Submission to Australian Law Reform Commission Review of Human Tissue Laws

February 2026

The Royal Children's Hospital, Melbourne

The Royal Children's Hospital (RCH) is a major specialist paediatric hospital in Victoria and provides specialist care for children from Tasmania, southern New South Wales, and other states around Australia. It is also Victoria's designated major trauma centre for paediatrics.

The hospital delivers the statewide Paediatric, Infant, and Perinatal Emergency Retrieval (PIPER) service and is a Nationally Funded Centre for paediatric heart transplantation, paediatric liver transplantation (in collaboration with Austin Health), and paediatric lung transplantation (in collaboration with Alfred Health).

The RCH delivers forensic medicine services, treatment for complex congenital heart disease (including hypoplastic left heart syndrome) and provides an internationally recognised Gender Service.

The RCH is part of the Melbourne Children's Campus and collaborates with its campus partners, the Murdoch Children's Research Institute and the University of Melbourne, Department of Paediatrics to provide global leadership in integrated clinical care, research and education.

The RCH leads a number of statewide services, including: • Victorian Paediatric Rehabilitation Service (with Monash Health, Ballarat Health Services, Barwon Health, Bendigo Health, Eastern Health and Goulburn Valley Health). • Victorian Paediatric Palliative Care Program (with Monash Health and Very Special Kids). • Victorian Forensic Paediatric Medical Service (with Monash Health and Victorian Institute of Forensic Medicine). • Victorian Infant Hearing Screening Program.

The RCH is a Nationally Funded Centre for:
• paediatric heart transplants
• paediatric liver transplants (in collaboration with Austin Health)
• paediatric lung transplants (in collaboration with Alfred Health).

We are also the national paediatric intestinal transplant service and perform bone marrow and renal transplants for paediatric patients.

Our submission

This submission focuses on those questions and proposals within the Discussion Paper that have a direct and practical impact on paediatric clinical care and paediatric research.

Responses

Questions 1 and 2

We broadly agree with the objects proposed in Proposal 5, noting that they include meeting international human rights obligations. However, this could be strengthened by explicitly including the principle that the best interests of the child be a primary consideration, as set out in the United Nations Convention on the Rights of the Child, within Australian legislation.

Question 4

We address issues relating to decision-making and the role of the 'senior next of kin' in our responses to later questions.

Question 5

The precise wording of such a definition would need to be informed by the structure and operation of the legislation as a whole, to ensure consistency, clinical coherence and proper legislative fit.

Comment on Proposal 10 (no specific question listed)

We fundamentally support the intent of Proposal 10. However, the proposed wording could be improved to better align with how death is determined in contemporary paediatric clinical practice.

The majority of deaths in Australia occur outside of the highly controlled and monitored environment of ICU. Furthermore, the precise testing of neurological function required to determine that brain death has occurred is poorly understood outside of the ICU setting, even amongst skilled clinicians. The language used to define death needs to be clear and unambiguous.

While there is no single perfect unifying descriptor, framing death around the "permanent cessation of critical brain functions" risks unnecessary abstraction and potential ambiguity. In clinical reality, a less ambiguous unifying descriptor is that death is declared once blood flow to the brain has ceased and will not return. This physiological endpoint is the common foundation across all accepted pathways for the determination of death.

In paediatric practice, irreversible cessation of cerebral perfusion (to the extent already accepted for neurological determination of death) is currently established through one of the following mechanisms:

- a clinical neurological examination consistent with brain death in circumstances where such testing is known to be reliable;
- confirmatory imaging demonstrating absence of cerebral blood flow, for example where sedation, metabolic disturbance, or age limits the reliability of clinical testing; or
- clinical examination confirming irreversible cessation of whole-of-body circulation, which necessarily includes cessation of blood flow to the brain.

Framing death around the cessation of blood flow to the brain would provide a clearer, more intuitive and biologically accurate definition. Such an approach accommodates both neurological and circulatory determination of death without privileging one pathway over another and more accurately reflects how clinicians reason and communicate with families about death, particularly in neonatal and paediatric intensive care settings.

A formulation such as:

"Death has occurred once blood flow to the brain has ceased and will not return"

captures the essential physiological threshold, is modality-neutral, and allows accepted medical practice to determine how that state is confirmed in different clinical contexts.

This approach would reduce legal ambiguity, improve consistency across jurisdictions, and avoid unintended barriers to ethically sound donation practices, including donation after circulatory death and the use of normothermic regional perfusion. Importantly, it preserves the dead donor rule while recognising that restoration of circulation to organs, excluding the brain, does not negate death once irreversible cessation of cerebral blood flow has been established.

If the ALRC proposed wording is retained, further clarification will be required. In patients dying following withdrawal of life sustaining therapies who are not brain dead according to the current criteria, death would be declared after a defined period of circulatory arrest as a surrogate marker of permanent loss of critical brain function. In the current ALRC proposal, it is assumed that five minutes of absent circulation is sufficient and that formal clinical testing of brainstem reflexes, respiration and consciousness would not be performed. Specifically, performing routine extensive brainstem clinical testing for all patients that die would be impractical, unethical, and have potential for unintended consequences, regardless of organ donation intent.

Clarifying death in 'brain blood flow' terms would strengthen public trust, align the law with established paediatric intensive care practice, and better support families who have consented to donation by removing unnecessary uncertainty at an already profoundly difficult time.

Question 9

Given our role in operating nationally funded centres for paediatric organ transplantation, we support national consistency in the determination of death. It is essential that any mechanism adopted aligns with clinical practice and supports the full range of clinical needs.

Comment on Proposal 13 (no specific question listed)

The requirement that practitioners confirming death cannot be involved in the care of recipients requires clarification for highly specialised paediatric services like RCH. In nationally funded subspecialty programs like our cardiac program, it is sometimes unavoidable that the small number of paediatric intensivists who are involved in determining death may at some stage also contribute to the longitudinal care of transplant recipients over the course of their childhood and, in some cases, across their lifespan within the same service. Safeguards should therefore focus on clear temporal and functional separation of roles. We suggest the limitations on the

medical practitioner confirming death being involved or responsible for the medical, educational or scientific use of the removed tissue be limited to involvement **at the point of death determination and immediate procurement and implantation**, rather than an absolute exclusion, to maintain workforce viability without compromising ethical integrity.

An example of this would be our subspecialist Paediatric Cardiac Intensivists who may be responsible for declaring death in a child who then goes on to donate their heart, having also been involved in providing clinical care for the recipient at some point, or at some stage later in their clinical course.

Questions 11 and 12

These proposals would create an entirely new framework for the donation of tissue from living paediatric donors. In our view, they would have significant and potentially unintended effects across multiple areas of paediatric clinical care and research. We are very happy to be involved in ongoing consultation around this issue.

Regenerative tissue (including bone marrow and stem cells)

The proposed framework would introduce a substantial new administrative burden when compared with current arrangements under Victorian law. There is a real risk that this additional process could delay time-critical, and in some cases life-saving, transplants.

Availability of alternative donors

The assessment of alternative donors is complex in contemporary transplant practice. Where a matched sibling donor has been identified, this is generally considered the optimal donor for paediatric stem cell transplantation, and an unrelated donor search is not commenced. Initiating an unrelated donor search is both time-consuming—often taking 6–8 weeks to yield results—and costly, with costs borne centrally by the Commonwealth.

The suitability of any alternative donor is also increasingly complex and highly specialised. It is unclear whether a committee would rely solely on the treating medical practitioner's clinical assessment that no suitable alternative donor exists, or whether documentary evidence would be required. If documentation were required, the committee would need access to appropriately skilled expertise to meaningfully assess whether an alternative donor would in fact be clinically suitable.

Risk of delay arising from committee approval

Requiring committee approval creates a material risk of delay, particularly if the committee does not meet frequently or has a full agenda. Decisions regarding progression to transplant often need to be made rapidly. Even delays of a few weeks can significantly disrupt transplant planning, as it is not possible to coordinate other critical elements of care until the donor is confirmed. For urgent transplants, any delay may have direct clinical consequences.

Removal of legislative barriers for non-regenerative tissue

The proposal to remove legislative barriers for the donation of non-regenerative tissue from living paediatric donors raises complex clinical, ethical and practical issues. In our view, this proposal requires further consideration and input from a broad range of stakeholders across the paediatric and child health sector.

Meaningful consultation on these issues would need to extend beyond the timelines available to respond to this review. Further collaborative discussion with paediatric services and clinicians, ethicists, consumer representatives and researchers would be necessary to fully understand the implications for children, families and clinical practice.

Tissue donation following removal for clinical reasons

The proposals appear to be silent on the use of tissue that has been removed for clinical reasons and subsequently considered for donation. This creates uncertainty as to whether such circumstances are intended to fall within the scope of the proposed legislative framework. One example is the donation of cardiac valves to the Victorian Tissue Bank after a heart is explanted from a child undergoing heart transplant as a recipient.

If tissue removed for clinical purposes is captured by the proposed reforms, this may introduce an additional and unnecessary administrative burden on established clinical processes. Clear guidance would be required to ensure that routine paediatric care is not adversely affected and that any new requirements are proportionate, clear and workable in practice.

Question 15

In addition to our broader comments on this proposal, the proposed Committee function appears to lack a clear mechanism for ensuring independent representation of a proposed child donor. Where the recipient is a sibling or other family member, it is not appropriate to rely solely on parental consent or decision-making, given the inherent potential for dual and competing interests.

Any framework governing donation by a child should include a mechanism to ensure that the child donor's interests are considered independently and exclusively. This is particularly important in the paediatric context, where decisions may involve complex emotional and familial dynamics. Independent representation would help ensure that decisions are made solely in the best interests of the child donor, rather than balancing or conflating the interests of multiple family members.

Further, any such Committee would need to include members with appropriate expertise relevant to the specific type of transplant under consideration (for example, stem cell transplantation, kidney transplantation, or other organ or tissue types). It is likely that state-level committees would be required to manage workload in a timely and practical manner. Even a committee meeting on a monthly basis has the potential to introduce clinically significant delays to transplantation.

Transplant physicians already carry substantial clinical workloads. Requiring their participation in committees that may need to meet frequently, or at short notice in urgent cases, may be difficult to operationalise and risks further delaying time-critical clinical decision-making.

Question 16

We support the retention of the Designated Officer role. However, the role requires clearer definition, national standardisation, and consideration of whether its scope should be expanded.

A clearly legislated decision-maker at the hospital level is essential to authorise the removal of organs from a deceased patient. In the paediatric setting, this will most often involve a child who has not provided prior consent, nor expressed any views regarding organ donation. In this context, a clearly identified and independent decision-maker is critical.

Paediatric organ donation involves multiple clinical teams across the donation and transplantation pathway, including the team caring for the deceased or potential donor child, retrieval teams, transplant teams, and teams caring for recipients. In quaternary paediatric services, these teams are often located within the same organisation. A single, independent point of oversight is therefore required to consider the process in its entirety and to make authorisation decisions free from involvement in clinical care and from any perceived conflicts of interest.

In complex clinical and ethical circumstances—such as parental disagreement, questions regarding consent, or uncertainty about donor suitability—the Designated Officer provides essential independent advice and oversight. This role functions as a critical safeguard, supporting consistent interpretation of legal and ethical requirements and reducing risk for clinicians and institutions. Retaining the Designated Officer role ensures that difficult decisions are not made in isolation and strengthens governance, transparency and accountability in paediatric organ donation processes.

National retrieval programs frequently require paediatric transplant teams to operate across hospitals and jurisdictions. A consistent legislative requirement for authorisation by a Designated Officer provides assurance that appropriate governance processes have been followed, enabling teams to undertake retrieval activities with confidence across jurisdictions.

We also support the development of a nationally consistent definition of the Designated Officer role. While the role is currently limited in some jurisdictions to a medical practitioner (for example, in Victoria), this definition is overly narrow and, paradoxically, may allow relatively junior medical staff to act as Designated Officers while excluding senior nursing and allied health professionals. Given that the role is fundamentally one of governance, process oversight and legal authorisation, it would be appropriate for it to be performed by a suitably senior Ahpra-registered health professional with relevant knowledge of transplantation legislation and processes, formally authorised by the hospital to act in this capacity.

Question 19

We support the proposed shift from reliance on “a parent” to an “authorised decision-maker”.

This change is particularly important in the paediatric context, where decisions are routinely made on behalf of a child who has not provided prior consent and, in many cases, has not expressed any views regarding organ or tissue donation.

Under existing frameworks, ambiguity arises because a decision about deceased donation may not clearly fall within the scope of a “medical” or “health care” decision, given that the child is deceased at the time the decision is made. This creates uncertainty as to whether parental authority for medical or health care decision-making continues to apply in this context.

Further complexity arises in families with diverse arrangements, including shared care, court orders, or limits on parental authority. While the concept of “senior next of kin” commonly refers to a “parent”, it does so without reference to whether that parent holds legal authority to make medical or health care decisions for the child. This raises uncertainty as to who is lawfully empowered to consent to donation in these circumstances, and whether multiple parents or carers remain involved.

Aligning consent for deceased donation with the concept of an authorised decision-maker helps to resolve these ambiguities by anchoring decision-making within an established legal hierarchy. However, to be effective, the legislation must clearly provide that post-mortem decisions regarding organ and tissue donation fall within the scope of medical or health-care-related decision-making for the purposes of determining who is an authorised decision-maker.

Clear legislative wording to this effect would improve certainty for families and clinicians, reduce the risk of dispute, and support timely and ethically sound decision-making in paediatric donation contexts.

Question 20

In the paediatric context, these issues differ materially from adult donation. Decisions are frequently made on behalf of a child who has not expressed any wishes regarding donation, and it is common for there to be multiple authorised decision-makers. This creates a higher likelihood of disagreement and uncertainty, particularly in emotionally charged circumstances.

Legislation should align with parental responsibility for making medical decisions for their children. However, clear mechanisms and guidelines for donation decisions when there is disagreement will be needed. Explicit criteria should address circumstances in which a second parent is not reasonably accessible despite documented attempts, lacks decision-making capacity due to intoxication or acute injury, is subject to family violence protections, or has no legal decision-making authority due to court order. Clear legislative guidance in these circumstances would reduce distress for the available consenting parent and help prevent avoidable loss of donation opportunities.

Experience in Victoria highlights the importance of clarity in this area. In 2024, there were two

cases in which parents with equal decision-making authority held differing views regarding organ donation. In both cases, donation did not proceed. In one case, one parent may arguably have been considered "not available" for the consent process. The meaning and application of parental "availability" in this context requires clarification.

Where parents hold equal decision-making authority, the absence or limited engagement of one parent should not automatically be taken to equate to unavailability without clear and consistent criteria. Ambiguity regarding what constitutes parental availability risks undermining the validity of consent processes, contributing to moral distress among clinicians, and creating perceptions of inequity or coercion.

Clear guidance is required to define parental availability in the context of organ donation discussions, including consideration of physical presence, contactability, cognitive capacity, emotional readiness, and genuine opportunity to participate in decision-making. Explicit clarification of this concept would support ethically sound practice, respect parental authority, and provide clinicians with a transparent and defensible framework for navigating situations of parental disagreement.

Question 22

Minor investigations required to assess donation suitability, including blood tests and clinically indicated imaging, should be treated consistently with other investigations undertaken during end-of-life care, intensive care, or the management of critical illness. Where such investigations align with accepted medical practice and established goals of care, they should not require separate or additional consent.

Where consent is required, it should be proportionate to the nature, invasiveness and impact of the investigation. Clear legislative guidance in this area would support timely clinical decision-making, reduce unnecessary administrative burden, and avoid placing additional stress on families during end-of-life care.

Question 23

We do not consider that additional safeguards beyond valid consent and adherence to accepted medical practice are required. Safeguards should be proportionate to those that apply to comparable clinical interventions in other contexts. Introducing additional or heightened restrictions risks delay, loss of donation opportunities, and increased moral harm to families who have consented to donation.

However, legislative clarity is required to ensure that consent for invasive antemortem procedures undertaken for the purpose of donation under this framework is recognised as lawful and sufficient. In particular, the legislation should expressly provide that such procedures are not to be characterised as "special medical procedures" requiring separate court approval, where they are authorised under the human tissue legislation for the specific purpose of facilitating donation.

Explicit recognition of this point would provide certainty for clinicians and families, avoid unnecessary legal escalation, and support timely, ethically sound donation processes consistent with established clinical practice.

Question 25

We support this proposal, including the inclusion of a child who has decision-making capacity in relation to post-mortem examination.

Recognising that some children and young people may have the capacity to understand and make decisions about post-mortem examination respects their autonomy and aligns with contemporary paediatric practice and children's rights. Any assessment of decision-making capacity should be specific to this decision and undertaken in accordance with accepted clinical and legal principles.

Clear legislative recognition of this approach would support ethically sound practice, provide clarity for clinicians and families, and ensure that the views of capable children are appropriately respected in decisions relating to post-mortem examination.

Question 27

Further clarity would be required regarding the meaning of a "small sample". The impact of tissue sampling is not determined by size alone, but by the nature and intended use of the tissue, particularly where genetic material is involved.

We do not support permitting the taking or retention of additional post-mortem tissue on the basis that it constitutes only a "small sample". Any such definition would need to be tightly and clearly framed. Given the historical investigations into unlawful post-mortem tissue storage, it is important that the legislative framework avoids reintroducing ambiguity or practices that could undermine public trust.

Comment on tissue use in research generally

We note that the various proposals related to management of human tissue in research potentially may not align with the Victorian Aboriginal Research Accord which has specific clauses on Indigenous Data Governance and Sovereignty Principles. This is an emerging requirement for Human Research Ethics Committees, and so it is imperative that any legislative changes take these principles into account.

Comment on proposal 33 – no specific question

In relation to proposal 33 point 2 - 2. If consent for future research uses is withdrawn, any unused tissue must be discarded.

The withdrawal of consent to continue to participate in research and the withdrawal of consent to continue to store should be separate from request to discard tissue. Withdrawal of consent for ongoing participation should not automatically require destruction of tissue, this should be a separate request.

Comment on Proposal 35 – no specific question

We support this proposal in principle in relation to children. However, rather than vesting the relevant approval solely in a medical practitioner (as per the Tasmanian legislation wording), consideration should be given to assigning this function to an authorised approval body, such as a Human Research Ethics Committee.

We suggest that the wording in s22B (1) (a) be updated to be 'for the purpose of ethically approved research in line with the National Statement'.

We also suggest that the wording in s22B (1) (c) (i-iii) be removed as these considerations are part of the approval process as undertaken by the Human Research Ethics Committee. An alternative, if this was deemed to be unable to removed, would be to expand the wording in (c) (i) to be 'for the *potential* benefit of the child' to allow collections within clinical trials where benefit is not guaranteed.

Where a research project has been reviewed and approved by a paediatric-accredited Human Research Ethics Committee under the National Mutual Acceptance (NMA) scheme, the committee has already assessed the scientific merit of the project, the integrity and experience of the research team, and the ethical acceptability of the proposed tissue collection and use. Consent processes are also assessed against the requirements of the *National Statement on Ethical Conduct in Human Research*, including parental consent where applicable. In these circumstances, additional legislative barriers risk duplicating existing safeguards without adding meaningful protection, and may unnecessarily impede ethically approved research.

We also strongly support national standardisation in this area. Consistent rules across jurisdictions are essential to enable paediatric research to proceed efficiently and lawfully. At present, research projects may receive ethical approval in one state but be unable to proceed in another under the NMA scheme because the proposed tissue collection or use does not align with that jurisdiction's human tissue legislation.

A nationally consistent approach to tissue collection and use from children for research purposes would reduce duplication, remove unnecessary barriers to multi-jurisdictional research, and support high-quality paediatric research while maintaining appropriate ethical safeguards.

Question 29 and 30

The use of stored human tissue for research is appropriate where the research has been ethically approved in line with the National Statement.

Consent for the storage and use of tissue should clearly specify how tissue will be stored and used. This should include explicit information about any proposed use of the tissue in future ethically approved research projects, and the intended breadth of that consent.

Clear, upfront consent regarding storage and future use supports informed decision-making, maintains public trust, and provides certainty for clinicians and researchers, while enabling ethically approved research to proceed within established governance frameworks.

Further, guidance is required in relation to samples collected from children where consent was originally provided by parents, including whether re-consent is required for ongoing storage and use once the child reaches adulthood. Any legislative requirements in this area would need to align with the NHMRC National Statement on Ethical Conduct in Human Research, to ensure consistency with established ethical frameworks and existing research governance arrangements. Further, there needs to be separation between legislation and the National Statement to avoid duplication or inconsistency when the National Statement is updated.

Questions 31-33

We would support further legislative development in this area, noting that the issues involved are complex and would require broader consultation and detailed consideration beyond the scope and timeline of this submission.

Question 34

We agree that the development of guidelines for access to stored human tissue is an appropriate measure. Further consultation and discussion should occur about whether this is best situated within legislation or in guidance documents.

Such guidelines should include clear requirements for consent for access, including transparency about the consequences of access. In particular, consent processes should outline that accessing tissue for testing may involve removal or consumption of a sample that cannot be returned or restored at a later time.

Guidelines should also clarify that, while holders of stored tissue have a role in facilitating appropriate access in accordance with consent and governance requirements, the costs associated with access, processing and testing should appropriately rest with the requesting party.

Clear guidance in these areas would support informed decision-making, protect the integrity of stored collections, and promote consistent and fair access arrangements.

Questions 42-44

We support a centralised and regulated approach to the oversight of biobanks and other tissue collections. However, this needs to be balanced against the risks and burdens to research programs. A centralised, regulated approach may preclude Australian patients participating in internationally-led research. Australian led research may also be impacted due to the cost and time implications related to this.

There is some support for mandatory reporting of a consistent set of de-identified information by all biobanks and tissue holders. Such information could include, for example: the type of biological material stored (such as tissue, blood, DNA, RNA, cell lines, gametes or embryos), sample volume, storage state (for example frozen or FFPE), origin, and date of collection.

Consistent reporting has the potential to improve transparency, enable system-wide oversight, and support better coordination of research activity.

Biobanks function, in effect, as libraries of biological material. They should not be operating in competition with one another, particularly where they serve the same population and research purpose. Fragmentation and duplication risk inefficiency, inconsistent quality standards, and suboptimal use of limited funding.

By way of example, there are currently two paediatric cancer biobanks operating in Victoria, both storing biological material for research purposes. These biobanks perform substantially similar functions, resulting in duplication of infrastructure, governance and funding. Consolidation into a single, coordinated paediatric cancer biobank would improve quality, consistency and stewardship of samples, while reducing duplication and improving the return on public investment. Conversely, the time/cost implications of consolidating these, may reduce the return on public investment.

A centralised and regulated framework, supported by mandatory reporting and oversight, could promote coordination rather than competition, improve equity of access, enhance research quality, and ensure that scarce biological material is managed as a shared public resource.

In relation to data related to donation for transplantation, improved access to data beyond individual jurisdictions is also critical. Enhanced national and inter-jurisdictional data sharing would support collaboration, benchmarking and research, particularly in paediatric transplantation where case numbers are small but clinical complexity is high. Strengthening data visibility across systems would enable a more accurate understanding of unmet need, support service planning, and inform strategies to expand paediatric donation and transplantation pathways.

A clear example of this is the critical shortage of paediatric heart valves. This need only became apparent locally when national valve stock levels declined to the point that surgeons were unable to proceed with transplantation. Until that point, the extent of the shortage and its direct impact on children awaiting surgery was largely invisible outside specialist clinical teams. This illustrates how gaps in system-wide visibility can translate into real and immediate consequences for paediatric patients.

Improved data sharing, national oversight and earlier communication across jurisdictions would allow emerging shortages in critical resources, such as paediatric heart valves, to be identified sooner. This, in turn, would support timely collaboration, contingency planning and targeted community engagement to address unmet need.

Question 46

Our two priority areas for reform would be in relation to the determination of death (to allow normothermic regional perfusion) and paediatric research collections. We welcome further discussion and engagement with the Commission on these topics.

Reform is needed in the stored tissue collection and biobank regulatory landscape; however, this will require further input and consultation across the sector.

As outlined in our responses above, changes to paediatric living donation are complex and may have multiple impacts in different directions. While we support the objective of national consistency and synergy, further work is required to develop a clear understanding of the practical mechanics, operational requirements, and oversight arrangements of any proposed scheme. Broader and collaborative consultation across the paediatric and child health sector, informed by detailed operational modelling, would be necessary before a final position can be reached.

Determination of death

Normothermic regional perfusion, including thoracoabdominal perfusion with exclusion of cerebral circulation following determination of death, should be explicitly recognised as lawful. Doing so would bring Australia into line with contemporary donation practice internationally, including in New Zealand.

Australian paediatric heart transplant recipients experience among the longest waiting times globally. Children awaiting a donor heart are generally unable to be supported at home, as the only durable mechanical circulatory support available is the Berlin Heart ventricular assist device. As a result, children commonly live in hospital for one to two years, dependent on technology while awaiting transplantation. During this time, they experience prolonged separation from family life and significant physical and psychological burden.

Australia also has among the longest organ transport distances and retrieval times. Paediatric donor hearts are frequently procured from across the country, and at times binationally, before being transported to Melbourne for implantation. These challenges are compounded by the technical complexity and duration of explanting long-standing Berlin Heart cannulae at the time of transplantation, further increasing the vulnerability of the donor organ.

Where families have consented to donation, failure to facilitate donation due to legal uncertainty causes profound and enduring moral distress for parents. Legislative clarity expressly permitting normothermic regional perfusion would honour parental intent, reduce avoidable moral harm, and materially improve transplant viability and outcomes for children with life-limiting cardiac disease.

Paediatric research collection

The Royal Children's Hospital participates in hundreds of clinical trials at any one time. Participation in clinical trials can provide children and families with access to novel and potentially life-changing therapies that would otherwise not be available. The ability to collect and use tissue samples in accordance with ethically approved research protocols is often fundamental to the conduct of these trials.

Where a research project has been reviewed and approved by a paediatric-accredited Human Research Ethics Committee under the National Mutual Acceptance (NMA) scheme, the committee has already assessed the scientific merit of the project, the integrity and experience of the research team, and the ethical acceptability of the proposed tissue collection and use. Consent processes are also assessed against the requirements of the *National Statement on Ethical Conduct in Human Research*, including parental consent where applicable. In these circumstances, additional legislative barriers risk duplicating existing safeguards without adding meaningful protection, and may unnecessarily impede ethically approved research and access to clinical trials.

We also strongly support national standardisation in this area. Consistent rules across jurisdictions are essential to enable paediatric research and clinical trials to proceed efficiently and lawfully.

A nationally consistent approach to tissue collection and use from children for research purposes would reduce duplication, remove unnecessary barriers to multi-jurisdictional research, and support high-quality paediatric research while maintaining appropriate ethical safeguards.

Additional information

We welcome the opportunity to contribute to this review and value the Australian Law Reform Commission's consultative approach. We remain willing and available to engage further with the Commission to support its consideration of these issues.

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