Australian Law Reform Commission: Review of the Human Tissue Laws

Joint response from the **Biotherapeutics Association of Australasia (BAA)** and the **Eye Bank Association of Australia and New Zealand (EBAANZ)** regarding **Discussion Paper 90, published Nov 2025.**

*Response endorsed by **Vision 2020 Australia**.*

6th February 2026

Dear Dr Toews,

On behalf of the members of the Biotherapeutics Association of Australasia (BAA) and the Eye Bank Association of Australia and New Zealand (EBAANZ), we welcome the opportunity to provide this formal response to Discussion Paper 90 (the Paper).

Our members acknowledge and support the Commission's efforts to modernise Australia's human tissue laws. We believe the review is moving in a positive direction, including recognition of inter-jurisdictional movement, international movement and importation, the need for coherent national oversight, and clearer treatment of costing models and ethical safeguards that are not consistently addressed in current laws and arrangements.

While Appendix 1 provides our response to the Commission's questions, we highlight three issues that are particularly important for eye and tissue banking, biobanking and the biotherapeutics sectors, and which we consider necessary to ensure the resulting framework is ethically coherent, operationally workable, and economically sustainable:

1. The Designated Officer role remains an essential governance safeguard at the point of recovery and should be modernised, not abolished.

2. Future-proofing and managing commodification pressures requires clear separation between durable legislative principles and agile regulatory standards administered by an empowered national regulator.

3. Cost recovery and prohibitions on trade must be aligned with concurrent Commonwealth reforms (including Prescribed List Part B work on costing standards) to avoid unintended commodification, legal uncertainty, or economic settings that disadvantage domestic altruistic banks relative to commercial imports.

We offer the following expanded comments:

1. Designated Officer – retain and modernise, rather than abolish

The Paper indicated that the Designated Officer (DO) role should be removed. While we appreciate the limited value of this role in organ donation, for the tissue banking sector the DO plays an important role in verifying the activity of tissue banks across facilities, particularly where banks are separate to the state health department. Some version of this role or function is essential to remain, otherwise it may have unintended consequences for tissue bank access to donors and facilities, and therefore the sustainability of our services. We would welcome re-design or delegation of the role to

ensure that these safeguards and supports remain; however, would not support its removal in entirety.

2. Future-proofing, innovation, and commodification pressures

We support future-proofing as a core objective. The tissue and biotherapeutics sector is evolving rapidly—through advanced processing, novel storage methods, bioengineered products and increasing global supply chains. These developments continually raise boundary questions about what constitutes 'tissue' versus tissue-derived products, what level of processing changes regulatory expectations, how altruistic donation principles are protected when materials are processed, and what safeguards are required to prevent commodification as the boundary between donation and commercialisation becomes blurred.

If these questions are resolved only through primary legislation, the framework will either become outdated or inadvertently exclude legitimate innovation. Conversely, if legislation is overly broad or vague, it will create uncertainty for banks, researchers, and manufacturers. We therefore recommend a clear separation between durable legislative principles (including prohibition on reward/trade; respect for donor autonomy; transparency) and agile regulatory standards administered by the proposed national regulator, with an explicit mechanism for regular review of emerging technologies and commercial models.

3. Cost recovery, trade prohibition, and alignment with concurrent Commonwealth reforms

We support the Paper's focus on clarifying the boundary between lawful cost recovery and prohibited reward or trade in human tissue. However, this work is occurring concurrently with Commonwealth reforms to Prescribed List Part B, including development of costing standards and associated debates about benchmarking and benefit-setting. These parallel streams risk producing an ethically coherent framework in principle but an economically unworkable framework in practice, unless the concepts of 'cost recovery,' 'profit' and 'trade' are aligned across the legal and funding settings.

The Part B consultation record indicates strong support for developing costing standards, alongside significant concern about simplistic benchmarking. Banks do not share uniform cost structures (including regional/low-volume services), and benchmarking that compresses benefits below real costs creates perverse pressures: either banks operate at a loss (unsustainable), or prices drift into contested territory that may be characterised as 'profit' or 'reward.'

There is also a material risk of asymmetry between domestic not-for-profit banks operating within an altruistic model and imported/commercial products operating under different ethical and regulatory regimes. If domestic banks are constrained by a narrow cost-recovery interpretation while imports are not subject to equivalent ethical sourcing transparency and cost scrutiny, the system will inadvertently favour imports and undermine domestic altruistic donation capacity.

We recommend that new human tissue legislation: (a) define 'cost recovery' to include legitimate direct costs and necessary overheads (quality systems, compliance, storage infrastructure, wastage/expiry, and resilience capacity); (b) distinguish cost recovery from profit in a legally clear and operationally auditable manner; and (c) empower the national regulator to set/update costing standards, verify cost recovery through audit, and oversee

ethical equivalence of imports. We note positively that concurrent government reviews are beginning to recognise that a degree of regulatory asymmetry—supporting domestic altruistic banks while requiring high transparency for commercial/imported products—may be ethically justified and practically necessary; the ALRC framework should support rather than undermine this emerging direction.

BAA and EBAANZ representatives are available to assist the Commission with their review and welcome the opportunity to meet to discuss further and participate on the Review's working panel group. We can be contacted [redacted]

On behalf of our members, thank you for this opportunity.

Regards

Chris van Diemen (BAA Chair)

Pierre Georges and Dr Heather Machin (EBAANZ co-Chairs)

Submission Endorsement

This submission has also been reviewed and endorsed by Vision 2020 Australia, who are the peak body for eye care in Australia. They have over 48 members across community, acute, tertiary, and academic levels of eye care and contribute to eye care development internationally. Their mission is to prevent avoidable vision loss and improve opportunities and outcomes for people living with blindness or low vision. Vision 2020 Australia are strong advocates for continued sustainability and growth of the tissue banking sector and recognise the valuable work banks do across the country supporting patients in need of transplants.

Appendix 1: Response to Commissions Questions.

Theme	Q#	Question	BAA-EBAANZ Response
The objects of human tissue laws	1	Do you agree with the objects listed in Proposal 5 for human tissue legislation?	Yes
	2	Aside from the objects set out in Proposal 5, should new human tissue legislation include other objects?	-
Promoting Equity	3	Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?	Yes. This needs to encompass both equitable access to becoming a donor and equitable access for recipients and other end users to access lifesaving/enhancing donations. In doing so, the Commonwealth needs to support providers, such as eye and tissue banks, to meet these goals because the sector can only sustainably provide equitable access through inter-jurisdictional collaboration.
Removing Barriers	4	If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (Question 3), what are the specific barriers that new human tissue legislation needs to address?	There is a need for new legislation to remove barriers. Barriers are varied, and in many cases driven by operational or system constraints. However, reiterating the importance of addressing them within the objects of the legislation will support continued sector evolution and inter-jurisdictional collaboration. For example: 1. Cultural/language barriers (CALD); 2. Logistics (e.g., distance between donors and bank and bank and end-user); 3. Donor pool access, management, and referral processes vary between the jurisdictions which can cause inequity in public access to donation services and deliver disadvantages to Banks by limiting access to donors and/or their relevant medical history;

			4. Greater definition of what is included and excluded (e.g., other materials collected during the retrieval to qualify the donation should not be treated in a restrictive manner under the state, federal laws); 5. Cost 5.1 Regulatory costs for providers to meet TGA requirements – including the cost to facilitate TGA audits and product implementations and the infrastructure/operational costs that the bank providers incur meeting the requirements. (We note that this is not a cost burden experienced by organs, yet organs receive a lot more support in comparison to banked services); 5.2 Cost to deliver tissue interstate - as some banks with specialised services bear the brunt of additional transport costs, which are difficult to quantify and address due to changing demand cycles (e.g. surgeons move to other locations, thus the 'cost assumed' by the banks if they integrate that cost into their service is never accurate); 5.3 Support the development of 'support services' e.g., for specialist testing laboratories who test blood and/or medium preservation samples from the banks. Support them to offer reduced non-profit prices to the banks and/or improved turnaround time and/or support more to take on cadaveric testing by supporting them to fund the TGA license requirements; and

			6. Create a level playing field to support Australian non-profit banks to operate sustainably, by introducing regulations that monitor imports and the for-profitisation of the donation.
Definition of human 'tissue'	5	How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?	The label/field should be changed to better reflect the origin of products that are now (and into the future) utilised within Australia. It must also reflect the bunching together of service types, e.g., those that operate under similar mandates (e.g., similar regulations). We support a broad, future-proofed definition, for example, labels such as Substances of Human Origin for transplant, training, and/or research, or similar, would better reflect the the Australian model. This would encompass human tissues, cells, and other materials such as blood, gut microbiome, and human milk While such labels are accurate, there needs to be consideration on the interpretation and understanding of the label by the general public. The Act should remain durable while the national regulator clarifies technical demarcation points as science evolves. It is noted that there are differing layers of regulation applied to different human donated materials. An example of this around the transplantation of organs vs human tissue. Traditional human tissue products (ocular, bone, skin, cardiac) are under the regulatory framework of current

			human tissue legislation as well as the safety and efficacy regulation of the Therapeutic Goods Administration. (TGA) Organs on the other hand, like tissue are regulated under current human tissue legislation, and have limited safety and efficacy legislation under the TGA. We acknowledge this, however there is a requirement for a degree of future proof of human material legislation and therefore must be a consideration of a future state. An example of this is around organ perfusion, where in the future there may be processes introduced which blur the boundary between the currently nonregulated organ safety and efficacy arena and the currently highly regulated tissue safety and efficacy area. We present this example to demonstrate how the sector has and continues to evolve, and therefore the label and the legislation must guide but not enclose and restrict the transition of human donations, their definition of management and/or their use as medical science and the health service evolves.
	6	In new human tissue legislation, should the word ‘tissue’ be replaced with another label?	See response to Q5. *FYI, change 'cornea' to 'eye' in the final report, as other parts of the eye, e.g., sclera, are transplanted, and vitreos fluids are used in research*.

Exclusions from the definition	7	Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?	We support the inclusion of banked donations, regardless of their intended end-use across transplant, training, and/or research. For example, existing donations such as eyes, tissues, cells, blood, microbiome, and milk. We extend this to also encompass emerging practice across banked perfused organs, cellular therapies, and bioengineered solutions. The legislation must support recovery of non-coerced donations from interested Voluntary Assisted Dying (VAD) donors, however there must be a separate VAD legislation to manage the overall VAD process. We encourage separate VAD legislation/practice to in turn support donation.
Consequences of a determination of death provision that applies for all purposes	8	If the proposed determination of death provisions apply for all purposes rather than only for the purpose of human tissue laws, will there be any adverse and unintended consequences in areas of law other than human tissue laws?	While death definitions are outside of our scope of expertise, we note that any definition needs to consider public interpretation and understanding because some parts of the community continue to find donation taboo. Any definition needs to be clearly understood to help dispel fears and urban myths around death and donation.
Maintaining national consistency	9	To maintain national consistency, which of the following statutory locations or approaches would be most appropriate for provisions relating to the determination of death, assuming that these provisions apply for all purposes?	-
Additional safeguards	10	Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?	In addition to Proposal 14, we recommend the following safeguards: 1. Clear guidelines on situations where a person who has registered to become a donor on the Australian Organ Donation Registry (AODR) is denied the chance to fulfill their wish of becoming a donor

			because there is no Next-of-Kin (NOK) available and/or listed (e.g., they are estranged from their family). In this instance, support from an alternative authorised decision maker from the donor's immediate network (e.g., a friend) would help to advocate for the donor, to ensure their wish is respected. 2. Consideration that if Australia were to develop a national Regulatory body, then several aspects discussed in this discussion paper could be the responsibility of that body to develop and maintain, rather than specific detail be included at the Act Level, though consideration of what needs to be in the Act vs. managed by the Regulator would need to be thought through and future proofed. For example, the Act could indicate that consent is required whereas the regulator defines what consent must include and ensure adherence by the provider.
Donation of tissue by children	11	Are the considerations listed, and the guidance provided, in Proposal 19 appropriate? Are there additional considerations that the Committee (Proposal 17) should take into account?	See Proposals 17 and 19. Broadly yes for the living donation contexts, but a committee-style prospective approval is operationally impractical for routine deceased donation given the time-critical recovery. Oversight should occur through standards, accreditation, and audit rather than delay-creating approvals.
	12	Aside from the removal of tissue from a child for use in research (Proposal 35), are there situations where the removal of tissue from a child should not require approval by a Committee, and where new human tissue legislation should require only	While there is a value in a committee review for living donors (child or adult) and those with diminished capacity (e.g. intellectual disability) who are potentially considered for donation during their life (e.g., for research) and their involvement might require evaluation, if there is an

		parental consent, or individual consent where a child has decision-making capacity?	effective system in place then a committee may not be needed routinely. Similarly, while a committee may be functionally and operationally manageable for living donation, e.g., because time is not a factor, for deceased donations, however, a committee would be a hindrance and barrier to donation. This is because often, end-of-life donations are time sensitive. Currently, for research donations, in most instances the donation is only recovered and allocated to research projects that have human ethics and organisational governance approval – and they meet the biobanks requirements, so the review process on its appropriateness has already been determined. Therefore, a committee for each donation is not required. In terms of time sensitivity, we provide an example of eye donation. Routinely, eyes are recovered within 24 hours otherwise the cells start to deteriorate, and therefore, the donation may not be optimal for transplant or research. Therefore, waiting until a committee meets would be too late for the donation's viability, and operationally impractical. Recovery should take place in a timely fashion, as per the protocol of the bank (which should have a governance/ quality system/ regulator review process in place), and only after informed consent has been granted. If these things are in place, there is no need for a committee for routine recovery regardless of child or adult.

Donation of tissue by adults who do not have decision-making capacity	13	Are the considerations listed, and the guidance provided, in Proposal 22 appropriate? Are there additional considerations that the Committee (Proposal 20) should take into account?	The listed considerations are appropriate.
	14	Are there situations where donation from adults who do not have decision-making capacity should not require approval by a Committee and where new human tissue legislation should require only consent by a legally authorised substitute decision-maker?	See response to Q#12 as there are crossovers here.
Composition of committee	15	What is an appropriate composition for a Committee under Proposals 17 and 20?	While the purpose of the committee would need to be determined and/or indicated where it sits, a committee composition may include: 1. donation experts (e.g., living and/or deceased pathway donor representatives); 2. donation banking experts - for that relevant organ or tissue (e.g., a tissue person for a tissue, an organ person for an organ); 3. persons with lived experience (either as a donor/donor-representative and/or recipient); 4. end users (e.g., transplant surgeon - relevant to the donation type - e.g., a tissue, and/or researchers, 5. persons of diverse backgrounds as appropriate, and as required; 6. ethicists, pediatric specialists, community leaders, and/or religious representatives as required; 7. community leaders with relevant qualifications in this field. 8. For all, except people with lived experience, recency of practice.

			Note: Banked services already have in place governance committees and other services specific to their service. Banked services already use the Act, regulations, state-based health policy directives and in the instance of research, human ethics, and governance approval. Many also sit on existing committees. With this in mind, a new committee would need to confirm its validity, demonstrate its purpose, and seek to prevent overlap and redundancy.
Consent and authorisation for removal of tissue after death	16	Proposal 23 removes the role of the Designated Officer, who under current legislation is required to authorise tissue removal when a person dies in a hospital. Do you agree the role of the Designated Officer is no longer necessary? If you agree that Designated Officers are no longer necessary, please explain why. If you think the Designated Officer role remains necessary, please explain why.	We believe that the Designated Officer role is necessary. Please see our opening statement on the importance of the role on page 1 and 2 of this submission.
	17	Does Proposal 23 strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach?	Yes, however, consideration regarding the determination of the authorised decision maker is required to accommodate and reflect contemporary society.
	18	Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required?	The Act should be broad, simply stating that consent is required. This will allow for adaptability across verbal, written and/or e-consent forms. The new national regulator would be positioned to take on the role of defining the terms of the consent, to ensure it meets contemporary community expectations and is adapting to changing consent types (e.g., first and third person, future inclusion

			of donation use in bioengineering and/or biobanking practices).
Authorised decision-maker	19	How should the hierarchy of decision-makers in Proposal 25 be tailored to the deceased tissue donation context?	Hierarchy needs to be considerate of contempory Australian society and cultural differences, e.g. 1. first-nation's use of other community members and elders in their decision making. 2. a situation where a potential donor has separated from their spouse, but their spouse remains their legal NOK. This is problematic and can cause distress to families and friends as well as the donation staff involved in navigating this family dynamic. 3. A situation where a potential donor's NOK is overseas and/or non-contactable, but their next available family member/friend is willing to help respectfully fulfill the donor's wishes. Mechanisms to allow for non-traditional/conventional NOK are essential in Australia today. This should especially be done when the donor has expressed their desire to donate through the Donation Register. For the donor coordinators on the front-line working with the donor and/or their NOK and extended friends and family, the above examples can be problematic in the current legislation. It is not their place to interfere or get involved in family dynamics. Therefore, steps to address this in the up-dated legislation will support the coordinators, ensuring they can perform their role effectively and support both the donor and their NOK/family/friends.

	20	How should new human tissue legislation address situations where authorised decision-makers with equal decision-making status in the hierarchy in Proposal 25 disagree about whether to consent to donation?	See our response to Q#19. The default should be to prioritise evidence of the deceased's known wishes (including registration) and provide clear processes to determine who is best placed to represent those wishes. The sector is very cognisant of not adding additional distress to the family and authorised decision makers in complex family dynamics. Where there is informed disagreement between authorised decision makers of equal status then it is not appropriate to force an outcome that is contrary to either decision makers position.
Pre-mortem interventions	21	Is the definition in Proposal 26 an appropriate definition for pre-mortem interventions? Why or why not?	The definition seems appropriate. *FYI: For the final report, we recommend that this proposal says 'viability of tissues' or similar, rather than 'organs'.*
	22	We have heard that it is sometimes necessary to conduct a minor procedure such as a blood test to determine a person's suitability to donate tissue after their death, and that it may not be practical to obtain prior consent. Should new human tissue legislation contain an exception to the need for consent? If so, how should the exception be expressed, and what limits should there be on it?	This is not universal. For example, tissue donors can use either post-mortem bloods they recover at the same time they recover the donations; and/or bloods that were recovered by the hospital 7 days prior to death (these bloods may not have been recovered for donation purposes and instead may have been recovered as part of the donor's routine care). This is outlined in the regulations. Regardless of pre and/or post-mortem recovery of blood, this should be automatically listed on the donation consent form as a procedure that may occur as a consequence of consenting to donation. Such information should be outlined on the Australian Organ Donor Register, DonateLife's FAQ sections, VAD and public information pages, and bank pages/documents to

			ensure transparency, and to improve public understanding that this is a normal requirement of the donation process.
	23	Should new human tissue legislation have any additional safeguards for the use of pre-mortem interventions beyond the need for valid consent? If so, what safeguards should it have?	Safeguards should ensure there are no conflicts of interest and that the authorised decision maker does not provide consent for procedures that may cause undue stress, pain, or discomfort to the donor. Similarly, the professional performing the consent and/or recovery should not be the one receiving the donation (e.g. surgeon/researcher) without there being a system in place to ensure the ethical validity and equitable allocation of that donation (e.g. they must be reviewed and tracked through a centralised eye and/or tissue bank, and/or biobank) prior to the person consenting and/or recovering receiving the tissue for their research project.
Coronial consent to donation	24	Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?	Successful tissue donation relies on close cooperation between tissue banks and the coronial system. Human tissue laws should reflect the importance of tissue donation to the community in the granting of coronial consent relating to donation. The anecdotal but strong evidence in favor of a reduced complex grief response from families is also worth considering in this context.
Authorisation for non-coronial post-mortem examination	25	Should new human tissue legislation allow for an individual to provide their own consent while alive to a post-mortem examination?	Yes. Add it to the Australian Organ and Tissue Donation Register to prevent the person having to navigate other registers.

	26	Should new human tissue legislation contain an exception to the need for an authorised decision-maker to provide valid consent to a post-mortem examination; for example, if the authorised decision-maker cannot be located?	Yes, though note our comment above that in current practice, if a NOK cannot be located, the donation would not proceed. For this to occur, then, wider changes about continuance without NOK would be required.
Use of tissue removed during a post-mortem examination	27	Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?	The legislation should require consent for all donations that are not for the purposes/benefit to the donor (e.g., not required for post-mortem determination of death). We do not think the legislation should specify what types because as practice changes, the sample types will change. Therefore, keeping it broad, through ensuring a consent is signed, will future proof any donation. For example, this exception exists in NSW - and involves the use of small samples, i.e., blocks swabs etc., for validation and accreditation functions - for example for use as a histology standard or similar process validations the reliance in a practical sense should be gathered from pathology laboratories.
Consent and authorisation for tissue removal for research – living persons	28	Should new human tissue legislation contain a similar provision to Proposal 35 that allows tissue to be removed from adults without decision-making capacity for use in research? If so, what safeguards are appropriate to enable legitimate research while protecting participants from harm and exploitation?	See responses Q#12 and 14 above.
Consent and authorisation for use of tissue samples	29	Should there be a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes that they did not consent to?	Ideally yes when general consent does not adequately explain unusual use, e.g., use in animals. Further specific consent should be undertaken. We note however the practical complexities of this with banked research samples from living donors, e.g., when:

			1. time has lapsed and the living donor subsequently dies. 2. time has lapsed and the living donor and their NOK have died.
	30	If a legal requirement for consent is imposed (Question 29), should there be exceptions to it? If so, what exceptions should exist?	No exceptions - consent at start should be all encompassing.
Regulating stored tissue collections	31	Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?	Yes. This needs to be consistent across stored donations for transplant, training, and research purposes as our Custodian duties to the donor are the same regardless of their end use. There are, however, differences between use for transplant vs. use for training/research, and the latter should not be restricted or hindered by the former. Therefore, use for training/research should not be regulated by the TGA.
	32	Would it be beneficial to have national regulation, guidance and oversight for: a. research biobanks that store and/or distribute human tissue or human bodies; or b. educational collections of human tissue?	Yes, for both. This would be beneficial to the donor to ensure respectful management of their donation as well as support the system, and access itself, as it has been demonstrated that this will accelerate research and development across healthcare, which is beneficial for all.

	33	If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:	Yes. We are in support of this proposal. In addition, steps to prevent and reduce 'clinician/scientist pop-up' biobanks would be beneficial. This is out of step with contemporary biobank practice and binds the donation to one user who is not always familiar with the expectation of donor management. Therefore, there should be steps to move all researchers to access through a biobank. We do acknowledge however that there are no funds to support biobanks to meet these objectives, and research grant/philanthropic funding is limited, so researchers are often unable to pay the full reimbursement cost. Therefore, the government would need to support this as part of its support towards improving R&D and med-tech in Australia and support banks through infrastructure support. Without these steps, biobanks would not be able to meet the requirements, and R&D in Australia will stagnate.
Accessing stored tissue	34	Should new human tissue legislation provide that individuals have a right to access their stored tissue? If so, what should 'access' entail in this context and who should be granted the right?	Withdrawal of consent for use of donated tissue is a standard premise whether the tissue has been donated for use in a clinical setting or for use in training/research. Generally current practice is to discard/dispose of the tissue sample and other associated data. The ability to access and potentially have tissue returned to a donor or other designated individual (i.e., NOK) is a difficult question to answer. We appreciate that there may be cultural and other reasons why donated tissues may need to be returned to

			the donor or other designated individuals and encourage the review to determine appropriate scenarios for this to occur. Scenarios for consideration by the Commission: • that some living donors may want to change banks or research institutes so they would require the tissue to be transferred. • A donor may want their autologous tissue back. • A donor may want to have some of the tissue released to a researcher not associated with the bank or research institute.
Giving extra-territorial effect to the prohibition	35	Should the prohibition on exchanging human tissue for reward have extra-territorial effect? If so, what would be the best mechanism to achieve this? For example, an amendment in new human tissue legislation, or an amendment to the Criminal Code Act 1995 (Cth)?	We agree that Australian entities should not trade for reward overseas when they are not permitted to do so within Australia. Oversight from the National Regulator will support this effect and ensure the ethical operation of all suppliers of human tissue in Australia, including ensuring their export and import activity (if relevant) is held to the same standard.
Exceptions to the prohibition on the exchange of human tissue for reward	36	Are the exceptions to the prohibition of the exchange of human tissue for reward listed in Proposal 42 appropriate?	The Australia donation for transplant system already adheres to a non-payment-to-donor model. This should remain and be further supported. We are unaware of any payment of living research donors. Any exchange of human tissue under this exception should be subject to the same safeguards for commoditisation. The requirement for trade to be conducted aligned to Principle 10 of the NHMRC ethical guidelines (i.e., not sold or exchanged for profit)' or Principle 5 of the WHO Guidelines should be explicit for all suppliers. Any

			arrangement for reward should only be permitted where safeguards exist to ensure the health and safety of donors and recipients, and mitigate the risk of any perverse effect, or moral hazard associated with reward for donation. A prohibition of trade that accommodates, on specific exception, reward for donation that has a net positive impact is sustainable and flexible.
	37	a. Are the factors listed in Proposal 43 that the relevant decision-maker must consider when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue appropriate?	Yes. As set out in Proposal 43, this could be to allow the national regulator to grant exemptions from the prohibition provided that the application and decision-making processes of the national regulator are transparent.
		b. Should the relevant decision-maker be required to consider any other factors when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue?	Yes.
Prohibiting advertising	38	Is there a need for a prohibition on advertising that is broader than the prohibition in Proposal 45?	We are supportive of the refined prohibition of advertising as described in Proposal 45. While legitimate public awareness campaigns and communications are not captured by the prohibition, advertising for excepted tissue products should continue to be monitored for potential negative impact on public perception of donation and transplantation. For example, advertising for the sale of excepted tissue products should be targeted such that they cannot be misinterpreted as commodification by the broader community. This may not be a necessary broadening of the prohibition of advertising (Question 38), but monitoring conducted by the National Regulator (or similar) in accordance with the objects of the legislation (Proposal 5).

Trade	39	If a prohibition on advertising is imposed in accordance with Proposal 45, should this prohibition have extra-territorial effect?	While legitimate public awareness campaigns and communications are not captured by the prohibition, advertising for excepted tissue products should continue to be monitored for potential negative impact on public perception of donation and transplantation.
	40	Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced?	Yes. This is a moral imperative. The legislation can outline this by stating this is a core function of the national regulator.
	41	If a prohibition is legislated of the kind described in Question 40(a), or reporting requirements introduced of the kind described in Question 40(b), should new human tissue legislation include a mechanism to exempt importations of human tissue from the prohibition or reporting requirements, and if so, what factors should be considered as a basis for justifying an exemption?	There should be no exception to reporting requirements or as reasonably required by any entity to demonstrate compliance with requirements of legislation and prohibition of trade, including were related to importation. This could be examined and/or monitored by the national regulator.
Improving access to data	42	We have heard there is a need for data from donation agencies, tissue banks and other tissue product manufacturers, distributors, and sponsors to better understand the demand for tissue and inform future policy development.	Yes. This is imperative for the long-term sustainability of the sector. We agree that improved reporting is required for activities such as the economic and financial activities of suppliers, importation of tissue, and the use and transplantation of human tissue. A focus on quantifying sector activity, sustainability and self-sufficiency. Data should be used to review and ensure compliance with the legislation, and to support ongoing public education, awareness and trust in the tissue sector. This should be addressed in the legislation but the function of this should rest with the national regulator.

	43	In relation to Question 42, how should the data be reported?	It should be reported to the national regulator. The framework of that can be developed by that team, e.g., quarterly reporting and determination of data sets.
	44	In relation to Question 43, if you support mandatory reporting, should the National Regulator (or alternative) have the power to conduct mandatory inspections of records?	If the new regulator is set-up appropriately, they will automatically review records as part of their audit review. The transplant banks already prepare the majority of activity data for the TGA (with all but one providing it to the national data collector), so it would be easy for them to report the same general data to the new national regulator without a significant administrative burden to the banks. Biobanking has no such mandatory system in place, though biobanks who have ethics committee approval to recover and allocate donations to research projects automatically collect donor data as they must report it to their ethics committee. Therefore, similarly to transplant banks, biobanks have the capacity to report their data too.
Compliance mechanisms	45	Do you have views about the best mechanisms to encourage or enforce compliance with the obligations and prohibitions that we are proposing should be included in new human tissue laws, regulations or standards?	Set up the new national regulator. Banks must be licensed through the regulator to meet these non-TGA aspects (e.g., ethics, cost recovery models and so on). This will help to enforce the expectations set out by the legislation. Explicit criteria and potentially a defined business structure should be required as prerequisite to an application for exemption to the prohibition of trade in Human Tissue. It should be an explicit application and means tested evaluation rather than being an assumption with no enforcement capability. In this way it can be assured that business commences correctly and determining any deviation from this would be commensurably easier.

Discussion paper timeframes	46	Do you have views on the timeframe/s within which the reforms set out in this Discussion Paper should be implemented, or on how the implementation of these reforms could be staged or prioritised?	The priority, after the implementation of the new Acts would be the establishment of the new national regulator. Once established, most issues outlined in the Paper would be addressed.
Are other reforms urgent?	47	Is there an urgent need for reform of human tissue laws that we have not addressed in this Discussion Paper?	Proposal 46 should ensure that all hospitals, banks, and the coroner are included - the current proposal just says DonateLife which is not realistic as there are other providers in the space. Public opinion on death and related processes seem to have shifted over the last 20 years. There is a residual tendency for the sector to make protective decisions and buffer the impact of conversations and even realities when engaging with families. Indeed, in its worst case this can extend to imposing decisions through the operation of concept bias and similar discourses. In support of this reform, a broad canvassing for public opinion to test the assertions of the experts engaged thus far would be highly advisable.