Overall comment on discussion paper

The comments made here are directed mostly towards the issues associated with body donation and thus use of human bodies and body parts for education, training and research. It also responds to recommendations relating to the importation of bodies and body parts.

Australia is internationally regarded as having high standards of practice for the regulation and use of human bodies and body parts for education and training, and associated research Jenkin and Keay, 2025; Zdilla and Balta, 2023). The combination of legal regulation with an active jurisdictional licensing and inspection capacity ensures a robust practice of procurement, use and disposition of human tissue acquired from **local informed and consented donors**.

In the context of the focus of this submission, the proposals to create a National Regulatory Authority and National Standards for the collection, use and retention of human tissue are broadly supported. In relation to body donation, such a National Authority should primarily aim to develop and direct the implementation of standardised policy and practice for body donation, including development of national uniform consent forms and processes, retention timeframes and infection control practices. However, achieving uniformity in standards should not come at the cost of weakening existing regulation. Jurisdictional licensing has been extremely effective in ensuring ethical and legal practice; licensed anatomy facilities invest resources to ensure that their practices meet regulatory standards and expect to be held to account for their practices through annual inspection. The existing system has ensured that, in general, Australian facilities have avoided the occurrence of the unethical (and sometimes illegal) incidents that have been reported internationally (e.g. Harvard mortuary scandal involving Cedric Lodge). The existing system necessitates that each jurisdiction directs resources to anatomy licensing, inspection and compliance. A National Authority would be most effective if it set uniform policy and practice for body donation, and harmonised existing jurisdictional licensing and inspection systems. A National Authority could also create a platform for collaboration in addressing issues such as the need to increase local freezing facilities to reduce or remove reliance on imported bodies and body parts for post-graduate training and medical device testing/training. However, legislation and regulation under a National Authority must recognise in substance and practice differences between organ donation, body donation and other uses of human tissue.

The proposal to establish a national consent standard for human tissue donation is welcome. However, it is critical that a uniform consent standard for body donation enshrines as a minimum the requirements of the existing and accepted international gold standards for body donation and consent – the International Federation of Associations of Anatomists (IFAA) guidelines (IFAA, 2012) and the American Association for Anatomy (AAA) recommendations for best practice (Balta et al., 2025). To mandate requirements that are contradictory would diminish Australia's reputation and practice in body donation. It would be a retrograde step, with the potential to undermine public trust in the existing body donation programs.

***Question 43**:*
The suggestion for national reporting on human tissue donation and use is welcome. It is suggested that this be a mandatory rather than optional requirement. Particularly in relation to body donation, informing the public about the substantial community support it receives is long overdue. There is no logical or ethical basis for having transparent national reporting for organ donation but not body donation.

Question 42:
Such reporting should include the number of donors, information about their characteristics, and the beneficiaries of the donation (how donated bodies are used, and their contribution to education, research and professional skills development).

***Question 44**:*
Compliance with reporting requirements should be a component of annual inspections. Anatomy Inspectors currently review anatomy registers and the details recorded for each body received, its use, retention and ultimate disposition. They could also collect and compile these records on a jurisdictional basis for national reporting.

Consent and authorisation for body donation after death

> ***Proposal 38** New human tissue legislation should provide that an adult may give valid consent to donate their body after their death to a school of anatomy or other licensed facility for medical, educational or scientific purposes. The requirements for valid consent should mirror the requirements set out in **Proposal 23** regarding deceased donation of tissue.*

There are several problems with the second part of this proposal – that is, the requirements for valid consent. Implementing the valid consent requirements of ***Proposal 23*** equates body donation with removal of a tissue or organ. In addition, the ***Proposal 23*** requirements for valid consent to donation effectively permit next-of-kin consent to body donation. In both regards the proposal demonstrates a lack of understanding of the complexity and confronting nature of body donation and the existence of international ethical standards for consent to donation (e.g. IFAA, 2012), and the substantial differences between use of an organ and use of a donated body.

Body donation is not equivalent to tissue donation. Removal of tissue or an organ from the human body does not irrevocably disturb the intactness of the body to the same degree as occurs with body donation. Donated bodies are either embalmed or frozen to ensure that they may be retained and used for an extended period. Donated bodies are then dissected (progressively examined through removal of anatomical parts by layer/region/physiological function for educational purposes), prosected (divided into body parts which are retained and used for education), or otherwise used, for example, as road safety crash dummies, to test defence equipment and armaments, to demonstrate, evaluate and instruct in the use of medical devices, for cosmetic and other surgery and clinical intervention practice. The donated body is subject to invasive

and destructive procedures different in substance and quality from the simple removal of tissue or organs.

Body donation also entails medium-term (generally less than two years), long-term, or sometimes indefinite retention of the body. Although frozen bodies are preferentially used for surgical and post-graduate training and are retained for a shorter time (18-24 months), embalmed bodies are routinely retained for extended periods. Once no longer required, the body parts are reunited and generally disposed of via cremation after donation. Depending on the Australian jurisdiction, retention of donated bodies ranges from 2-5 years, or in perpetuity. If donors consent to indefinite retention, some body parts may be used as anatomical museum specimens or retained for a decade or longer and disposed of separately to the rest of the body. While families may elect to receive the cremated remains, this generally occurs years after the passing of their family member. In addition, they must relinquish the possibility of a funeral service and other usual burial rites because of the limited timeframe in which bodies must be received by anatomy facilities, and because the donated body cannot be reconstructed to permit viewing of the body. Body donation is thus a more confronting and difficult concept and one which requires considered and sensitive consent processes.

The requirements set out in ***Proposal 23*** do not accord with ethical best practice nor with the guidelines of the IFAA or the AAA, the professional organisations to which the Anatomy/Clinical Anatomy societies in Australia (and New Zealand) belong (IFAA, 2012; Balta et al., 2025). IFAA explicitly recommend against next-of-kin/executor post-mortem consent to donation (IFAA, 2012). In addition, international consensus is that permitting next-of-kin to either consent to body donation, or to override the decision of the deceased to donate, violates the deceased's ethical right to assert autonomy and control over their body after death (IFAA, 2012; Balta et al., 2025), notwithstanding that legally these rights cease on death. It is thus contradictory to ethical best practice. Adoption of the requirements set out in ***Proposal 23*** would therefore position Australia outside of ethical best practice in the anatomical sciences. This should not occur.

This proposal is also at odds with the practice of most body donor programs in Australia, which only accept registered donors, or donors who have willed or otherwise made explicit their consent to donate their bodies (Jenkin and Keay, 2025). As reported in this paper, there is no shortage of potential *informed* body donors in Australia. There is thus no necessity to provide an alternative pathway to donor consent. A related shortcoming of this proposal is that it would effectively legalise the dubious practices of body brokers, particularly those who operate in the United States, regarding the standard of consent required for tissue imported into Australia. Permitting next-of-kin consent to donation ignores the well-documented coercive practices of these operators (Grow and Shiffman, 2017; Champney et al., 2019), and the commercialisation of human tissue (Champney, 2016; Champney et al., 2019). It also opens the potential for next-of-kin to be swayed by incentives such as the avoidance of funeral costs (a not insubstantial burden) and the possibility of donation for nefarious purposes, or against the wishes of the donor.

Notwithstanding the position outlined above, if the proposed standards are implemented, several safeguards should be legislated. Firstly, the requirement that consideration should be given to the views and wishes of the deceased while alive, should be emphasised in practice by requiring the next-of-kin to provide a statutory declaration to support their assertion that the deceased did not object. The legal consequences of making inaccurate declarations should be emphasised. Secondly, there should be an explicit requirement that the authorised next-of-kin consult with other family members in deciding to consent to body donation. Implementation of the practice adopted in New Zealand (*New Zealand Human Tissue Act 2008*), requiring senior-next-of-kin to attest to consultation with, and agreement of, family/community to the donation, should be a core component if this proposal is adopted. Ideally, minimum standard practice should be to require registration of donors prior to death and the attestation of family support at the time of donation. Posthumous donation by next-of-kin should not be supported.

In response to ***Question 40:***
Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced? If so, should the mechanism be:
a. A prohibition of the importation into Australia of human tissue that was originally obtained without the consent of the donor, or in exchange for reward or profit? or
b. A reporting mechanism similar to that contained in the Modern Slavery Act 2018 (Cth)?

The new legislation should most definitely include a mechanism to ensure that imported tissue has been ethically sourced. Ideally, it should also clearly require that all options for procurement of human tissue, especially bodies and body parts, from local consented donors have been exhausted before importation is permitted. Currently, the existing practice in effect permits the importation of bodies and body parts with little to no review of the need for the tissue, the procurement practices, or the provider. It is well documented that the primary source of imported bodies and body parts in Australia, Science Care (based in the US), is a for-profit organisation (Grow and Shiffman, 2017 (Part 9); CBS News, 2023). Indeed, Science Care now states this clearly on its website (https://www.sciencecare.com/blog/science-care-a-for-profit-body-donation-program-facilitating-advancements-in-medical-science (Science Care was sold to private equity in 2016)). There is evidence that their procurement practices are predatory, focussed on vulnerable populations, with ambiguity in consent information about the potential use, distribution and disposition of donated bodies (Champney et al., 2019; Grow and Shiffman, 2017; Sherman, 2023). The new legislation should establish and enforce a regulatory system for importation that will prevent the importation of unethically procured tissue sourced from profit-making companies into Australia.

In relation to the preferred mechanism - ***Option (a)*** is clearly preferable.
This is because it would go a long way towards effectively prohibiting the importation into Australia of human tissue sourced from the major US for-profit companies (Science Care, MedCure, Biological Tissue Services and Biological Resource Centre) responsible for the distribution of human bodies and body parts internationally (Grow and Shiffman,

2017; CBS News, 2023; Sherman, 2023). However, ***Option (a)*** requires expansion to ensure it prohibits the current practice of contracting with a not-for-profit arm of a profit-making company to import tissue, thus circumventing the existing prohibition on commercial trade. As suggested in ***Proposal 44***, it should also provide guidelines on reasonable cost-reimbursement – again, it is well-established that US-based body-brokers game the system by charging "process and handling" fees which are not commensurate with the costs incurred (Champney et al., 2029; Grow and Shiffman, 2017; CBS News, 2023; Sherman, 2023), especially given that bodies are supposedly donated (as noted previously, serious concerns about the accuracy and completeness of information provided to donors and their families by these companies is well documented). Domestically, body donation programs transfer bodies on a cost-recover basis mutually agreed across anatomy facilities. There is currently no evidence of profiteering on such exchanges (Jenkin and Keay, 2025).

It would be preferable to expand the criteria to prohibit importation from any for-profit body-broker. There are reputable institutions, predominantly based in academic settings, which are viable alternatives. In addition, a licensing framework should be implemented – with requirements including production of evidence related to standards of informed consent obtained from donors; clear tracking of all bodies and body parts with the distribution of both made available to families if they wish to know and removal of license for infringement. The regulation of body donation and use of bodies in Australia mandates licensing and includes these kinds of practices. It is contradictory (and an ethical double-standard) to have a high level of regulation and audit for local donors and little/no regulation/audit to establish ethical practice if the "donor" is based outside Australia.

Option (b) is problematic in its application to entities currently importing human tissue. *The Modern Slavery Act* 2018 reporting applies to the Commonwealth Government and to entities with >$100 million in revenue. Not all Australian universities would meet this financial threshold and thus would be exempt from reporting. In addition, several smaller entities which currently import human tissue in the form of bodies or body parts are registered as charities and/or also would not meet the threshold for reporting. These requirements therefore create an avenue for continued importation of tissue procured from for-profit body brokers in the US and elsewhere. ***Option (b)*** also enables the establishment of entities which avoid compliance through artificial structures limiting their revenue and/or structurally separating them from an institution that would otherwise be required to comply with the Act. In addition, the suggestion in ***Proposal 39*** that donated bodies may be used for research in unlicensed facilities, potentially creates another mechanism by which organisations can avoid the scrutiny currently imposed via anatomy licensing requirements and other reporting.

and in response to ***Question 41***:

If a prohibition is legislated of the kind described in Question 40(a), or reporting requirements introduced of the kind described in Question 40(b), should new human tissue legislation include a mechanism to exempt importations of human tissue from the prohibition or reporting requirements, and if so, what factors should be considered

as a basis for justifying an exemption? For example, relevant factors could include but not be limited to:

- *the health needs of Australians;*
- *if it is possible to meet the health needs of Australians through domestic supply of the relevant tissue; and*
- *the risk that the people from whom the tissue was originally obtained were coerced or exploited.*

This question appears to be suggesting that a utilitarian approach to exemptions should be considered. This is highly problematic from an ethical perspective, particularly in the context of importation of human tissue. The salutary and well-documented example of the sub-continental bone trade (Agarwal, 2025; Jones, 2023) should be considered an ethical reference point here. As the question is phrased, it appears to suggest that a higher value be afforded to consideration of the potential benefit to the health and wellbeing of Australians than to non-Australians when considering whether to permit the importation of human tissue potentially sourced unethically. This is an unacceptable principle. No exemption to the prohibition suggested in ***Question 40*** should be possible where to do so would violate an individual's human rights or dignity. The potential for enduring harm to the deceased's family or community should also be considered (cf. Henrietta Lacks case; Skloot, 2010). It is suggested that if any such exemption is accepted, it should be narrowly limited to therapeutic purposes, not available for education, training and research purposes. It is also suggested that such exemptions be considered on a case-by-case basis by an expert committee whose representatives should include clinicians, ethicists, ministers of religion, patients, and members of the public.

It is recognised that there is a shortage of donated organs, and that some human tissue preparations are not readily available in Australia. However, creating a legislative loophole for importation of human tissue, especially bodies and body parts, where the procurement of such tissue has not met the bare ethical standards (informed consent and prohibition on commercial reward) is an unacceptable option.

Legacy and contemporary collections of human tissue.

Question 32

Would it be beneficial to have national regulation, guidance and oversight for:
a. research biobanks that store and/or distribute human tissue or human bodies; or
b. educational collections of human tissue?

Yes, especially in relation to legacy collections and in relation to the retention of human tissue from medical or surgical procedures, post-mortem and anatomical examination. The American Association for Anatomy has published comprehensive guidelines for legacy collections (Cornwall et al., 2024a). These should constitute the minimum standards for management of legacy collections. In relation to contemporary collections, a critical issue is the digital reproduction, dissemination and commercialisation of images of specimens including in 3D form (Jones, 2018) and as online anatomy atlases or image repositories(Cornwall et al., 2024b). The majority of Australian body donor consent forms do not explicitly inform donors of this possibility nor give them the option to refuse consent to the taking of such images, nor of other potentials uses such as 3D imaging, genomics research and similar activities (Jenkin and Keay, 2025). Such uses may generate products or results which are identifiable, and their dissemination is largely uncontrolled. Any use of donated tissue which involves a secondary use, or which involves potential harm through identification of commercial exploitation should be detailed in consent forms and donors given the option to refuse consent. The definition of educational collections should include digital reproductions. The guidelines for digital use should be based on the IFAA standard published in 2024 and include specific consent requirements for the taking of digital images and their dissemination and sale (Cornwall et al., 2024b).

Other matters:
Voluntary Assisted Death
Any national authority and/or national guidelines should consider the issue of consent for a deceased person who has engaged in a voluntary assisted death.

Proposal 15 - Definition of a child

It is noted that the proposal to define a child as aged under 18 is inconsistent with existing legal precedents regarding health-related decision-making capacity (Gillick's principle and Marion's Case). Children aged 15 and older are entitled to have their own Medicare Card, and in some jurisdictions can obtain a probationary driver's license aged 17. In addition, young people can register as organ donors from age 16. The definition of a child should recognise and uphold the capacity of young people to make their own decisions and to understand the consequences of those decisions.

The requirement in ***Proposal 17*** that a child (someone aged less than 18 as defined in ***Proposal 15****)* or their parents/authorised person should have to make an application for removal of tissue for transplantation (and medical, educational and scientific purposes) seems unduly onerous and unreasonable. It does not recognise the autonomy of young people, nor their capacity to make an informed decision. Likewise, young people who are terminally ill can make informed health decisions including about donation of their tissue or organs. The process for consent should recognise their autonomy and the role of parents/carers in fulfilling their wishes and values. Existing organ retrieval and transplantation services in Australia and New Zealand constitute highly trained health professionals who are sensitive to the circumstances in which transplantation may be considered and the need to support and inform families. In most circumstances,

Committee decision would be undesirable and add to the distress and stress of the circumstances.

References:

Agarwal SC. The disposability and inclusion of Brown bodies. Am J Biol Anthropol. 2025. Jan;186(1):e25003. doi: 10.1002/ajpa.25003. Epub 2024 Jul 21. PMID: 39034490; PMCID: PMC11775433.

Balta JY, Champney TH, Ferrigno C, Johnson LE, Ross CF, Schmitt B. and Smith HF. 2025. Human body donation programs best practices and recommended standards: A task force report from the American Association for Anatomy. Anat Sci Educ, 18: 8-26. https://doi.org/10.1002/ase.2520

CBS Reports. 2023. Body Brokers. https://www.cbsnews.com/video/body-brokers-cbs-reports/

Champney TH. 2016. The business of bodies: Ethical perspectives on for-profit body donation companies. Clin. Anat., 29: 25-29. https://doi.org/10.1002/ca.22643

Champney TH, Hildebrandt S, Jones GD, & Winkelmann A. 2019. Bodies R us: Ethical views on the commercialization of the dead in medical education and research. Anatomical Sciences Education, 12(3), 317–325.

Cornwall J, Champney TH, de la Cova C, Hall D. Hildebrandt S, Mussell JC, Winkelmann A, & DeLeon VB. 2024a. American Association for Anatomy recommendations for the management of legacy anatomical collections. The Anatomical Record, 307(8), 2787–2815. https://doi.org/10.1002/ar.25410

Cornwall J, Hildebrandt S, Champney TH, Billings B, Schmitt B. and Winkelmann A. 2024b. IFAA recommendations for the ethical use of anatomical images. Anat Sci Educ, 17: 7-10. https://doi.org/10.1002/ase.2349

Grow B & Shiffman J. 2017. Cashing in on the Donated Dead. The body trade. Reuters Investigation. Parts 1-9. https://www.reuters.com/investigates/special-report/usa-bodies-brokers/

IFAA. 2012. International Federation of Associations of anatomists. Federative International Committee for Ethics and Medical Humanities (FICEM). Recommendations of good practice for the donation and study of human bodies and tissues for anatomical examination. Plexus, 2012, 4–5.

Jenkin RA, Keay KA. 2025. Body donor programs in Australia and New Zealand: Current status and future opportunities, Anatomical Sciences Education, 10.1002/ase.70004, 18, 3, 301-328.

Jones DG. 2018. Three-dimensional printing in anatomy education: assessing potential ethical dimensions. Anat Sci Educ. 12(4): 435–443.

Jones DG. 2023. Anatomists' uses of human skeletons: Ethical issues associated with the India bone trade and anonymized archival collections. Anat Sci Educ.16: 610–617. https://doi.org/10.1002/ase.2280

Kleeman J. 2024. The price of life. PanMacMillan: Australia.

Mintz L. 2025. The trade in US body parts that's completely legal - but ripe for exploitation. BBC News. https://www.bbc.com/news/articles/ce83r56xwj7o

Sherman J. 2023. Inside the largely unregulated market for bodies donated to science: "It's harder to sell hot dogs on a cart". CBS News. https://www.cbsnews.com/news/bodies-donated-to-science-largely-unregulated-cbs-reports/

Skloot, R. 2010. The Immortal Life of Henrietta Lacks. Crown/Random House: New York

Zdilla MJ, Balta JY. 2023. Human body donation and surgical training: a narrative review with global perspectives. Anat Sci Int 98, 1–11. https://doi.org/10.1007/s12565-022-00689-0