Submission to the Australian Law Reform Commission

Review of Human Tissue Laws
Discussion Paper

Australian Centre for Transplantation Excellence and Research

Austin Health, Melbourne

Incorporating perspectives from the
Australian Donation and Transplantation Biobank

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1 Executive Summary

The Australian Centre for Transplantation Excellence and Research (ACTER) unifies transplantation programs at Austin Health (Melbourne, Victoria) including haematopoietic stem cell, kidney, liver, vascularised composite allograft, and intestinal/multivisceral transplantation. Our vision is to honour the gift of organ and stem cell donation and transform lives through advanced transplantation research and holistic care. We host the Victorian and Tasmanian Organ Retrieval Service (VICTORS), servicing Australia's largest retrieval jurisdiction by volume, and have conducted over 200 clinical abdominal organ *ex situ* machine perfusions. ACTER pursues five interconnected goals: improving access to transplantation, enhancing patient outcomes and quality of life, embedding consumer engagement, driving innovation and research, and cultivating multidisciplinary operational expertise.

ACTER also supports the Australian Donation and Transplantation Biobank (ADTB), Australia's first biobank systematically integrated with a routine organ donation and transplantation system. Established in October 2019, the ADTB facilitates ethically approved research use of donated organs and tissues through a unified consent model that has proven operationally successful in enabling high-impact research whilst honouring donor and family intentions. This consent model employs tiered, unspecified consent aligned with the National Statement on Ethical Conduct in Human Research (the National Statement), allowing families to provide broad consent for future research whilst avoiding information overload at the time of consent to organ donation for transplantation. Since establishment, the ADTB has supported over 27 research projects across over 9 institutions nationally and internationally, distributing more than 1,700 samples from over 173 consented deceased organ donors and generating more than 15 peer-reviewed publications with a field-weighted citation index 2.5 times the world average. The ADTB also manages all research requests for deceased organ donor samples in Victoria.

This submission addresses specific proposals and questions where the clinical and operational experience of ACTER and ADTB provides relevant insights. We have focused on areas where we can offer perspectives grounded in direct transplantation practice rather than general policy positions, and have avoided restating rationale that the Australian Law Reform Commission (ALRC) has already set out in the Discussion Paper.

From a clinical and operational perspective, we identify three reforms as particularly urgent. First, the proposed unified brain-based standard for death determination (**Proposal 10**) would resolve the current statutory-clinical mismatch that prohibits normothermic regional perfusion (NRP) in Australia, placing us out of step with international best practice and limiting organ quality and transplant outcomes for Australian recipients. Second, express statutory authority for practitioners and health authorities to access and share donor-relevant information for identification and screening purposes (**Proposal 49**) would address current legal uncertainty that delays donor suitability assessments. Third, alignment of research consent provisions with the National Statement would preserve the ADTB unified consent model, which has proven operationally successful in enabling high-impact research whilst honouring donor and family intentions, and avoiding information overload at the time of consent to organ donation.

Transplantation is functionally cross-jurisdictional. VICTORS regularly retrieves organs interstate, organs retrieved in Victoria are transplanted across Australia, and the ADTB provides samples to research projects nationally. This operational reality informs our support for national consistency throughout the submission, and shapes our emphasis on reforms that can be implemented in time-critical clinical environments.

2 National Framework and Principles

2.1 National Consistency

The donation, retrieval, and transplantation of human organs and tissues in Australia is delivered by state-based health services but is functionally cross-jurisdictional:

- VICTORS regularly conducts retrieval surgeries interstate.
- Organs retrieved in Victoria are regularly transported to and transplanted in New South Wales, South Australia, Queensland and Western Australia.
- Recipients transplanted at Austin Health receive organs from donors across multiple states.
- ADTB provides samples to research projects nationally.

We support national consistency (**Proposal 1**) and express no strong preference between coordinated state and territory legislation or Commonwealth legislation. The legislative mechanism should be selected to maximise the probability of achieving genuine national consistency over time and supporting efficient updates.

2.2 Legislative Framework

We support the proposed structure that places core requirements in primary legislation whilst delegating technical and operational detail to regulations and guidelines (**Proposal 2**). This flexibility matters in transplantation. Over the past decade, we have seen the emergence and rapid clinical adoption of practices such as *ex situ* machine perfusion and normothermic regional perfusion. Locking technical specifications into primary legislation would impede adoption of future advances.

Any criminal sanctions in the primary legislation should be reserved for clearly culpable misconduct rather than good-faith clinical judgement exercised in areas of inherent uncertainty. In donation, retrieval, and transplantation, we assess organ quality with incomplete information, make time-critical decisions about suitability, and weigh risks against the urgency of recipient need. Maximising utilisation of donated organs inevitably means accepting some marginal organs where outcomes may be suboptimal. The alternative is leaving organs unused whilst patients die on waiting lists. Overly broad criminal liability could make clinicians inappropriately risk-averse, reducing transplant opportunities and disadvantaging patients who would benefit from considered acceptance of marginal organs.

2.3 National Regulator

We support establishing a National Regulator by expanding the statutory powers and functions of the the Organ and Tissue Authority (OTA, **Proposal 3**(a)). OTA already possesses expertise in organ and tissue donation, established relationships with clinical stakeholders, and infrastructure that can be built upon. The National Regulator must be properly resourced to carry out expanded functions effectively, with scope clearly delineated to avoid duplication with the Therapeutic Goods Administration and the National Blood Authority.

From our experience, regulations and guidelines developed centrally are only effective if they are workable in time-critical clinical environments. Close clinical consultation during development is essential.

The regulatory approach should be risk-proportionate, supporting quality improvement without creating administrative barriers to time-critical care.

2.4 Objects of the Legislation

We support the proposed objects (**Proposal 5**, **Proposal 6**, and **Question 1**). We suggest one additional object: to promote safety, quality, and traceability across the donation–retrieval–processing–use continuum through appropriate assurance mechanisms (**Question 2**). Traceability is fundamental in transplantation. When adverse events occur, the ability to rapidly identify tissues from a donor, all recipients who received tissue from that donor, and all processing steps undertaken is essential for recipient safety and public health protection.

We support requiring the National Regulator to have regard to the objects when carrying out its functions **Proposal 6**, including through transparent consultation processes with clinical stakeholders.

2.5 Promoting Equity

We support the inclusion of specific provisions to remove barriers and promote equity, beyond the equity object itself (**Question 3**). From our operational perspective, one under-recognised equity issue is variation in clinical practice between transplant centres. High-volume centres with experienced teams may be better positioned to accept marginal organs that lower-volume centres would decline, creating geographic inequity in access. Nationally consistent provisions that support evidence-based practice standards, training, and quality improvement can help reduce unwarranted variation whilst recognising that some variation in risk tolerance reflects legitimate clinical judgement.

Operational equity requires resourced infrastructure, skilled workforce, and accountability. Specific legislative provisions could create obligations that can be funded, measured, and enforced. From our perspective, equity provisions should enable rather than prescribe, allowing tailored approaches that reflect local circumstances whilst maintaining consistent standards.

2.6 Specific Barriers

The ALRC has invited identification of specific barriers that new legislation should address (**Question 4**). Beyond barriers addressed through other proposals, we identify four additional barriers.

First, information overload in deceased donation consent processes. Feedback from donor families, gathered through the ADTB and DonateLife Victoria, confirms that consent processes are onerous. Families consent to organ donation for transplantation, then separately to tissue donation, then to research uses, each with detailed explanations. In acute grief, this volume of information becomes overwhelming and risks families declining donation not because they oppose it but because the process is too burdensome. Legislative reform should enable streamlined consent processes that obtain valid authorisation without information overload.

Second, over-prescriptive legislative requirements for research consent duplicate and potentially conflict with established national research ethics frameworks. When legislation specifies detailed consent content, it risks creating inconsistency with the National Statement, particularly as research practices evolve. Legislation should require compliance with the National Statement rather than attempting to reproduce its detailed requirements.

Third, restricted or unclear authority for timely access to clinically relevant donor information. When potential donors are identified, rapid access to medical history, pathology results, and medical imaging is essential for determining suitability. Current legal frameworks create uncertainty about when and how this information can be accessed, particularly from My Health Record. Express statutory authority for donor screening, modelled on section 45(4)–(6) of the *Human Tissue Act 1982* (Vic), would address this uncertainty.

Fourth, legalistic statutory wording and jurisdictional variability increase the risk of inconsistent implementation. Human tissue legislation is implemented by doctors, nurses, technicians, and coordinators in often time-poor circumstances. The Victorian *Human Tissue Act 1982*, for example, contains consent and certification requirements that are legally precise but not clinician-friendly. While we maintain compliance at Austin Health, we observe variability in interpretation and application nationally. Clinician-friendly drafting and clear guidance materials from the National Regulator can bridge the gap between legal precision and practical implementation.

3 Definition and Scope of Human Tissue

From our perspective, the tissue definition must accommodate current practices whilst being sufficiently flexible to evolve with medical science. Our experience with *ex situ* machine perfusion, emerging interventions, and future technologies underscores the importance of getting this foundational element right.

3.1 Tissue Definition

We strongly support the ALRC proposal for a broad definition with a flexible adjustment mechanism (**Proposal 7**). Contemporary transplantation practice increasingly operates at the boundaries of traditional tissue definitions. Austin Health has conducted over 200 clinical abdominal organ *ex situ* machine perfusions (where organs are perfused and assessed outside the body using specialised equipment). This practice, now standard across our kidney and liver programmes, along with future advancements, is anticipated to increasingly raise definitional questions. As an example, we occasionally use whole blood retrieved from deceased donors as perfusate in these systems. This blood serves organ preservation and viability assessment rather than transfusion, creating ambiguity about whether it sits within human tissue laws or blood banking regulations.

Looking forward, emerging *ex situ* interventions including defatting, immunomodulatory therapies, enzymatic blood group conversion, and potentially gene therapy delivered via perfusion will further challenge conventional boundaries between tissue donation, therapeutic intervention, and research. A technology-neutral definition provides the necessary foundation to accommodate innovation whilst maintaining appropriate regulatory oversight. Future developments such as xenotransplantation, bioengineered organs, and organoid-derived transplantation products will require similar flexibility.

Of the two options presented in **Question 5**, we prefer the New Zealand approach defining tissue as the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from human cells (**Option B**). Its explicit reference to material "removed from a human body" provides clearer boundaries for biobanking operations like the ADTB, where samples undergo processing and may be cultured for research purposes. We need clarity about whether and when cultured derivatives

cease to be "tissue" for regulatory purposes, and the framing of Option B better supports that operational distinction.

3.2 "Tissue" Label

We have no strong preference on replacing the word "tissue" with an alternative label (**Question 6**), provided the chosen term is clearly defined and consistently used throughout the legislation. The term "tissue" is well understood within the transplantation community and aligns with existing terminology in the OTA Act and clinical practice. If the ALRC determines that a different label better serves broader stakeholder understanding, we would support "human material" as a clear alternative.

3.3 Adjustment Mechanism

We strongly support authorising the National Regulator to adjust the scope of the definition through delegated legislation (**Proposal 8**). The pace of innovation in transplantation and regenerative medicine makes this flexibility essential. Five years ago, normothermic machine perfusion was experimental; today it is standard practice in our programme. Ten years from now, interventions we can barely imagine may be routine. Legislation must be able to keep pace.

From an operational perspective, any adjustment mechanism needs to work for services operating across state boundaries and time-critical pathways. When we retrieve organs in one jurisdiction, perfuse them in another, and transplant them in a third (all within 24 hours), we need absolute clarity about what rules apply. Adjustments to scope should therefore be made transparently, with clear rationale and consultation with clinical stakeholders, and implemented uniformly across jurisdictions. Where changes affect existing practices, reasonable transition arrangements should be made to avoid disrupting patient care or research programs.

3.4 National Regulator Guidance

We support the National Regulator developing guidelines to provide interpretive guidance about the definition and scope of "tissue" **Proposal 9**.

ACTER and ADTB have encountered boundary contexts where the tissue definition is unclear. For example, whether cell lines cultured from donated samples remain "tissue" for regulatory purposes, at what point processing transforms donated material into something regulated differently, and whether whole blood retrieved from deceased donors and used as perfusate falls within tissue laws or blood banking regulations. Worked examples addressing such boundary questions, developed in consultation with transplantation and biobanking communities, would assist operational decision-making.

3.5 Exclusions

On **Question 7** regarding specific exclusions, we offer positions where these materials intersect with transplantation or ADTB operations.

We support excluding cell lines created outside the human body from the tissue definition, or at minimum excluding them from provisions relating to consent and trade. Once biological material is cultured in laboratory conditions and transformed into self-sustaining cell lines, it becomes qualitatively

different from the original donated tissue. These cultured products are better regulated through existing research ethics frameworks and therapeutic goods regulations than through tissue donation laws.

We would note that ADTB has occasionally been approached by researchers interested in accessing biological materials that sit at the boundaries of traditional tissue definitions. For example, perfusate fluid containing cellular material, or tissue that has undergone significant processing. A clear definition with adjustment mechanisms would support the ADTB and the broader research community in navigating these boundaries appropriately.

4 Death Determination

4.1 Current Statutory-Clinical Mismatch

As hosts of VICTORS, servicing Australia's largest retrieval jurisdiction by volume, we experience this barrier directly. We cannot offer donors and families the improved outcomes that NRP enables. The growing international evidence base and adoption of NRP across comparable jurisdictions means Australia's transplant programs operate at an increasing disadvantage.

We note that abdominal NRP can be implemented independently of thoracoabdominal protocols, enabling improved abdominal organ outcomes whilst preserving traditional retrieval approaches for thoracic organs where programs prefer this. This reform is operationally urgent. In response to **Question 47** regarding which reforms ACTER considers critical, death determination reform stands out as enabling contemporary donation practices currently legally unavailable in Australia despite their established clinical benefit.

4.2 Brain-Based Standard

We strongly support **Proposal 10**. The proposed definition reflects the clinical reality of DCDD pathways and provides clear authority for contemporary techniques including NRP whilst maintaining robust death determination principles. We particularly support the proposal's reliance on accepted medical practice, with capacity for regulations to identify relevant professional standards, ensuring the legal standard remains current as medical evidence and techniques evolve.

4.3 Determination of Death

As hosts of VICTORS, we emphasise the operational necessity of nationally consistent death determination provisions. Multi-jurisdictional retrieval services cannot function effectively when death determination standards, and related regulations, vary between states. We support **Proposal 11** and, in response to **Question 8** and **Question 9**, we prioritise the outcome of a single nationally consistent, clinically aligned death standard over the particular legal mechanism used to achieve it.

We support **Proposal 12** and recommend that "accepted medical practice" be operationalised through nationally consistent guidance developed by the National Regulator in collaboration with professional bodies such as the Australian and New Zealand Intensive Care Society and the Transplantation Society of Australia and New Zealand.

Regarding **Proposal 13**, we support robust safeguards to uphold the "dead donor rule" whilst emphasising these must remain workable in time-critical donation pathways. The key is clear separation between

death determination (which must occur first, according to established clinical criteria) and subsequent interventions to optimise organ quality.

4.4 Deceased Donation Consent

We support **Proposal 23**, emphasising two points from our operational perspective. First, the framework's separation of research uses into dedicated research consent provisions is essential for the ADTB. Prescriptive requirements to specify all intended research uses at the time of deceased donation consent would create an unworkable information burden for grieving families and donor coordinators, and would compromise the ADTB unified consent model serving multiple research projects. Second, whilst family engagement remains essential, "respect for next of kin" should be operationalised as culturally safe, well-supported communication rather than implicit veto over an adult's valid consent.

In response to **Question 17** and **Question 18**, we support a technology-neutral approach that recognises consent as valid when it meets the substantive elements in **Proposal 23**, regardless of particular modality.

Regarding **Question 16**, we support removal of the Designated Officer role provided governance, accountability and traceability are secured through the National Regulator's standards and hospital/DonateLife operational frameworks. The historical function is now undertaken primarily by DonateLife through more sophisticated processes than legislation can specify.

4.5 Authorised Decision-Makers

We support **Proposal 25** in principle, emphasising that the hierarchy must be readily operationalised in time-critical circumstances. Clear processes for progressing through the hierarchy when higher-priority decision-makers cannot be contacted or are unwilling to decide are essential.

Regarding **Question 20**, from our perspective, where the deceased person's own valid consent is documented, donation should proceed on that basis. Where consent is being sought from decision-makers who disagree, we would not be comfortable proceeding unless disagreement can be resolved promptly.

We support **Proposal 24**. From our perspective, protocols should preserve clear separation between end-of-life decision-making and donation conversations, enable proportionate consented investigations and donor management, and reduce procedural friction that could prevent willing donors from realising their wishes.

4.6 Pre-Mortem Interventions

We support **Proposal 26** and **Proposal 27**. Regarding **Question 21**, our concern is that the definition should not inadvertently capture routine end-of-life care delivered for the person's own benefit merely because such care incidentally preserves organ function. National Regulator guidance will be needed to operationalise this distinction.

In response to **Question 22**, we support a narrowly framed exception for minimal-risk, clinically routine investigations where delay would compromise viability. Blood typing, organ function assessment and infectious disease screening are examples. Any exception must include documented clinical rationale and operate within clear National Regulator parameters.

Regarding **Question 23**, from our perspective safeguards beyond consent are best delivered through nationally consistent professional standards rather than additional legislative prescription.

4.7 Respectful Treatment, Technicians and Coronial Processes

We support **Proposal 28**. The qualifier "practicable in the circumstances" is important for time-critical organ retrieval where respectful treatment must be balanced against preserving viability through expeditious, skilled organ recovery.

We support **Proposal 29** in principle, emphasising that any framework must not interfere with organ donation pathways, must be nationally consistent and proportionate to risks, and should specify technician qualifications through regulations to enable adaptation to existing and evolving workforce models.

Regarding **Question 24**, we support nationally consistent, principles-based factors that preserve coroners' investigative function whilst recognising donation's time-critical nature and the deceased person's wishes.

4.8 Post-Mortem Tissue Use

We support **Proposal 31**. In response to **Question 27**, we do not support a size-based exception for "small samples". The ethical rationale for requiring consent does not materially change based on sample size. Where exceptional circumstances genuinely warrant use without consent, these should be managed through existing ethical governance mechanisms rather than a broad statutory exception.

5 Living Donation

Austin Health conducts proportionately more living donor transplants than other centres in Australia, with particular experience in living kidney and liver donation. Our living donor program operates under the Victorian *Human Tissue Act 1982* and incorporates all statutory safeguards alongside additional clinical protocols. This experience informs our positions on the ALRC proposed framework.

5.1 Consent Framework

We support **Proposal 14** as a sound foundation for nationally consistent living donation regulation. The requirement that valid consent provides sufficient legal authority for removal and use addresses a current gap in some jurisdictions where additional authorisation steps create procedural complexity without substantive benefit.

From an operational perspective, the statutory wording of consent requirements needs to support clinician comprehension and consistent application. Our experience with the Victorian Act demonstrates that legalistic phrasing can create risks of misinterpretation.

5.2 Additional Safeguards

Question 10 asks whether additional safeguards should be set out in legislation beyond those in **Proposal 14**. From our experience delivering living donation services, we support three principles-level safeguards being reflected in legislation for living donation involving material risk.

First, legislation should require an independent donor assessment by a practitioner who is not involved in the recipient's care. This is a practical safeguard against subtle clinical coercion and conflicts of interest. The operational detail (who may perform the assessment, required competencies, minimum documentation) should sit in national clinical guidelines.

Second, legislation should require that living donors have access to independent psychosocial assessment and support. Living donation decisions occur within complex relational contexts where family expectations, reciprocity, and perceived obligation can influence choices. Psychosocial assessment provides protections distinct from, and not reducible to, cooling-off periods.

Third, legislation should require proportionate reflection or cooling-off periods for non-regenerative tissue donation, while preserving limited flexibility for genuinely urgent, life-saving circumstances where delay would materially compromise recipient outcomes. Where an exception to a standard cooling-off period is applied, the framework should require documented reasons and demonstrable safeguards, with implementation detail in clinical practice guidelines.

Living liver donation illustrates the classification challenges. Although the liver has regenerative capacity, the donor risk profile is closer to other living solid organ donation pathways. In our program, we apply safeguards appropriate for higher-risk living donation. However, clinical necessity sometimes requires living donation within timeframes that conflict with the legislation. Our experience aligns with the Discussion Paper recognition that flexible consent safeguards may be needed in situations of clinical urgency, with donor protection secured by safeguards that directly test voluntariness and informed consent (as we have proposed above) rather than elapsed time alone.

5.3 Donation Arising from Therapeutic Interventions

We note a category of cases where the proposed living donation framework requires clarification. "Domino" transplantation, and related secondary-use pathways, occur where an organ or tissue is removed as part of a person's clinically indicated treatment and is then transplanted into another recipient.

These scenarios arise in several established contexts, including:

- Domino liver transplantation after transplantation for metabolic liver disease (for example Maple Syrup Urine Disease, MSUD), where the explanted liver may function adequately in a recipient without the underlying metabolic disorder.
- Domino liver transplantation after transplantation for hereditary transthyretin amyloidosis, where the explanted liver is structurally normal but carries a known long-term disease risk requiring explicit recipient disclosure.
- Domino heart transplantation following heart–lung transplantation, where the native heart may be suitable for transplantation.
- In carefully selected circumstances, transplantation of kidneys removed for therapeutic reasons (for example nephrectomy for a small renal tumour) following bench assessment and excision. This is an example of secondary use that is not domino transplantation.

The framework as drafted does not clearly distinguish these pathways from elective living donation. While domino scenarios share some practical requirements with living donation, they differ fundamentally in risk profile and decision structure. The removal of the organ or tissue is not an elective act undertaken to benefit another person; it occurs because it is necessary for the individual's own treatment. The donation element is the subsequent use of material that would otherwise be discarded.

From our perspective, **Proposal 14** should clarify that in domino scenarios, the consent required is for *secondary use* of explanted tissue, not for the therapeutic removal itself. This consent should be obtained

and documented as a distinct decision, clearly separated from (and not perceived to influence) access to, timing of, or conditions attached to the person's treatment (removal of the tissue). Given this context, living donor safeguards that are designed to manage the ethics of *elective* risk-taking for another's benefit (including cooling-off periods and the suite of independent living donor processes in **Question 10**) are likely excessive as mandatory requirements, given there is no additional physical risk arising from the donation aspect. The Committee pathways in **Proposal 17** and **Proposal 20** are similarly designed to protect individuals where tissue removal itself creates risk; in domino scenarios, removal is therapeutically necessary.

However, recipient safeguards remain relevant. Donor suitability assessment still occurs, including infectious disease screening, organ function assessment, and malignancy risk evaluation (and, where relevant, clear disclosure of any disease-related longer-term risks). The usual information-sharing pathways for organ acceptance decision-making also apply to support recipient teams to make informed decisions about organ acceptance based on donor characteristics, HLA typing and risks. Where the person has decision-making capacity, their informed consent to secondary use should be required. Where they lack capacity (including children), consent by an authorised decision-maker should be required. Committee approval under **Proposal 17** or **Proposal 20** would be disproportionate in this context, as those pathways are designed to protect individuals from risks created by elective tissue removal. In domino scenarios, the tissue removal occurs regardless for therapeutic reasons and the donation element creates no additional physical risk. We note that domino pathways can involve children as donors (for example, a child receiving liver transplantation for MSUD), and represent an ethically appropriate mechanism for paediatric solid organ donation where the child's therapeutic needs, rather than donation considerations, drive the clinical decision.

National Regulator guidance should explicitly address domino and related secondary-use pathways, including the required separation of treatment decision-making from secondary-use consent, to ensure consistent implementation across jurisdictions whilst preserving this valuable source of organs for recipients.

5.4 Age Definition

We support **Proposal 15**, which establishes 18 years as the age of adulthood for matters covered by new human tissue legislation. In living donation pathways involving material risk, particularly living solid organ donation, this threshold should be applied. We support the view that living solid organ donation should be confined to adults with decision-making capacity, however also recognise that unique circumstances may exist, including those articulated in Section 5.3.

5.5 Donation by Adults Without Decision-Making Capacity

We support the introduction of a Committee pathway (**Proposal 20**, **Proposal 21**, and **Proposal 22**) as a protective mechanism for the limited circumstances in which living donation is contemplated but ordinary informed consent processes cannot be satisfied. An independent, multidisciplinary Committee can provide consistency, manage conflicts of interest, and ensure that any authorisation is demonstrably risk-proportionate and centred on the proposed donor's welfare.

We consider the Committee may have particular value in low-risk circumstances and in marginal cases where the proposed donor demonstrates a clear, consistent wish to proceed, but their decision-making capacity is uncertain, fluctuating, or insufficient to meet typical consent standards. We do not offer a

position on where the appropriate boundary should ultimately be drawn for higher-risk donation, but emphasise that any framework would require an exceptionally stringent threshold and robust safeguards.

5.6 Best Interests Framework

We support **Proposal 21** using "best interests" as the protective lens, applied in a clearly risk-proportionate manner with a correspondingly higher threshold as risk increases.

We consider the factors in **Proposal 22** an appropriate minimum set. To operationalise a risk-proportionate approach, we suggest three refinements. First, the Committee should explicitly characterise the proposed donation's risk profile and consequences for the donor. Second, the Committee should explicitly consider the risk of undue influence and be satisfied that there has been independent clinical assessment and independent psychosocial assessment. Third, where the proposed donor can express a view, the Committee should place substantial weight on evidence of clear, consistent and contemporaneous wishes to donate.

We strongly support the safeguard in **Proposal 22** that the Committee must not authorise removal where the proposed donor has consistently expressed unwillingness.

5.7 Committee Approval Requirements

In response to **Question 14**, we consider Committee oversight an essential safeguard wherever donation is proposed from an adult who lacks decision-making capacity, or where capacity is sufficiently uncertain that ordinary informed consent requirements cannot be satisfied. Within our scope, this includes living solid organ donation and donation pathways undertaken to enable transplantation (including haematopoietic stem cell donation). Even where risks are lower than solid organ donation, these pathways involve intentional intervention and meaningful burdens, and in our opinion would benefit from the independent scrutiny offered by the Committee.

We acknowledge that a requirement for Committee approval may be disproportionate in a narrow class of circumstances involving negligible incremental risk and no additional intervention undertaken for the purpose of donation (for example, use of residual clinical samples incidental to the person's care where the proposed use is clearly disclosed and subject to appropriate governance). Any such exception should be tightly drafted and should not extend to donation pathways that involve an intentional procedure, pharmacological mobilisation, anaesthesia, or other material risk undertaken solely to enable donation.

5.8 Committee Composition and Structure

In response to **Question 15**, we support a single national Committee or national panel model. This ensures consistent reasoning across jurisdictions and concentrates specialist expertise for a low volume, high complexity activity.

The Committee membership should include: clinical expertise in transplantation (with members not involved in the proposed recipient's care); independent psychosocial expertise; ethics expertise; and legal/governance expertise. The panel should have capacity to co-opt additional expertise where required (including cultural, linguistic, or disability-specific expertise) and ability to convene urgently where clinically necessary.

6 Research Use of Human Tissue

6.1 Living Participant Research

We support the ALRC intent to legitimise broad and unspecified consent for research use of tissue from living participants (**Proposal 32**). In contemporary research practice, the full range of future uses is often not known at the time of collection, and overly specific statutory consent requirements risk constraining ethically approved research without a commensurate gain in participant autonomy.

From an operational perspective, the key implementation risk is duplication. Consent processes for research use of human tissue are already governed in detail by the National Statement, including the role of Human Research Ethics Committees (HRECs) in assessing whether proposed consent is adequate for the research context. If primary legislation prescribes consent content, it is likely to (i) drift from the National Statement over time, and (ii) inadvertently create rigid rules that do not fit different research models (single-project studies, platform studies, and biobanks).

We therefore support a high-level legislative stipulation that consent for the research use of tissue from living participants must be obtained and documented *in accordance with* the National Statement, with HREC oversight as the practical safeguard (**Proposal 32** and **Proposal 34**). Consistency is better achieved by drafting legislation to align with the National Statement and the Australian Code for the Responsible Conduct of Research (the Code), rather than attempting to restate their detailed requirements in statute (**Proposal 34**).

6.2 Participants Who Lack Capacity

We support the ALRC safeguard-rich pathway for tissue removal from children for research purposes, modelled on s22B of the *Human Tissue Act 1985* (Tas) (**Proposal 35**). In our view, this model appropriately enables legitimate paediatric research (including low-risk tissue sampling relevant to childhood disease) while protecting children through parental consent, HREC approval, and explicit limits around risk and burden.

In response to **Question 28**, we support an equivalent approach for adults who lack decision-making capacity, provided it is clearly confined to minimal risk and minimal burden tissue removal within HREC-approved research under the National Statement. This should be authorised through consent by a legally authorised substitute decision-maker applying a substituted-judgement approach (reflecting what the person would have wanted, so far as can be known), alongside the National Statement's existing requirements for research involving people with cognitive impairment.

6.3 Deceased Donation Research

We support creating a clear statutory pathway for deceased donation of tissue for research (**Proposal 36**). Our principal operational concern is that consent requirements framed around "intended research use(s)" risk becoming unworkable in biobank models and time-critical donation settings, and may unintentionally increase family burden at the worst possible time (**Proposal 36**(5)(d)).

This is particularly salient for biobanks integrated with deceased donation pathways, including the ADTB. In that setting, families are approached in the context of a broader donation conversation and are already managing a high information load in acute grief. For instance, ADTB currently supports projects

ranging from immunology to organ preservation to AI-assisted histopathology. Requiring coordinators to explain each project at the time of consent would be operationally challenging and ethically questionable. It risks either discouraging families from research donation through overload, or pushing programs toward fragmented, project-by-project tissue collection models that multiply (rather than reduce) the consent burden on families.

Operational clarity would be improved by aligning deceased research consent with the National Statement's established approach to biobanking. Donors (or authorised decision-makers) can consent to donation to a biobank for future ethically approved research, subject to appropriate governance and HREC oversight. Legislation should therefore avoid prescribing the informational content of research consent in deceased donation, and instead require that consent processes and downstream use occur in accordance with the National Statement and the Code (**Proposal 34** and **Proposal 36**). This preserves a workable pathway for both single-project donations (where specific project information can be provided) and biobanks (where broad categories, governance safeguards, and accessible project information can be provided without overwhelming families).

6.4 Withdrawal Rights

We support principles that enable transparency and withdrawal from *future* research use where tissue remains identifiable and has not yet been used (**Proposal 33** and **Proposal 37**). To be workable, these rights must reflect practical limits already recognised by the National Statement. Once tissue has been de-identified, distributed, or used in completed analyses, withdrawal cannot be fully implemented without undermining research integrity.

Legislation should reinforce, not compete with, HREC-approved withdrawal processes.

6.5 Research on the Recently Deceased

We support an explicit enabling pathway for research on recently deceased bodies outside schools of anatomy, subject to HREC approval (**Proposal 39**). This area is increasingly relevant to transplantation and surgical innovation (including procedural development, device testing, and donation pathway research), but requires clear safeguards to maintain separation between end-of-life decision-making and research interests.

Consent pathways should be clear and time-efficient, while avoiding pressure on families in the immediate period after death determination, particularly where organ donation discussions may also be occurring.

6.6 Secondary Use of Stored Tissue

In response to **Question 29** and **Question 30**, we support the general principle that identifiable tissue should not be used beyond the scope of original consent without further consent, unless an HREC-approved waiver applies. The practical solution is to make explicit that secondary use is permitted where (i) samples are not identifiable or re-identifiable, (ii) an HREC has granted a waiver consistent with the National Statement, or (iii) reasonable attempts to contact the individual or authorised decision-maker have failed.

6.7 Biobanking

In response to **Question 31**, **Question 32**, and **Question 33**, we do not support creating new stand-alone legal rules or a dedicated regulator for research biobanks. Research biobanking is already comprehensively governed through institutional governance, HREC oversight, the National Statement, and the Code. Adding a parallel legal regulatory layer would be duplicative and inhibiting.

Our preference is a coordination approach led through nationally endorsed guidance (for example, National Health and Medical Research Council-developed biobanking guidelines), with compliance leveraged through ethics approval expectations and research funding requirements, rather than through a new licensing regime.

6.8 Accessing Stored Tissue

In response to **Question 34**, we support a limited right for individuals to access stored tissue where it remains identifiable or re-identifiable and has not yet been used. This recognises that some individuals retain legitimate interests in their tissue, but the right must be framed around practical feasibility. Once tissue is consumed, processed, or irreversibly de-identified, there may be nothing retrievable or linkable to return.

Operationally, biobanks are not resourced to absorb open-ended retrieval and preparation work. Where access is feasible, it is reasonable that the requesting individual bears the direct costs of retrieval, preparation, and transport, analogous to cost-recovery models used for other administrative access rights. Legislation should also clearly distinguish between (i) withdrawal of consent for future research use (leading to disposal of unused identifiable tissue where practicable) and (ii) access/return of a remaining identifiable sample, as these serve different participant objectives.

7 Prohibition of Trade and Cost Recovery

7.1 Reward Prohibition and Permitted Cost Recovery

We support a nationally consistent prohibition on exchanging human tissue for reward (**Proposal 40**). We also support the ALRC distinction between prohibited "reward" and legitimate reimbursement and cost recovery. In clinical practice, donor reimbursement and documented cost recovery are routine and necessary across retrieval, transport, processing and distribution. The core rules should target inducement and commercial dealing without disrupting these pathways.

7.2 Key Clinical Pathways Needing Consideration

The Australia-New Zealand Paired Kidney Exchange Programme (ANZKX) should be clearly addressed within the core rules rather than treated as an activity requiring ongoing workarounds through exemptions (**Proposal 43**). The law should state plainly that the ANZKX matching and exchange structure is not "reward" (**Proposal 40**), with associated payments limited to documented delivery and logistics costs.

Comparable clarity is needed for interstate and Australia–New Zealand organ sharing arrangements. The Australian Intestinal Transplant Service, hosted at Austin Health, provides intestinal transplantation services for all of Australia and New Zealand. This and other clinical pathways routinely involve recoverable costs for clinical care, retrieval teams, aviation and courier logistics, preservation equipment and packaging.

The framework should make clear that recovery of these documented costs supports safe clinical delivery and does not change the underlying altruistic nature of donation.

7.3 Regulatory Pathways and Supply Chains

We support **Proposal 42**. The interaction between regulatory-aligned exceptions and the "reward" prohibition (**Proposal 40**) must be straightforward for clinicians to apply. The framework should not create uncertainty for regulated transplantation and cell-therapy supply chains where cross-border collection, processing and release are routine. This is especially relevant for allogeneic haematopoietic stem cell transplantation, where registry-mediated sharing arrangements depend on reliable cross-border logistics.

7.4 Guidance on Cost Recovery

We strongly support National Regulator guidance on cost recovery (**Proposal 44**). This guidance should draw a clear operational line between permissible reimbursement and impermissible inducement, with practical examples.

Living donor expense reimbursement is a priority example. Guidance should align with existing national supports (for example, the Commonwealth Supporting Living Organ Donors Program) and address travel, accommodation, and time away from work, so that donors are not left financially worse off for an altruistic act.

For research, the ADTB relies on cost recovery to function. Per-sample fees support procurement, processing, storage, transport, administration and governance oversight, enabling access for ethically approved research without commercialising donation. Guidance should make clear that such models are appropriately treated as cost recovery and not as prohibited trade.

7.5 Exemptions for New or Uncommon Situations

We support a mechanism to exempt specific exchanges from the prohibition **Proposal 43** and **Question 37**. In implementing this, we would prefer a model that draws on existing national governance and clinical standards rather than creating a parallel approvals system.

7.6 Cross-Border Conduct and Imported Material

We support in principle giving extra-territorial effect to the prohibition of trade (**Question 35**). The practical requirement is that extra-territorial legislation targets inducement and commercial brokering without creating uncertainty for legitimate cross-border clinical or research activity. This includes circumstances where an overseas-resident living donor travels to Australia to donate under established clinical safeguards.

We also consider **Question 40** and **Question 41** relevant because we use, and contribute to, international stem cell registries. We support national efforts to ensure imported human material is ethically sourced. Any mechanism should not introduce delays to timely patient access, particularly where products are sourced through established registry and quality-governance arrangements.

7.7 Advertising

We support **Proposal 45** as a targeted restriction on advertising that encourages or brokers exchanges involving prohibited reward (**Question 38**). The restriction should not interfere with appropriate donation education, public awareness activity, or donor and recipient stories that do not involve inducement.

8 Information Sharing, Privacy and Data

8.1 Disclosure and privacy

We support **Proposal 46**, **Proposal 47** and **Proposal 48**. These proposals appropriately enable clinically necessary information-sharing whilst protecting against non-consensual public disclosure.

We support the consent-to-disclosure framework in **Proposal 48**, with an important operational clarification for deceased donation. Consent to donation should be understood to include authorisation for the information-sharing necessary to determine suitability, allocate organs, and support recipient safety (including post-transplant traceability and adverse event management). Requiring a separate consent step for routine clinical disclosures could add complexity in a time-critical pathway without adding meaningful privacy protection. Separate consent should remain required for public disclosure, media engagement, or any disclosure not necessary for safe donation and transplantation.

The disclosure framework should also expressly accommodate publication in academic journals of appropriately de-identified clinical information (including case reports and case series) where necessary to build the evidence base for emerging donor utilisation practices and safety signals. It is often impracticable to seek additional, post-hoc permission for publication once donation has occurred, particularly where information can be presented without making an individual reasonably identifiable. Where there is residual risk of re-identification, that risk can be managed through HREC oversight. The legislation should include a clear permission pathway where de-identification standards are met and HREC approval is in place.

8.2 Access for donor assessment

We strongly support **Proposal 49**. From an operational perspective, the key drafting issue is ensuring the authority clearly operates across the practical information sources required in the pathway. This should expressly support access to relevant Commonwealth-held systems where needed to assess suitability and confirm donation status, and to private health services, cancer registries, medical imaging and pathology providers (both public and private). The provision should avoid unintentionally confining permission to a narrow "treating team" concept that does not reflect how DonateLife, hospitals, specialist clinicians, and custodians interact in practice.

8.3 National data

Improved national data infrastructure is essential for service planning, safety monitoring, quality improvement and equity analysis **Question 42**. We support reform that strengthens national coordination and access to fit-for-purpose datasets, provided it avoids duplicative data capture and does not create perverse incentives that discourage appropriate use of higher-risk organs in recipients with limited alternatives.

From a donation and transplantation perspective, priority national datasets include: (i) end-to-end pathway activity and utilisation measures (referrals, family approach and consent rates, offers, accept-

ance/decline decisions, discards and documented reasons); (ii) timeliness measures that directly affect organ viability; (iii) donor screening outcomes and adverse events (including donor-derived transmission); and (iv) outcome measures that are risk-adjusted and interpretable in context, so that transparency supports improvement rather than risk-avoidance.

In relation to biobanking, the ADTB supports a minimum national inventory dataset that improves visibility of sample types, volumes and associated health data captured by the biobank (**Question 42**). The ADTB already contributes to research impact through sample distribution tracking, but lacks standardised mechanisms to capture downstream research outputs systematically. National data infrastructure could support this capability across the biobanking sector.

We support mandatory reporting of a minimum necessary dataset (**Question 43**). Voluntary reporting predictably produces incomplete datasets, limiting the ability to identify unwarranted variation and equity gaps. Mandatory reporting should build on existing national collections rather than creating parallel reporting channels. Additional resourcing is also required as transplant services already struggle to fulfil reporting requirements due to inadequate staffing and local information technology resources.

If mandatory reporting is adopted, compliance and assurance should focus on data quality systems rather than broad inspection-based approaches (**Question 44**). A proportionate model would use clear data definitions, automated validation, routine data quality review, and targeted follow-up where anomalies suggest incomplete reporting.

9 Compliance

We support the general direction of the Discussion Paper towards compliance mechanisms that promote clarity, practical guidance and integration with existing clinical governance, supported by proportionate audit rather than punitive enforcement **Question 45**. In transplantation, compliance frameworks must preserve accountability while recognising the time-critical, information-limited and judgement-based nature of key decisions.

A compliance approach that is ambiguous or overly punitive risks creating a suppressive effect on good-faith clinical decision-making. The predictable consequence is inappropriate risk aversion in donor assessment and organ acceptance, reduced utilisation, and downstream widening of inequities for patients who already face longer waits.

We therefore support a graduated, risk-proportionate model that targets deliberate misconduct and repeated governance failures for the strongest enforcement response, whilst supporting good-faith practice through clear "safe-operating" pathways and accessible guidance.

For obligations that are predictable and protocolisable (core consent steps, documentation requirements, specified authorisations), compliance is best supported by clear articulation of minimum requirements. For obligations that inherently involve judgement (donor suitability assessment, clinically necessary information sharing), the framework should enable timely decisions without fear that reasonable professional judgement will be second-guessed with hindsight.

10 Implementation

We support staged implementation of the proposed reforms (**Question 46**). Staging should prioritise reforms that remove current barriers to safe, timely organ utilisation, while allowing adequate time to develop national standards and infrastructure for more complex reforms. Some proposed reforms will create additional state and Commonwealth resourcing requirements for donation, retrieval and transplantation services.

We would prioritise early implementation of:

1. Death determination and contemporary DCDD practice. Early legislative resolution of the statutory-clinical mismatch affecting contemporary DCDD practice, including NRP, should be prioritised (**Proposal 10**, **Proposal 11**, **Proposal 12**, and **Proposal 13**). Delayed reform prolongs a material barrier to contemporary practice.

2. Access to donor-relevant information. Early implementation of clear authority for practitioners and DonateLife staff to access and share information for donor identification and suitability assessment (**Proposal 49**).

3. Research alignment with the National Statement. Early alignment of research-related provisions with the National Statement would preserve effective, HREC-governed research workflows including biobank models like the ADTB (**Proposal 32** and **Proposal 33**).

Subsequent phases can address reforms requiring more extensive harmonisation or new national operational arrangements, including Committee-based pathways (**Proposal 20**, **Proposal 21**, and **Proposal 22**) and enhanced data capture arrangements (**Question 42** and **Question 43**).

The ALRC has asked whether there are urgent needs for reform not addressed in the Discussion Paper (**Question 47**). From our perspective, the key areas of urgency have been incorporated into the proposals and questions we have addressed throughout this submission.

11 Conclusion

The Review of Human Tissue Laws is a valuable opportunity to establish a nationally consistent, technology-neutral framework that supports donors and families, protects participants, and enables safe, contemporary clinical practice and ethically governed research. We have aimed to provide clinically grounded input focusing on areas where legal clarity and consistency will produce practical improvements.

If implemented in a staged manner that prioritises reforms with immediate operational impact, the proposals have the potential to reduce avoidable delays, support appropriate clinical judgement, and strengthen public confidence in donation and transplantation.

ACTER would welcome the opportunity to provide further clinical and operational input as detailed implementation pathways, standards and guidance are developed.

A Glossary

ACTER	Australian Centre for Transplantation Excellence and Research
ADTB	Australian Donation and Transplantation Biobank
ALRC	Australian Law Reform Commission
ANZKX	Australia-New Zealand Paired Kidney Exchange Programme
DCDD	Donation after circulatory determination of death
HREC	Human Research Ethics Committee
MSUD	Maple Syrup Urine Disease
NRP	Normothermic regional perfusion
OTA	Organ and Tissue Authority
TSANZ	Transplantation Society of Australia and New Zealand
VICTORS	Victorian and Tasmanian Organ Retrieval Service