Submission in response to the Australian Law Reform Commission's Review of Human Tissue Laws 2025 *Discussion Paper*

St Vincent's Health Australia, February 13th, 2026

Contact: Dr Dan Fleming, National Director of Ethics [redacted]

About St Vincent’s

St Vincent's has been a leader in Australia's health and aged care landscape for more than 165 years. Since our founders, the Sisters of Charity, opened our first hospital in 1857, our services and people have been behind some of Australia's most important medical breakthroughs.

The Sisters also gave us a mission: to provide care to the most disadvantaged members of our community. Their courage and compassion has been a hallmark of St Vincent’s since we began and is central to some of our proudest achievements.

St Vincent’s today is Australia’s largest not-for-profit provider of health and aged care services. With public and private hospitals, residential aged care, community and virtual care, and outreach programs for marginalised people, we are a microcosm of Australia’s health and aged care system and are uniquely positioned to lead and respond to our rapidly changing environment.

St Vincent’s is a recognised leader in organ and tissue donation and transplantation. We support a safe, transparent and ethical organ and tissue donation system.

Executive Summary

St Vincent’s is grateful for the opportunity to make a submission to the Australian Law Reform Commission’s Review of Human Tissue Laws in response to its 2025 *Discussion Paper*.

We are supportive of the efforts of the ALRC to address the current inconsistencies and gaps in the various Human Tissue Acts around Australia. We agree that greater coordination and clarity are needed to reduce uncertainty for practitioners and researchers, remove unnecessary administrative burdens, and strengthen oversight of tissue banking and biobanking. We welcome initiatives aimed at creating a more consistent and transparent regulatory framework. And we welcome all efforts to increase the availability of organs for donation through encouraging the generosity of potential donors. Such efforts much be combined with an unwavering commitment to the dead donor rule to ensure that the good end of organ transplantation is never pursued at the expense of commitments to the dying person.

That said, we are critical of several aspects of the *Discussion Paper*. In particular, we are concerned about its proposals to change the definition of death and its consideration of normothermic regional perfusion, and the way in which ‘accepted medical practice’ is used throughout the document. In addition to ethical concerns with each of these matters, we note their intrinsic relationship with the public trust required to ensure a well-functioning and ethically rigorous organ and tissue donation system in Australia.

We are also concerned that the ALRC has chosen not to consider regulation of anatomy schools as part of the Discussion Paper. We suggest that this ought to be re-included, as per the Terms of Reference.

Nothing our general support for the ALRC's efforts and the contents of the Discussion Paper, our submission is organised as follows:

Part 1 focuses on the place of trust in organ and tissue donation

Part 2 focuses on the definition of death.

Part 3 focuses on Normothermic Regional Perfusion

Part 4 focuses on the use of "accepted medical practice" in the Discussion Paper

Part 5 focuses on the regulation of anatomy schools

Part 6 focuses on other general matters

We once again thank the ALRC for leading this important work, and express our gratitude for the opportunity to contribute.

Part 1 – Trust in the organ and tissue donation system

We note that trust is foundational in Australia's organ and tissue donation system. National guidance in Australia, including the NHMRC's *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia*, recognise that earning trust is critical in meeting community expectations and supporting the community's willingness to engage with donation.[1] Similarly, the national Organ and Tissue Authority's current strategy emphasises the advancement of quality, safety and efficiency across the system in order to bolster "community trust that the organ donation and transplantation system is as safe and effective as possible."[2] At an international level, trust is also recognised as a central to a successful organ and tissue donation program.[3]

We note and welcome the central place that trust has in the *ALRC* Discussion Paper:

> People will not participate in Australia's organ and tissue donation and transplantation system, or support the use of human tissue for other medical, educational or scientific purposes, if they do not trust that the system and use of human tissue for other purposes are safe and ethical.[4]

Such trust is strengthened where the legal and policy settings demonstrate transparent decision-making, robust ethical standards, clear and consistent consent processes, and robust protections for privacy and confidentiality. In this setting, we welcome the efforts of the *ALRC*'s Discussion Paper to improve trust, particularly through its proposals to create

---

[1] NHMRC, Ethical guidelines for cell, tissue and organ donation and transplantation in Australia, p 1.
[2] Donate Life, Organ and Tissue Authority Strategy 2022-2027, page 8
[3] The Lancet, *Organ Donation Depends on Trust* (2016) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30886-8/fulltext
[4] Discussion Paper, no. 2.23

nationally consistent and publicly reviewable standards across the Human Tissue Acts, clarifying the legal test for determining death and locating it in a uniform statutory framework, simplifying and standardising consent pathways, and addressing privacy, information-sharing and oversight gaps in tissue banking and biobanking. That said, in what follows we suggest that several of the *Discussion Paper's* recommendations could function to erode this necessary trust, precisely because the reasoning behind them is opaque or inconsistent with widely held views. This is especially important in the most nuanced and sensitive areas the *Discussion Paper* contends with, especially those concerned with determining death and organ donation. In these areas it is imperative that the steadfast commitment to care for the dying patient remain a priority for law and practice, with the generous and potentially life-giving possibilities of organ donation never used to create compromises in this care.

Part 2 – The definition of death and the dead donor rule

The way in which we define death is significant and has wide-ranging implications. The *Discussion Paper* reflects this: "the time of death in accordance with the legal determination has implications for estate law, criminal law, and medical law."[5] More comprehensively, Sulmasy et. al. note:

> So much hangs on the declaration of death that it is important to be as certain and uniform as possible. Legal rights, burial, insurance matters, inheritance, marriage, organ transplantation, and more depend on the declaration of death.[6]

Given this, we note that the ALRC *Discussion Paper*'s focus on the definition of death narrows the discussion to its importance for organ and tissue donation. While an area of significance, we suggest that future work attend with due seriousness to the more expansive social implications of the definition of death.

In relation to organ donation specifically, St Vincent's supports the generous act of organ donation after a person has died when appropriate consent is provided by that person's designated decision-makers.

The preservation of the dead donor rule is essential to maintaining the ethical integrity of organ donation. It ensures that organ procurement only occurs after a person has died. This principle establishes a clear ethical parameter that the determination of death must never be influenced by, or subordinated to, the prospect of organ retrieval. Efforts to increase the availability of organs for donation ought to be focused on encouraging the generosity of potential donors, and not on relativising the dead donor rule.

We therefore accept the ALRC *Discussion Paper's* Proposal 13 that "new human tissue legislation should include provisions that provide safeguards to ensure deceased donation only proceeds after it has been determined that a person has died."

---

[5] Discussion Paper, no. 5.6.
[6] Daniel P. Sulmasy, Christopher A. DeCock, Carlo S. Tornatore, Allen H. Roberts, James Giordano, G. Kevin Donovan, A Biophilosophical Approach to the Determination of Brain Death, CHEST, Volume 165, Issue 4, 2024

The ‘dead donor’ rule is inherently connected with the definition of death. We have concerns about the ALRC’s Proposal 10, and we submit two matters in this regard.

Clearer distinctions between (a) the definition of death, (b) the standards for determining death, (c) the criteria for meeting each standard and (d) the tests for establishing that specific criteria have been met.

The ALRC Discussion Paper repeatedly collapses foundational distinctions that are essential for conceptual precision and public trust in relation to the definition of death. This collapsing binds together:

- Definition (what death *is*)
- Standards for determining death (the broad pathways by which death is determined)
- Criteria (the physiological conditions required for determination)
- Tests (the clinical testing used to establish that the criteria have been met)

For example, the *Discussion Paper* proposes that death be determined when there is a “permanent cessation of critical brain functions”, and then ties this definition to determinations being made “in accordance with accepted medical practice.” These are distinct areas which are presented as a single concept. This framing merges the legal requirements for determining death with procedural guidance. Such conflations introduce the risk that the legal standards for determining death will shift with changes in clinical practice rather than through transparent public deliberation. We note and accept the stated rationale for this in the *Discussion Paper* is that law reform should “seek consistency with clinical guidelines and practice that are based on the best available evidence and have the interests and dignity of the dying person at their core,”[7] but find that conceptual confusion in the paper – and the reliance on the heuristic of “accepted medical practice”, undermines this more robust goal for law reform.

To provide clarity, we suggest the paper reflect a more accurate distinction between these four domains.

By way of **definition**, death occurs when a person has ceased to exist as “an integrated and coordinated organism.”[8]

Australian law recognises two sufficient **standards for determining** when death has occurred: (a) irreversible cessation of circulation of blood in the body, and (b) irreversible cessation of all functions of the brain.

Each mode of determination has its own **criteria** for determining death. The cardiopulmonary requires the permanent cessation of circulation and respiration. The

---

[7] Discussion Paper, no. 5.23.
[8] Catholic Health Australia, *Code of Ethical Standards (2001)*, Part II, no 5.22

neurological requires the permanent cessation of the functions of the entire brain. Criteria for determining the standards is developed in line with best medical practice and guidance from professional bodies.

Clinical **tests** are used to establish that these criteria have been met. For the cardiopulmonary pathway, the absence of breath and pulse for five minutes. For the neurological pathway, no confounding cause; coma; absent brain stem reflexes; and failure of apnea test. Specific imaging can also be used where other clinical tests are not possible, or where doubt exists. Testing methods and precision evolve based on advancements in clinical science.

St Vincent's supports an approach to brain death which maintains a) the current definition of death and b) the two modes of determination for death.

We also support the current criteria for determining death and testing used to establish these criteria have been met. We note that our understanding of the brain is consistently developing, and support all efforts to improve our understanding of criteria for brain death and ongoing efforts to refine and strengthen the clinical processes used to confirm that the criteria for neurological determination of death have been met. We recognise that such improvements allow for advances in clinical knowledge and practice, enhance certainty, and increase public confidence without altering the underlying whole-brain standard.

We do not accept the ALRC's proposed determination of death as the permanent cessation of "critical brain functions". This approach narrows the neurological standard in ways that undermine conceptual clarity, effectively replacing a unified whole-brain framework with a more subjective higher-brain model. A functional whole-brain standard remains the most coherent and ethically robust basis for determining death.

We also note that the introduction of *consciousness* as a criterion for death (Proposal 10, section X 2) introduces a category confusion. Consciousness is an ontological category that is not fully understood. Clinical tools can only infer (not directly measure) its presence or absence. In view of this, tying the legal definition of death to the "complete absence of any form of consciousness" as in Proposal 10 risks confusing (a) the limits of practical tests with (b) the underlying ontological reality. Any proposed criteria should be tied to clinically attainable measurements rather than to states that cannot be directly assessed.

Part 3 – Normothermic regional perfusion

We note that the Discussion Paper includes an extensive analysis of Normothermic Regional Perfusion (NRP) in sections 5.42-5.50, which includes consideration of both the potential benefit of the practice and the significant ethical and legal contention attached to it. Given this significance, we were disappointed at the way in which the Discussion Paper's proposal 10 functions to "open the door for the practice of NRP"[9] while leaving the substantive ethical and legal issues to the later development of protocols.

[9] Discussion Paper, no 5.66.

NRP raises important questions precisely because it is unclear how the intervention intersects with the standards for determining death. At issue, as the Discussion Paper notes, are "questions about whether NRP invalidates legal requirements for death, whether a donor is 'resuscitated' when NRP restores circulation or heart function (in TA-NRP), and whether NRP causes death by ensuring the lost brain function remains permanent."[10]

These concerns are not limited to Australia. For example, the American College of Physicians has argued that NRP "raises profound ethical questions regarding the dead donor rule, fundamental ethical obligations of respect, beneficence, and justice, and the categorical imperative to never use one individual merely as a means to serve the ends of another, no matter how noble or good those ends may be." They further note that "the questions and concerns raised here have not been adequately considered to date" and that "the burden of proof regarding the ethical and legal propriety of this practice has not been met".[11]

As outlined in Part 2, the preservation of the dead donor rule is essential to maintaining the ethical integrity of organ donation. It ensures that organ procurement only occurs after a person has died. This principle establishes a clear ethical parameter that the determination of death must never be influenced by, or subordinated to, the prospect of organ retrieval. Efforts to increase the availability of organs for donation ought to be focused on encouraging the generosity of potential donors, and not on relativising the dead donor rule.

In view of this, we suggest that the *Discussion Paper's* proposal to "open to door for the practice of NRP" without entering into the substantive legal and ethical issues that NRP raises is an error. We submit that the work of considering the legal, ethical and safety issues of NRP includes considering the practice in relation to the law which happens "in conjunction with, and informed by, public engagement to make sure that the use of NRP has public support, and does not compromise public trust, or heart or long donation rates." This requires more than the development of ethically robust protocols by professional bodies. It also requires a considered effort to determine whether specific forms of NRP are consistent with the standards for determining death and therefore the dead donor rule.

Part 4 – "Accepted medical practice"

The discussion paper uses the phrase *"accepted medical practice"* as a benchmark for determining death and guiding post-mortem interventions (see Proposals 10 and 12, and related explanatory text). In Proposal 10 in particular, the Discussion Paper notes that "regulations may identify professional standards or guidelines for the purpose of determining accepted medical practices." We appreciate that this approach provides flexibility by embedding the norms of clinical practice and that it reflects the fact the clinical practice is

[10] Discussion Paper, no. 5.49.
[11] American College of Physicians, *Ethics, Determination of Death, and Organ Transplantation in Normothermic Regional Perfusion (NRP) with Controlled Donation after Circulatory Determination of Death (cDCD): American College of Physicians Statement of Concern* (2021) https://www.acponline.org/sites/default/files/documents/clinical_information/resources/end_of_life_care/ethics_determination_of_death_and_organ_transplantation_in_nrp_2021.pdf

continuing to evolve and improve. That said, using “accepted medical practice” as a benchmark in this way also raises concerns about robustness and transparency.

Unlike standards developed through formal public processes, “accepted medical practice evolves within the practice of medicine without the same level of public scrutiny, stakeholder engagement, or ethical debate that accompanies formal law reform. This means that significant shifts in what would otherwise be legal norms could occur without democratic oversight, potentially altering the threshold for determining death or the permissibility of interventions in ways that impact public trust.

For example:

- **Proposal 10** requires determinations of death to be made “according to accepted medical practice.” This delegates critical decisions about the legal status of death to clinical norms that may change over time without public input.

- **Proposal 12** similarly mandates that post-mortem interventions be conducted “in accordance with accepted medical practice,” again relying on professional standards rather than codified safeguards.

A more robust approach would combine reference to accepted medical practice with mechanisms for public accountability, such as requiring that designated guidelines be subject to consultation and periodically reviewed through transparent processes.

Part 5 – Regulation of anatomy schools

We note that, although the regulation of schools of anatomy was expressly included in the Terms of Reference for this inquiry, the Discussion Paper indicates that the ALRC does not intend to develop proposals on this topic at this stage. We express our disappointment at this decision. When families choose to donate the bodies of their loved ones to science, they make an act of profound generosity that supports the advancement of medical knowledge and clinical skill. It is essential that a nationally consistent and transparent regulatory framework exists to assure donors and their families that anatomical gifts will always be treated with dignity and reverence, and used solely for the purposes for which they were given.

Documented cases in Australia show that donated bodies and body parts have been used inappropriately in schools of anatomy, undermining public confidence in the donation of bodies for science.[12] Such abuses are well-known across anatomy schools in Australia. Given that the Terms of Reference originally included regulation of anatomy schools, and that the opportunity to work towards a nationally consistent framework presents itself, we urge the ALRC to reconsider this omission in its final report.

---

[12] Christopher Zinn, Sydney medical dean apologises to relatives for misuse of body parts *BMJ* 2007; 334, https://www.bmj.com/content/334/7589/335.3

Part 6 – General matters

We conclude by noting a number of general matters raised by the Discussion Paper. First, in relation to the proposed objects of human tissue laws, we recommend strengthening the articulation of the ethical commitments that guide this legislative framework. Proposal 5, Part E currently refers to ensuring "respect for individual dignity and autonomy, and for the human body." We suggest that this be expanded to include an explicit reference to respect for human life, which is foundational to public trust in all aspects of human tissue regulation. Likewise, Proposal 5, Part F presently focuses on preventing exploitation in the removal and use of human tissue; we recommend making explicit the particular need to protect vulnerable persons from exploitation, drawing on parallels in consumer-protection and other regulatory regimes that recognise heightened risks for those with limited literacy, disability, language barriers, or other forms of social vulnerability. This would strengthen the normative clarity of the legislation and better reflect the ethical complexity of the contexts in which tissue donation and use occur.

Second, regarding the definition of "human tissue" (Proposal 9, Question 7), we recommend that embryos and foetal tissue be expressly excluded from this definition. The ethical and legal considerations associated with embryos and foetal tissue are substantially different from those applying to organs, blood, or other bodily substances, and typically engage distinct regulatory frameworks, moral concerns, and community expectations. A clear exclusion would avoid conflating ethically heterogeneous categories and would prevent unintended regulatory consequences.

Conclusion

Once again, we thank the ALRC for the opportunity to respond to the 2025 *Discussion Paper*. We welcome any opportunity for further discussion with the ALRC, and any questions about our submission. Contact details for Dr Dan Fleming, National Director of Ethics for St Vincent's, are included on the first page of this submission and can be used for any further communications.