulatory scheme which would prevent the operations of companies such as Science Care, and which would also shut down the capacity to on-sell human remains for profit which was the motivating factor in the recently reported Harvard University scandal NBC, 2023). The current review of the human tissue legislation in Australia provides a window of opportunity for change to ensure that we are not party to the unethical dealings in human tissue originating in the US.

Suggestion:
That the human tissue legislation be amended in all jurisdictions to prohibit the importation of bodies and body parts for education and training except in limited circumstances. Such a prohibition should specifically exclude procurement from body brokers or other agents whose operations are part of a for-profit company.

It is acknowledged that, currently, local facilities do not have sufficient freezing capacity to meet the burgeoning demand. However, there is no shortage of potential donors – the mismatch is in capacity. Arguably, if institutions were unable to import tissue, they would be more highly motivated to invest in developing local facilities to freeze and appropriately prepare donated bodies. It is also likely that more donors would be accepted, with the UTS, Adelaide Uni and QUT programs demonstrating that potential donors are willing to have their bodies frozen and used for such training if fully informed as part of the consent process. The limited information available also suggests that optimization of local donors would reduce the costs associated with the conduct of workshops using frozen tissue. There would need to be a notice period to enable increased acceptance of donors.

It is also acknowledged that there are exceptional instances, for example, training where the tissue of children is required, where Australian body donor programs will not be able to supply the requisite donor tissue (no Australian program will accept a donor aged less than 18 despite this being permitted under the legislation with parental/guardian consent). A case-by-case system for review and approval of such cases, including ethical and scientific review would enable such importation to occur as needed.

2. ***The lack of consensus and gold standard criteria for body donation and absence of a common consent form across, and within, Australian jurisdictions***.

There are no national Australian “gold” standards or even minimum content specified for inclusion in a donor consent form. Internationally, bodies such as the American Association of Clinical Anatomists (AACA) (2017), the International Federation of Associations of Anatomists (IFAA) (2017), and the American Association for Anatomy (2019) have issued guidelines regarding the content of donor consent forms. These guidelines all recommend that as a minimum the consent form includes information about potential uses of the body, retention period, the taking and use of images, and transportation of the body, particularly to other institutions, whether local, inter-country, or overseas.

As noted previously, there are seventeen body donor programs in Australia. Each program has its own website, information brochure, consent form, conditions and procedures for accepting donors, using the donation, managing its disposition and interacting with families/next-of-kin. Despite multiple programs in each of NSW and QLD operating under their respective identical legislation and regulations, each program has a unique consent form, as does every other program in the country. The forms vary in length and content. All require written consent for donor registration, and all seek separate consents for the transfer of the donated body/body part to another facility and for indefinite retention. All provide an option for donors and their families to have ashes returned after disposition. Otherwise, the content and wording of forms is extremely variable.

Examples of variations in body donation informed consent forms include:

- No standardised collection of information such as religious practice, medical history and ethnicity – some programs do not record whether a donor is of First Nations origin and no program routinely collects information on ethnicity.
- No uniform requirement for a witness to the donor's signature. Where such a witness is required, the requirement for independence is varied – sometimes the witness must be independent (not a family member), on other forms a family member is able to witness the donor signature.
- Medical screening variably includes seeking access to past medical history and/or GP contacts, but even where permission is given this information is often not used.
- Infectious diseases screening using nucleic acid assays or serological screening is not mandatory in all jurisdictions. Where infectious diseases screening occurs, family may not be notified if a positive result is returned. The body may also be sent directly for cremation rather than returned to the family due to it being unsuitable for use. The IFAA (2017) Guidelines recommend serological testing and informed consent for pre-acceptance screening, and NSW implemented a policy mandating such screening post COVID.. However, there does not appear to be information regarding how uniform such screening is across body donation programs internationally.
- Information provided to potential donors and their families about how the body may be used, and potential applications, is lacking in detail and options for donors to refuse consent to uses they are not comfortable with, for example, cosmetic surgery training, contracted workshops.
- Insufficient or no information about the taking of images and their retention and sharing.
- A lack of explicit information about potential commercial uses, including imagery for compilation in production of anatomy atlases, use of donated tissue in contracted workshops, and other fee-for-workshop situations.
- A lack of explicit information about the potential for use in military, road safety, pharmaceutical and medical device company testing.

Again, there are internationally recognised standards for consent forms for body donation (IFAA, 2017; 2024 (images)). International literature has documented the deficiencies in consent forms in other jurisdictions (Zealley et al., et al., 2021; Johnson et al., 2023), and also the ethical issues associated with misunderstandings on the part of donors and their families about the donation (Jones, 2016; Cornwall et al., 2012; 2018).

The small number of programs and the existence of uniform human tissue legislation should allow for the drafting of a national consent form.

In addition to the consent forms there are differences in matters such as retention time (which varies from 3-5 years depending on the jurisdiction), responsibility for disposition, privacy provisions relating to the identification of donors, whether donors can be donated by families (this is discussed in more detail below) and exclusion criteria which prevent acceptance of donors. While differences in the location and facilities of programs explain some of these differences, most do not.

All facilities and body donor programs operate within a regulatory framework that includes legislation, regulations, and policy. In accordance with Australian Code for the Responsible Conduct of Research (NHMRC, 2018) research conducted in the Australian licensed schools is subject to ethical review by the institution's human research ethics committees (NHMRC, 2007, updated 2018).

All body donor programs reported that any request to use human tissue for research was required to be submitted as a full research application, and subject to scientific and ethical review. In addition, many of the programs, particularly those that have purpose-built facilities and which contract to provide human tissue for the use of external parties, have local governance arrangements to ensure that the use of all human tissue accords with the requirements of the regulatory framework and protects the dignity and humanity of the donor. These arrangements include formally constituted committees, with internal and external membership, and guidelines developed by the licensed school, and internal review meetings. There is some doubt as to whether proposals for the importation of human tissue are reviewed as part of these processes. Ultimately, decision-making rested with Heads of Schools, or Deans, or the officer who was authorised under the relevant legislation (Anatomy License Holder in NSW). There is thus considerable variation in the governance of anatomy facilities and no consistent requirement that all use of human tissue for teaching and training be subject to ethical review to ensure that the proposed use is appropriate, respects the dignity and wishes of the donor, and, importantly, that the tissue is sourced ethically.

Suggestions:
Based on international best practice, a set of Australian standards for body donation and operation of anatomy facilities be agreed upon and embedded in all local regulatory frameworks.

Nationally, all body donor programs should be required to use a common consent form which contains a set of consensus derived clauses covering the issues outlined above. Additional clauses could be otherwise added to fulfil individual program needs (provided they did not override the core clauses).

Work to develop such a form could be led by the Australian and New Zealand Association of Clinical Anatomists (ANZACA). Inclusion of NZ members would facilitate integration of their substantial experience in consent for First Nations people. A number of academics in NZ have senior roles in the IFAA, including in the ethics area and thus would bring this expertise to discussions.

3. Next-of-kin donation of the deceased without the deceased having elected to do so, pre-death, and the practice of permitting next-of-kin to override the pre-death election of the deceased and thus to refuse to honour a donation.

These two issues are considered together because they centre on the right of the deceased to have their autonomy and control of their body after death respected. As stated by the American Association of Anatomy "consent by the individual is the ethical foundation of donation".

Most Australians would expect that if they made a pre-death election to donate their body (or their organs) that this would be respected. Although the Australian legislation recognises that the deceased's election is legally binding, the capacity of family to veto a donation is common practice. No Australian program will accept a body where next-of-kin object. The most cited reason for this is to avoid causing additional distress to the family at a difficult time. Programs also recognise that enforcing the consent of the deceased may also cause them reputational damage if the family decided to publicly object. This issue also arises in relation ot organ donation. Our survey of student attitudes to organ and body donation reported that ignorance of the capacity of next-of-kin to override a donor election was high (Jenkin et al., 2022).

A number of international bodies have identified the capacity of next of kin to override permission for donation, both in refusing to honour a pre-death election by the deceased and donating the deceased after death without their pre-death consent, as potential violations of donor autonomy (Farsides and Smith 2020; 2023), and recommended that it not occur (Champney et al., 2019; Ghosh, 2020; Shaw et al., 2020). The practice in Australia contrasts with international consensus (IFAA, 2017) which recognises the autonomy of the deceased, and respect for donor choice. The view that the donor's documented election should be the prime factor in acceptance of a donation, has led several countries such as Italy (Law 10/202; Brenner et. al., 2024) to enact laws to recognise the deceased's election and remove the previous capacity of familial decision-making. Although all Australian body donor programs strongly encourage potential donors to discuss their decision with their family, there is no uniform requirement for next-of-kin consent to the donation. This is also in contrast to the New Zealand practice where senior next-of-kin consent is sought at the time of donor registration, and if given, it is presumed in good faith that family members have been consulted about the decision.

It is important to acknowledge that there may be cultural sensitivities which necessitate a wider definition of family and thus the people to be consulted about the acceptability of a donation, and there may also be cultural or religious beliefs about death, the sanctity of the human body and the necessity for it to remain intact. These beliefs are not incompatible with recognition of the primacy of the deceased's election. In some Australian jurisdictions, notably Queensland[1] and Tasmania,[2] the consent provisions include explicit accommodation of the cultural beliefs of First Nations peoples and other cultural groups, in relation to the concept of family and next of kin. These provisions in the Queensland and Tasmania legislation broaden the scope of who should be consulted, and who is legally able to determine whether the donation of their family member is acceptable. They also recognise that Western norms concerning family do not necessarily reflect those of other cultures. This recognition should be common to all Australian human tissue legislation.

The other side of permitting next-of-kin to have control over the body of the deceased is the acceptance of post-humous donations from unregistered donors. This practice is not uniformly applied across Australia. Some programs, for example, the University of Sydney, will only accept registered donors. Others will accept a donation by next-of-kin at the time of death, and others will accept donation via a will. Where next-of-kin donation is accepted, it is not mandatory for it to be accompanied by a statutory declaration from the next-of-kin that the deceased had not made any objection to such donation during their lifetime. Such a declaration is required in other countries where next-of-kin donation is accepted (for example, in China). Several programs have procedures in place to accept consent from the State Guardian if a pre-registered donor has no next-of-kin to consent to the donation at the time of death.

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[1] The definitions of "child", "parent", "sibling", "next of kin" and "senior next of kin" in Part 1, clause 4 of the Queensland *Transplantation and Anatomy Act 1979* specifically include a person of the relevant category according to "Aboriginal tradition, Island custom or cultural traditions of their community".

[2] The definition of "senior available next of kin" in Part 1, clause 3 (b)(v) of the Tasmania *Human Tissue Act 1985* provides that where no spouse, child, parent or sibling person referred is available and the deceased person is an Aboriginal person within the meaning of the *Aboriginal and Torres Strait Islander Commission Act 1989* of the Commonwealth – the senior available next of kin is considered to be "a person who is an appropriate person according to the customs and the tradition of the community or group that the deceased person belonged to."

There are inherent risks in accepting next-of-kin donations. These include possibility of malicious behavior including elder abuse and financial motivation on the part of next-of-kin. The principle that body donation is an altruistic act representing a gift from the donor is predicated on the donor having the autonomy to determine that they wish to donate. Permitting another to make that decision for them overrides their autonomy and is disrespectful.

Suggestions:
The right of next-of-kin to donate their family member's body and/or to veto their family member's decision to donate be considered as part of the development of national body donor program operating standards and a national position adopted. Consent forms for donors should reflect this position, fully informing donors if their decision can be vetoed by family members (should that be the national position).

All body donor programs should adhere to the same criteria when accepting donors.

If the national position endorses the capacity of next-of-kin to donate post-humously, they must provide a statutory declaration attesting to their broader family's support for the donation (akin to the NZ practice) AND attesting that the deceased had not objected to donation during their lifetime.

Ethically, the preferred position would be for the deceased's election to have primacy. However, it is acknowledged that this position is not necessarily one which the Australian public will accept currently. Active consultation would be required to make this change, in respect of *both* body and organ donation.

4. The lack of national information and public reporting on body donation.

Where organ donation is publicly recognised as an altruistic act encouraged and promoted by government, body donation is neither publicised nor reported upon with the same sense of positive recognition (Cornwall, 2011). The society representing undertakers, Gathered Here (2017), provides information on its website about body donation, as do a number of other websites focused on health, palliative care, and legal matters for the elderly. However, potential donors are required to identify their own local program at a university rather than being readily able to access national information about body donation procedures and how they might register to donate from a central government source. This is in contrast to organ donation where DonateLife is a readily accessible national resource.

Body donation is not for all. Those who are willing to donate, and are supported by their families to do so, can gift tangible benefits to the students, staff, and community who directly and indirectly draw from their donation. It is anomalous therefore that there is no national collation of information about body donation, nor any reporting on the number of body donors. This information is routinely collected across every jurisdiction from each licensed facility, but the government departments responsible for implementing the anatomy legislation do not issue annual or even occasional reports. Although Victoria and South Australia gazette the granting of new anatomy licenses, other states/territories do not. In addition, no jurisdiction in Australia appears to hold a central and current database of anatomy license holders.[3] There is no national repository of information about the use of bodies for anatomical examination.

A lack of knowledge within the donor community about body donation processes (Boulware et al., 2004; Larner et al., 2015), and how the body is used when donated have been reported in multiple studies (Chung and Soleymani Lehmann, 2002; Cornwall et al., 2015b; Cornwall et al., 2018; Jones, 2017; Champney et al, 2018; Farsides and Smith, 2020). Donors do not always understand differences between research and education uses of the donated body, and that parts of the body may be

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[3] NSW Health advised in response to a formal Government Information (Public Access) (GIPA) request for a list of all current anatomy license holders in NSW that there were 35 such license holders in June 2022. However, that number includes multiple locations within one institution, and single use license holders.

retained for years or in perpetuity raising questions as to the integrity of the informed consent (Chung and Soleymani Lehmann, 2002; Winkelmann, 2016; Champney et al., 2018; Farsides and Smith, 2020). Students have also been reported to confuse body donation with organ donation (Cornwall et al., 2015b) believing that they are the same form of donation. Evidence suggests that many health professionals are not familiar with the processes associated with body donation nor competent to advise potential donors about the implications of body donation including how their bodies may be used (Chung and Soleymani Lehmann, 2002; Champney et al., 2018).

The lack of national reporting consolidates the sense that body donation is somehow not a subject that should be openly discussed. It lacks transparency and importantly removes the opportunity for the broader community to be educated about the importance of body donation, its value in education, training and research. Individual institutions hold thanksgiving or commemoration services for donors (Strkalj and Pather, 2017) but attendees at these services are already aware of donation and support it. National reporting would also enable universities to demonstrate their reliance on the altruistic gift of donation, and its benefits to the public.

Suggestion:
Annual national reporting of body donation, including the number of bodies donated, and their (general) use in education, training and research should occur.

A national resource similar to DonateLife should be established enabling the public to readily access information (including in non-English languages) about body donation and what it entails.

Summary

Australia is at the forefront of ethical practice in body donation, especially in relation to the longstanding requirement that all local donations are from consented donors (Habicht et al, 2018). It is important, however, that ongoing review of existing practices and standards occur with international evidence and standards implemented into the Australian regulatory framework.

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