Submission to the Australian Law Reform Commission

Review of Human Tissue Laws – Discussion Paper 90 (2025)

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Introduction:

Our overarching position is that the legislative framework should **expand access to deceased donation and research** while preserving public trust, avoiding unnecessary regulatory duplication, and actively supporting innovation in organ preservation and utilisation.

National Regulator (Proposal 3):

With regards to the proposal for a National Regulator, we do not find that this will bring any added benefit; instead we propose the alternative option of either 1.18 where a ministerial council be formed to support legislative amendments or 1.19 We feel a national regulatory body risks overlap of function at added cost and manpower with an added layer of unnecessary bureaucracy.

Should a national regulator be the optimal and eventual choice, the act of establishing a national regulator should not precede the need to enact any legislative changes agreed upon a that end of this commission, so as not to delay changes that could have an immediate clinical impact on patients/recipients. Rather, establishing the regulating body should be worked in parallel.

Intergovernmental Agreement (Proposal 11):

We strongly agree with the proposal that Commonwealth, state and territory legislation contain a consistent legal standard for determining death ie intergovernmental agreement.

We also propose that once legislation change is agreed, it is changed across commonwealth, state and territory simultaneously, and not in sequence, to avoid unnecessary time and cost waste.

Determination of death and DCDD/NRP:

(Proposals 10–13, 11–12):

1. Support is expressed for Proposal 10's **unified brain-based standard**, defining death as permanent cessation of critical brain functions (consciousness and brainstem functions, including independent breathing). This aligns with ANZICS, NHMRC and international consensus guidelines and provides a clear conceptual basis for both neurological and circulatory death pathways.
2. The explicit articulation of "permanent" in terms of the impossibility of auto-resuscitation is suitable. It avoids the impracticality of "irreversible cessation of circulation" in an era where circulation can be restored mechanically long after meaningful brain function is lost.
3. The unified brain-based standard is particularly valuable because it **removes the conceptual barrier** to NRP: blood circulation can be restored below the diaphragm (or to thoracoabdominal organs) post-mortem without negating death, provided that critical brain function cannot and will not be restored (via vascular exclusion practices during the organ retrieval process). This is consistent with international ethics and practice.
4. The proposal that death be determined in accordance with "accepted medical practice" and that regulations may designate clinical standards is welcomed, but with the following caveats:
    - Designations should be **principles-based** and not overly prescriptive regarding technologies or specific tests, to allow evolving evidence and innovation.
    - The process for updating designated guidelines must be **timely and clinician-driven**, to avoid legal stasis when clinical practice advances.
5. The safeguards around independent determination of death (two senior doctors, separation from retrieval/recipient care) are appropriate to maintain the dead donor rule and public trust. **However, the requirement that one doctor be a specialist with ≥5 years' registration is not required to determine loss of circulation (circulatory death) – a standard straightforward assessment currently performed by non-specialist doctors - to avoid delaying DCDD pathways without safety benefit.**

Our Recommendations:

- **Endorse Proposal 10 with minor drafting changes that make explicit that NRP and other post-mortem perfusion technologies are compatible with the dead donor rule where brain reperfusion is prevented.**
- **Ensure regulations designating "accepted medical practice" reference ANZICS and OTA guidelines but allow for local protocol development and innovation within defined safety principles, rather than freezing a single national protocol in legislation.**

Normothermic regional perfusion and other perfusion technologies:

1. NRP is rightly recognised as a **transformative technology** that improves organ quality, utilisation, and recipient outcomes, particularly for abdominal organs and complex recipients such as children and diabetics requiring combined kidney-pancreas transplantation
2. International experience and emerging evidence, including physiologic and imaging studies showing no reperfusion of the brain during NRP when appropriate vascular exclusion is performed, demonstrate that NRP can be conducted while fully respecting the dead donor rule.
3. The current legal position in Australia, which prevents NRP primarily because of the "irreversible circulation" wording in HTAs, is out of step with comparable nations and directly limits the ability of Australian patients to benefit from improved organ quality and expanded donor pools.
4. The proposal that post-mortem interventions be conducted in accordance with accepted medical practice (Proposal 12) is a suitable vehicle for regulating NRP. However, there is a significant risk that if NRP protocols are not:
    - rapidly developed in collaboration with clinical stakeholders, and
    - designated explicitly as compliant with accepted practice,

    then NRP may remain effectively unavailable despite the conceptual legal change.

5. Ex vivo machine perfusion is already integral to many transplant programs and should be expressly recognised as a **standard part of post-mortem organ preservation**, with regulatory requirements focused on device and solution safety (via the TGA) rather than duplicative HTA-level controls.

Our: Recommendations

- **Explicitly acknowledge, in explanatory material and the legislative notes, that NRP is compatible with the unified brain-based determination of death, provided brain reperfusion is prevented and that appropriate vascular occlusion strategies are used.**
- **TSANZ and relevant advisory committees, model NRP protocols (for A-NRP and TA-NRP) to be designated as "accepted medical practice", with a clear mechanism for local adaptation and future updates.**
- **Clarify that ex vivo perfusion technologies fall under "post-mortem interventions" but require no additional consent beyond donation consent, and that their regulation should largely be through individual state based Transplant Units - rather than additional HTA-based licensing.**

Deceased donation, pre-mortem interventions and voluntary assisted dying:

1. The move to a modern, harmonised consent/authorisation framework for deceased donation, including a unified substitute decision-maker hierarchy and the capacity to appoint decision-makers via advance directives, is strongly supported. This improves clarity at the bedside and aligns donation decision-making with broader medical decision-making frameworks.
2. The new informed-consent standard for donation is ethically appropriate, but guidance will be crucial to avoid **over-legalistic conversations** that overwhelm families and unintentionally deter donation. Information about the commercial aspects of some tissue uses should be framed carefully so that it enhances understanding without generating unwarranted suspicion.
3. The proposals regarding **pre-mortem interventions** must strike a careful balance and must not result in harm to potential organ recipients – either through inadequate donor screening being performed (missing an incidental donor cancer because a CT-imaging was not performed) and also from utilising suboptimal quality organs because basic medications (eg. Pre-mortem IV Heparin administration prior to withdrawal of life-sustaining treatment during deceased donor retrievals) was not administered. While consent and legal authority are in general necessary, implied consent (if someone consents to undergo organ donation – implied consent to allow pre-mortem interventions (in order for the donation to be successful) must be allowed. Excessive procedural requirements (e.g. repeated separate consent events, complex forms) risk undermining DCDD and limiting organ quality by discouraging pre-mortem optimisation.
4. For voluntary assisted dying patients and other competent donors, the Paper is right to emphasise separation of the decision to die from the decision to donate, yet the law should affirm that such patients are **eligible and encouraged** to donate if clinically suitable and willing. WA already has VAD policy recognising this; national consistency will aid trust and coordination.

Our Recommendations:

- **Implement a single, integrated consent pathway for deceased donation that includes pre-mortem interventions in the same process, rather than requiring distinct consent encounters, provided the nature and risks of interventions are explained.**
- **Must ensure that pre-mortem interventions that optimise organ quality and safety for donation are not restricted, accepting implied consent is suitable.**
- **Include clear guidance that voluntary assisted dying does not disqualify patients from donation and that donation should be facilitated wherever consistent with voluntariness and clinical suitability.**

Research donation, deceased bodies and stored tissue collections:

1. Bringing research donation and stored tissue collections into a clearer legal framework is welcome. However, the regulatory design must recognise a

spectrum from small, single-centre collections to large, multi-site research biobanks and avoid applying **industrial-scale licensing requirements** to low-risk activities.

2. Donation for research should be widely enabled, including:
    - donation of organs/tissue not suitable for clinical transplantation,
    - donation of surplus organs after clinical allocation has been fulfilled, and
    - donation of whole bodies for research and advanced surgical training, particularly in transplantation and perfusion technologies.
3. Schools of anatomy and whole-body donation programs provide essential educational and research value; their treatment in the Paper is relatively limited. Any new requirements must be **proportionate** and must not inadvertently reduce access to bodies for teaching and research.
4. Tissue bank licensing (therapeutic and research) must be coordinated with existing TGA and NBA roles. Overlapping licensing and reporting systems would consume limited resources and may reduce the capacity of tissue banks to support both clinical and research uses.

Our Recommendations:

- **Explicitly provide that authorised decision-makers may consent to donation for research where clinical use is not possible or has been exhausted, subject to NHMRC ethics frameworks, with a presumption in favour of enabling such use consistent with donor wishes.**
- **Treat schools of anatomy and body donation programs as priority partners in developing proportionate standards; avoid imposing requirements that would significantly restrict anatomical and surgical training, including transplantation-related simulation.**

Implications for Paediatric deceased donation and paediatric transplantation

1. Paediatric transplantation faces unique challenges that the Paper touches only indirectly: smaller donor pools, size-matching constraints, and the particular vulnerability and high mortality risk of paediatric patients awaiting organs. The legislative framework should therefore explicitly recognise **paediatric deceased donation and transplantation** as priority areas for improving access and outcomes.

2. The proposed unified determination of death (Proposal 10), coupled with explicit facilitation of DCDD and the opening for NRP, has significant potential to **increase availability and quality of organs** for paediatric recipients. NRP and ex vivo perfusion are especially relevant to small or marginal organs, where optimised preservation can be decisive for transplantability in children.

3. In paediatric settings, parental or guardian decision-making is central. Proposals 23, 25, 36 and 37 properly allow authorised decision-makers to consent to both clinical and research use of tissue from dying or deceased children, guided by the child's known beliefs and preferences where they can be ascertained. To promote paediatric donation while respecting autonomy, the Final Report should:

    - emphasise that parents/guardians may, and should, be invited to consider deceased donation (including for research) as a **positive option** for their child, with specialist psychosocial support; and
    - encourage national donation-conversation protocols that are tailored to paediatric contexts, avoiding excessive legal complexity at the bedside.

4. To maximise paediatric transplant access, it is recommended that the ALRC:

    - **Explicitly recognise paediatric transplantation** and paediatric deceased donation as areas where increased donation and improved organ utilisation are key legislative objectives, for example in explanatory material under the objects clause (Proposal 5).
    - Develop **paediatric-specific guidance** on:
        - death determination and DCDD pathways in children (aligned with ANZICS paediatric guidance),
        - the ethical use of NRP and ex vivo perfusion in paediatric donors, and
        - best-practice communication with families, including culturally safe approaches for First Nations children and communities.
    - Ensure that paediatric tissues and organs not suitable for clinical transplantation can be readily donated for **research use** with appropriate

consent, without requiring complex or multiple authorisation steps beyond those already contemplated for research donation (Proposals 35–37).

Taken together, these adjustments would ensure that the new national human tissue framework not only protects paediatric donors but actively supports **greater paediatric deceased donation and higher paediatric transplantation rates**, particularly through NRP, DCDD optimisation, and robust paediatric research infrastructure.