Donor Families Australia Inc (DFA) response:

Australian Law Reform Commission, Review of Human Tissue Laws: Discussion Paper (2025)

Introduction

Thank you for the opportunity to provide a response to the Discussion paper. The inclusion and respect of the voices of people who have experienced being a Donor Family, to improve the experience for others is vital to **"promote and uphold public trust" (ALRC, 2025. p.145)** in organ donation regulation and practice in Australia. DFA is the only organisation in Australia wholly dedicated to advocating for and supporting Organ and Tissue Donor Families. DFA, an independent, unfunded NGO, has for over 11 years represented over 1,000 members nationally. DFA propose that Australia's consistently low organ and tissue donation rates will rise if Donor Family recommendations to change Human Tissue Laws are heeded.

DFA accept the Review Terms of Reference aims and principles but **strongly argue the first** (not last) principle **must be to "promote and uphold public trust" (ALRC, 2025.p.145).** To be effective, the ALRC review must extend beyond the Terms of Reference which seek to **"harmonise and modernise human tissue laws" (ALRC, 2025. p. vii)** to privilege the **urgent need to *humanise*** Human Tissue Laws to empower public trust.

DFA thanks the ALRC for the inclusion of Donor Families, Recipients and the Community into this review, and for valuing our input. Ultimately the Community holds access and acceptance of this very important lifesaving/life improving process. The **regulators and associated organisations** that provide governance and create practice outcomes **are accountable to build community trust**. We hold the ALRC responsible to ensure that the updated Laws **reflect community expectations,** are enforceable and enforced, and are **consistent with the National Health and Medical Research Council (2025) Ethical Guidelines** for cell, tissue and organ donation and transplantation in Australia.

DFA look forward to collaborating with the ALRC to ensure contemporary, compassionate, transparent and effective Laws support altruistic Australians wishing to help others through organ and tissue donation. Please don't hesitate to contact me with any questions or clarification.

Sincerely,

[redacted]

Bruce McDowell,

Chair, Donor Families Australia

26th January 2026 Email: admin@donorfamiliesaustralia.org

Reform Proposals: National regulatory framework

Proposal 1:

b) HTA should be regulated by –

- Uniform Commonwealth legislation. An Independent national regulator that oversees and advises all states and territories is to put in place an agreed legislation for all. **The regulatory authority and regulatory practice must be compliant with the National Health and Medical Research Council Ethical Guidelines for cell, tissue and organ donation and transplantation in Australia (2025).**

- States and territories must be required to enact the new legislation without delay and will be guided by the National Regulator to support ongoing changes as seen necessary.

Proposal 2:

a) The regulatory framework established should be structured so:

- Individual legislations should acknowledge a central regulatory body that is authorised to work with the states and territories and other entities as appropriate.
- any necessary corresponding detail is dealt with by delegated legislation, or codes of practice, guidelines or standards set by the National Regulator (Proposal 3) or other responsible agencies or organisations.
- Any centralised agency will incorporate Donor Families and Recipients who will represent other Donor Families and Recipients recognising the value of healthcare consumers.

Proposal 3:
National Regulator

c) With changes:

DFA proposes independent regulation and accountability of the OTA by an independent national regulator who must provide **accountable oversight, supervision and scrutiny of the OTA, and all the agencies and interests involved in the procurement, distribution and use of human tissue**.

- This new regulator must be accessible and accountable in communication with the community. DFA would like to see the new National Regulator accountable to the Federal Minister of Health.

- A process of co-creation of the law, polices, guidelines and education is recommended to enhance community acceptance and trust. Selection of these individuals will not be done by the centralised agency or politician, rather selection will be via the Donor Families and Recipients organisations themselves using transparent approaches.

- DFA have no trust in the communication, processes and practices of the OTA. Following over 10 years of disrespect, failure to respond, or to respond in ways that are silencing of DFA and most Donor families, the inconsistent application of Laws and policies and complete lack of accountability for a declining consent rate- despite significant public spending points to the need for independent oversight of the OTA. The regular omission of DFA and labelling as 'pathological grievers' have contributed to mistrust of this public institution. DFA have presented evidence to numerous inquiries regarding the OTA and other organisations involved in the application of Human Tissue Laws whose leadership in practice appeared to have little knowledge or understanding of the legislation that they worked under and its application.

- We recommend an **Ombudsman position** to be created specifically within this new regulatory body to address communications, concerns or complaints raised by the public. This role is essential to address contemporary issues and to minimise the actual and potential risk and perception of conflict of interest to promote and uphold community trust at a national level.

Examples of comments received:
"The Organ and Tissue Authority (OTA) should play not part in any National Regulator.
It historically has been the main contravener of legislation. With its history Donor Families would not be comfortable with this organisation having any controlling role to play. If trust is to be restored and maintained the OTA needs to play no part in legislation. It has shown in the past to have little regard for legislation. Where DFA has correctly challenged the OTA on legislation the OTA merely put up barriers and carried on with its own interpretation of legislation."

"DFA would see this centralised body's powers and functions as:

1. create binding codes of practice and standards;
2. provide legislative guidelines for medical practitioners, researchers, and organisations that retrieve, store or use human tissue;
3. accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors;
4. monitor, collect data, investigate, **audit cost recovery principles**, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.
5. Oversee complaints. This body needs to be separated from the OTA or other providers as most complaints will be directed at the service providers. There cannot be a conflict of interest."

Proposal 4:

Implementing a national legislative framework.

- DFA sees the National Regulator responsible for overseeing workable legislation that is enforceable and enforced and on behalf of the states and territories. The states and territories will be accountable for their individual legislation but will be legally accountable Federally, to agree to contemporaneously or within an agreed timeframe, agree to directives by the National Regulator with any recommended changes for the present and the future.

Proposal 5:

Proposal 5 on reading by DFA, has omitted consideration of the Senate Committee Inquiry into the Human Tissue Laws and other Inquiries (*available on request) **on the need to humanise as well as harmonise the Human Tissue Laws as they stand to enhance community trust.**
The recently updated **National Health and Medical Research Council Ethical Guidelines for cell, tissue and organ donation and transplantation in Australia (2025) are also difficult to identify in the proposal.**

Respect for the donor (it is their tissue that is involved): and respect for the impact donation has on those they love should be first and foremost as an object of the human tissue laws to enhance community acceptance and trust.
DFA argue, the Ethical Guidelines (NHMRC, 2025) must be incorporated into all aspects of the drafting and enacting of these laws.

DFA seek a much greater emphasis on the first principle espoused in the guidelines (NHMRC, p.39), respect for the dignity of donors - including potential donors. **The guiding principle remains that a donor should never be treated solely to achieve the goal of transplantation for another individual.**

- **Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes an ethical violation and is exploitation.**

This Ethical Guideline for Organ and Tissue Donation (NHMRC, 2025) definition of respect for dignity (NHMRC, p, 39) needs to be the object of the human tissue laws first point (a). It must encompass the recommendation that Donors should have a voice. For all Donors have done in contributing to the wellbeing of others, they have earned the right to be heard. The Donor's Family needs to be able to represent their loved ones, and they need this right protected by Australia's human tissue laws.

Donor Families remain oppressed or silenced from speaking and sharing loved one's stories under contemporary law. They should be able to speak freely about their loved one and the wonderful gift they have given. Consenting Families should be able to have the freedom of speech to share their story with anyone they so wish including the Recipient of the donation if the recipient agrees.

It is critical the legislation recognises that without community trust and confidence, there will be no donors. Without Donors the benefits of transplantation and research cannot legally occur. You can have the best doctors and hospitals but if you don't have Donors, it cannot progress.

Proposal 5 b. is described as 'Increase access to human tissue, and to the benefits of human tissue donation, transplantation and use'; it should be written and **considered in the context of the Ethical Guidelines. These Guidelines take precedence**. In DFA's experience, this point will be used and misused by the medical, governance and political interests as a way of justifying existing legislation which was drafted without formulated without Donor Family consultation. It is so important that legislation and ethical guidelines do not contradict each other. How access is to be increased should be articulated so we can see it will not disrespect Donors.

Q.1
No DFA does not agree with the list in Proposal 5. The ethical requirements for respect of the Donor should be at the top and the list and be the basis of all other points as mentioned earlier.

The legislation must respect the Donor and the Donor Family. A real example is the response to the Issue Paper. (So this sentence does not get redacted due to legal requirements, no names will be mentioned). A Donor Family response to the Issue Paper had the name of the Donor redacted, the words 'her', 'she', 'daughter's name', 'she was 19', and 'our daughter' were all redacted. All efforts were made to dehumanise the Donor Hero.
If the public were made aware of this at the time of giving valid consent i.e. you cannot mention your loved one again after you leave the hospital, one must wander what the response would be. The system knows this so currently makes a point of not telling families prior their donation decision, only after the retrieval has occurred. **Trust is a critical element within organ and tissue donation. Either change the legislation to give the Donor a human face or transparently tell the families, as**

part of being informed prior to valid consent being given, that henceforth they are not to mention their loved one and the gift they have given again.

Q2.
Answered above.

Proposal 6:
Agreed, providing the law, its objects and the new regulator are values and rights based consistent with the Ethical Guidelines (NHMRC, 2025) are incorporated all aspects of this work; always of power imbalance and conscious of the voices of those who are most impacted and ensuring their voices are supported in ways that are transparent and equitable. Require transparency in all aspects and publicly reportable outcomes.

Q3.
Removing barriers is critical for equity and fully supported. This is inclusive of recognising the donors (if living) and their families (if deceased) need to be fully informed about what is to happen to their loved one during retrieval of tissues. Information equity is critical. Respect and care must be provided to recognise inequity in all its guises. Typically, terms such as 'informed' are used to describe community engagement in decision-making. What does informed mean? It can mean something different to every medical staff member who approaches a family. There needs to be a very clear legal definition of what is meant by informed that is understood and accessible to all those who make decisions that have long term consequences on themselves and their families regarding human tissue donation, transplantation and its use. Questions of literacy, language and disability barriers as well as fatigue and factors associated with mental stress need to be considered. A widespread community education program as well as health professionals is critical to mitigate some of this inequity.

Q4.
As above.

Proposal 7:
Q5.
b). Is more respectful in recognising the connection to person- the human body.

Q6.
c) Is preferred as it is seen as much clearer. It is important to be as accurate as possible to avoid confusion.

Proposal 8:
This proposal is supported.

Proposal 9:
This proposal is supported.

Q7.
They are all 'human body cell, organ or tissue'. Should not be excluded.

Proposal 10:
Noted

Proposal 11:
This proposal is supported.

Q8.
This should be used for all deaths and purposes of the law for consistency and clarity for professionals and the public. Unintended consequences are more likely to occur if appropriate education and regulatory oversight does not accompany this change.

Q9.

a) A uniform determination of death act for clarity and consistency.

Proposal 12
Needs additional specification including the professional qualifications and process of accreditation/accountability to ensure respect and dignity for the deceased. Regulators must specify professional standards and guidelines to be complied with when addressing the meaning of "accepted medical practice". This proposal needs further clarity and information to be fully supported.

Proposal 13.
There needs to be independent oversight- the use of a Designated Officer role to ensure death is appropriately confirmed, the case does not require coronal oversight or has appropriate approvals and that there is no 'deceit' Ethical Guidelines (NHMRC, 2025) 'conflict of interest' or other harms of failure to communicate appropriately with family members.

Proposal 14.
Reforms relating to the donation of tissue by living adult donors

- 2 c.) Has 'been informed' needs to be clearly defined and by whom?
- 'Decision- making capacity needs to be clearly defined and who assesses it?
- 'Valid consent' as per Ethical Guidelines (NHMRC, 2025)
- 2 d.) More information should be given around 2. d The Donor needs to be made aware of how the tissue will be managed, including if packaged i.e. will it be referred to as 'product' and on sold as such and how the sale process will be conducted.
- Any ongoing obligation to the Living donor for notification of outcomes related to the donated tissue and its implications?
- Can living donor/ recipients meet each other – where does this fall in legislation? Please ensure this is transparent and aligns with the Ethical Guidelines (NHMRC, 2025)
- The Donor should be informed of their rights to meet the Recipient if both parties consent. Currently (to our knowledge) there are no legislative restrictions with both parties meeting as they have rights over their personal decision making capacity and respective information. Both parties should be told whether the law will allow them to meet if they both so desire. This is a question that the Donor may not ask at the time of decision-making, because they could rightfully assume that this would be possible. It may arise as an issue after some time has lapsed.
- 3. – Valid consent. This needs to include, the consent must be current, as mentioned in the Ethical Guidelines (NHMRC, 2025).

Q10.
As discussed above.

Proposal 15.

This is supported; however, it is noted that many young people are ‘Gillick’ competent at a much younger age and it is important to consider the ethical consequences of not enabling them to be responsible for their own decision-making- especially in circumstances that may have long lasting consequences to their emotional, spiritual and physical wellbeing. This should be factored into the law.

Proposal 16.

It is inconsistent for a child aged 16 to be deemed an adult in the donation of blood but not for other human tissue decision making. This needs to be justified more fully or changed so that the law recognises adult decision making at the same age.

Proposal 17.

Noted.

Proposal 18.

Supported.

Proposal 19.

Noted.

A strongly held view of a Donor family member responds to Dot point 7 the availability of an alternative donor:

“THIS NEEDS TO BE REMOVED. THE DONOR IS NEVER TO BE TREATED AS A SOURCE OF TISSUE. THIS DOT POINT IS UNETHICAL.”

Q11.

The relationship between the child and carer also needs to be considered and assessed in this proposal.

This does generate concern that important relationships and spiritual/ social needs- especially in diverse situations are not being properly assessed that could lead to harm.

Q12.

The legislations should be flexible enough to enable lifesaving interventions if the circumstances prioritise this. Time appropriate to support health and well-being and limit harm.

Proposal 20.

Align with Ethical Guidelines (NHMRC, 2025)– use consistent name of the guidelines.

committee composition- balanced approach.

Proposal 21.

Supported, but must align with– Ethical Guidelines (NHMRC, 2025).

committee composition- balanced approach ensuring authentic representation that understands the perspectives of the potential donor. Donor family members.

Proposal 22.

Noted

Q13.

The relationship between the proposed donor and carer also needs to be considered and assessed in this proposal.

This does generate concern that important relationships and spiritual/ social needs- especially in diverse situations are not being properly assessed that could lead to harm.

Q14.

The legislations should be flexible enough to enable lifesaving interventions if the circumstances prioritise this if it is believed that is what the individual would want to do. Time appropriate to support health and well-being and limit harm.

Q15.
committee composition- balanced approach ensuring authentic representation that understands the perspectives of the potential donor. Donor family members.

Proposal 23.
Issues: the use and authority of the Australian Organ Donor Register and how this register may be used in determining the soon to be deceased/ deceased wishes. This is a cause of great concern to DFA as the consent on the Register is unlikely to have ever been given the information listed in 4. C) and d).

The over-riding view from DFA is so much must change in the management of the AODR for registrations to be considered 'valid consent'.
At present there are concerns following the advocacy from Transplant Australia and others that the Register information should override all other known information about the person that is held by the family.
Questions arise regarding ignoring family concerns and understandings of the deceased wishes and decisions. Questions include 'How would it be enforced? Security guards?' 'What about the moral injury to staff required to implement it?'
It would have very negative media outcomes.
The harms of 'cold calls' to families by unknown callers needing more information for donation, and distress for family members required to providing 'valid consent' with no preparation with information or support.

Protection is required for Families of potential donors in the requesting process that is highly medical, and which needs to align with ethical guidelines.

4. C) **not acceptable.** The challenge includes: under what conditions? What does voluntarily mean? Possibility of coercion- what does it look like? How is humanity recognised and the sacred life passage of death- including time to say goodbye; the perception it is heavily medically based. People doing the requesting- seeking valid consent need to be appropriately skilled.

- Capacity of a grieving, shocked, stressed person- how is the capacity informed and what are the checks and balances?
- The information to be given needs to be clear and accurate. Where is the tissue going? Public/ private?

Q16.
No. Do not remove the Designated Officers.
Designated Officers are vital, and their roles must be standardised and supported nationally to help support community trust and concerns of poor medical practice (for example in the US) and conflict of interest. Very important for transparency and dependence. Can't be involved in the care of either patient. Must be universal across states and territories.

Q17.
Yes, if applied following the ethical guidelines.

Q18.

This needs to be valid consent, recognising the fact that there must be equity in being able to fully engage in the information acknowledging not all people are literate or able to communicate in English. Consent along with NHMRC ethical guidelines.

Victorians can give consent right up to their death, but how informed are these people? This is important for clarity and transparency.

Proposal 24.

Yes, but make sure families are involved. Obliged to consult families.

Proposal 25.

Please read Section 13 of the Health Care Decision Making Act 2023 (NT). Then apply to Q.19 and Q 20.

Keep Designated Officers. In addition, there should be Designated Officers for coronial cases for people who die outside hospitals and similar institutions and wherever donation occurs.

- Essential all states and territories are the same for consent/ authorisation frameworks and law for deceased tissue donation.

- A ‘cold call’ is a lot to take in when a request for donation is presented- needs protections, support, boundaries and accountability.

- There needs to be accountability to complying with ethical guidelines.

- Clarify terminology and educated the community: make sure there are enough Designated Officers.

- Designated officers need to be consistently accountable for independent assessment that the requirements of consent and the law are met including ‘cold call ‘tissue donation’.

- Consistency required and humane “Valid consent” clinical guidelines- must be written.

- Registering a ‘no’ has great legal weight. Clarify the role of substitute decision makers
- The risk of blaming families for refusals to donate when poor practice may be at the root of the refusal. Moral Injury is a risk for families and staff if the process is done poorly.
- Current HTA don’t need consent of NoK if it is known what wishes are, and this is distressing to families.
- Consider the impact on regions and locations without DL staff access and ensuring access to donation?
- Commercial use of some types of tissue donation.
- What is “nature and effect?!” This needs to be defined.
- Families must always have the final say. Drs and nurses do not want to have a confrontation over a dying or deceased patient. Care needs to be taken in drafting the law that the potential for coercion of families is removed.
- DF view is often don’t sign the register, have your family make the decision at the time.
- New approach needed- stop blaming families. Is very coercive statement. DonateLife Clinical guidelines should align with NHMRC statement.
- 7.10: Those donating need to know where the tissue will go and what it will be used for.

Q19.
As decided and articulated by the potential donor.

Q20.
Unless there is written advice, it should not proceed.

Proposal 26.
Q21.
It needs additional information to explain why.

Proposal 27.
Q22.
It should cause no harm to the donor of their loved ones. It should be written is a way that is more accurate- in organ donation it is around 250 mls of blood and very obvious and sometimes traumatising for the family watching if they were not involved in the decision-making process.

Q23.
It should cause no harm to the donor of their loved ones.

Proposal 28. And 29

- Respectful, dignified treatment of deceased body is a given.
- Need consistency and regulatory oversight.
- Clear qualifications must be stated so the decision makers know.
- This possibly must be known before consenting on the AODR.
- Must pass the 'pub' test.
- Not only dignity, respect.
- A skilled technician / professional must be able to ensure the body is suitable for viewing as requested.
- What are the regulatory safeguards to ensure this happens in practice?

Proposal 29.
Q.24.
Yes. They should be obliged to consider the fact donation is a social and moral good. The potential harms of a failure to agree to the health and well-being of patients. They should also be accountable to make timely decisions that do not inflict additional time in hospital for the deceased and their family, and the occupation of scarce ICU beds.

Proposal 30.
Noted.

Q25.
Yes

Q26.
Yes, so long as there are clear processes that are defined that show that every effort was made to find the decision-maker.

Proposal 31.
Q27.

- Must have consent. It should be included in things like the AODR.

Proposal 32.

Consistent with our previous concerns re ensuring valid consent is only achieved when sufficient information is shared. 2. Valid consent requires the adult who is consenting to have been informed about the nature, effect, and material risks of the removal; **It is important to define nature and effect.**

Proposal 33.

Research: tissue from living persons.

Agree with Proposal.

Proposal 34.

If there are any inconsistencies between new human tissue legislation and the Australian Code for the Responsible Conduct of Research or the National Statement on Ethical Conduct in Human Research, the terms of the legislation should prevail. **This is a problem and as highlighted before, the law must be humane. Legislation should never allow unethical behaviour; ethical outcomes should prevail.**

Proposal 35.

Agree with proposal.

Important that there are clear benefits from research but not compromising- independent committee, independent complaints.

Q28.

Yes. Safeguards should be valid consent sought from next of kin with a committee having oversight.

Proposal 36.

As mentioned earlier in feedback. Nature and effect needs to clearly defined. Does it include who will do the operation, what qualifications have they, where will the operation be done, will there be an exchange of money, how is the tissue packaged i.e. will it be on sold as a commodity/product and will there be regulatory oversite and a complaints process?

Legislation should never allow unethical behaviour; ethical outcomes should prevail, and the law should be written to enable this and be changed if there are ethical anomalies.

- No mention of advice for the family with regard to who will remove the tissue.
- Returning of unused tissue to the family?
- All information should be given prior to consent including all procedures/ research- how it will be used/ to be modified/ sold/ not for profit etc.

Proposal 37.

- Agree with this proposal. Although sound like they are not going to be told and probably won't know they have that right. Discarded but does not state how. This needs clarification.
- No problem with access to stored pathology. Not much benefit of having a right if you don't know you have it. Wording can be improved to allow for that.

Proposal 38.

Who provides oversight and regulation of organisations who are gifted deceased bodies? Agree, needs to meet the requirements of Proposal 23 where Nature and Effect are clearly defined as who will do the operation, what qualification have they, where will the operation be performed, will there be any money changing hands, will it be cost recovery, **what are the laws around owning my loved ones information?**

Proposal 39.

Same as Proposal 38 where Nature and Effect are clearly defined.

Q29.

Valid Consent should be sought for every use of tissue. Implied Consent is not good enough.

Q30.

There should be no exceptions to the requirements as mentioned in Question 29.

Q31.

Legal rules **are** needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks.

Q32.

It would be beneficial to have national regulation, guidance and oversight for a and b.

Q33.

It is so important that these organisations remember that they are dealing with someone's loved one. It is not a product or commodity. There needs to be more control over these organisations to ensure the proper respect is given to the work that they do.

Q34.

Those that gave valid consent should have the right to access the stored tissue. The organisations that take the tissue should never think they own the tissue. The tissue always remains the property of those that gave valid consent.

Proposal 40.

Agree with this proposal

Q35.

Yes, the prohibition on exchanging human tissue for reward should have extra-territorial effect. Australia should not be accepting tissue that has been acquired unethically.

Proposal 41.

Noted. This is not clear.

Proposal 42.

Noted. This is not clear.

Q36.
Noted. This is not clear.

Proposal 43.
Agree with this. The work of the National Regulator (or alternative) in this regard needs to be transparent and open to public scrutiny along with all organisations working in this area. Transparency is essential. The public has a right to know how this sector operates so they can make their own mind up.

Q37.
Noted. This is not clear.

Proposal 44.
Yes. Not just provide guidance but provide regulation i.e. audit the books and penalise where needed. Page 110 11.5 Discussion Paper- 'To maintain public trust and an ethical system, it is important that human tissue donation and transplantation 'are not driven by financial gain', and that the sector is transparent and accountable. But how the HTAs address cost-recovery:

- is inconsistent;
- lacks clarity about what costs can be recovered; and
- lacks oversight to ensure tissue banks are operating ethically'.

The paper recognises the need for oversight but does not give this as a solution in Proposal 44. Oversight needs to be included at Proposal 44.

Proposal 45.
Agree with this Proposal.

- No advertising regarding trade in human tissue, this must be consistent across Australia. The deceased should not become merely 'spare parts'.

Q38.
No within the confines of what the group are aware of.

Suggestion: "Perhaps those wanting to donate an organ whilst alive could be placed on a list rather than have someone advertising that they want one. As a Donor family I do not want to be faced with this. Advertise and promote lists not individuals."

Q39.
If it is possible to regulate outside Australia as well, but no advertising should happen within Australia either by a local or someone from overseas.

Q40.

a) Australia should not be party to unethical behaviour of other countries. Australia should not be encouraging this behaviour by purchasing unethically retrieved tissue.

Q41.

Gaining human tissue for health needs is a gift not a commodity. It is not something that should be farmed or harvested. There should be no exemptions. Australians need to be educated about the need to do more to be self sufficient in ethically sourced tissue.

Q42.

There is a clear need for data to be provided in this area. Transparency is totally lacking now. It is all done under a veil of secrecy, not what this gift deserves.

- Without data you cannot adequately plan or evaluate
- Mandatory reporting with power to conduct checks at any time, NHMRC 'transplant activities to be open to scrutiny.
- Watch financial operations of actors.

Q43.

Data reporting needs to be mandatory and publicly accessible.

Q44.

Yes.

Proposal 46.

Agree

It is important that OTA/Donatelife **understands that the family decision makers ownership of the deceased's information is unconditional.** The decision maker was given the responsibility to give valid consent for retrieval and medical and social information about their loved one, they should be able to decide what they do with their loved one's information, even if that means passing on that information to a consenting recipient e.g. first name of a loved one in a letter to a recipient.

Proposal 47.

Agree. This needs constant involvement between ALRC and co-creation with Donor Families to ensure the legislation is drafted in a humane and trustworthy way.

As this Proposal is about public trust it needs to be promoted more at the front of this paper along with other Proposals involving public trust. This process needs to demonstrate to the community any changes to law is about improving the conditions for the Donor and their families. If we are serious about increasing consent rates, we need to tell the community you can trust the system and it is safe to say yes.

Proposal 48.

Agree.

Proposal 49.

There are some concerns about what information is accessed and why. Critical to ensure it is only as relevant and not shared inappropriately. Examples of some views:

"Not sure how I feel about access to My Health Records."

"Agree, except the Organ and Tissue Authority. This organisation is about policy and not individual health records."

Q45.

- As mentioned at the beginning. There must be a new, independent regulator -not OTA or DonateLife and a total review of the AODR.

A quote displaying the frustration of many,

"The history of compliance with tissue legislation around Australia is that there has been none. All government bodies around Australia have totally ignored legislation. They have even led Donor Families down the same path, exposing them to potential penalties and fines, by not letting them know what the legislation around them says. It is a shameful part of the history of Organ and Tissue Donation. Despite continual examples of contravening legislation there has never been a prosecution in Australia over all these years.

Before we go forward with the topic of Compliance the question must asked as to why has Tissue Legislation been ignored in the past? Could it be the main offender has been the bureaucrats, those that should be upholding and monitoring that legislation. We have been told that the prosecutor of Tissue Legislation is the State Medical Director. Not much chance that they will prosecute themselves. DFA has a letter from one state Health Minister that agreed that the legislation is being contravened but they said don't worry the State Medical Director won't prosecute. That piece of legislation is still in place, and the State Prosecutor still has no intention of prosecuting, and the state government has no intention of changing the legislation. It appears that Tissue Legislation in that state is not taken too seriously.

Going forward it is essential that the prosecutor is not someone that is involved in Organ and Tissue Donation i.e. no vested interests. There needs to be a body that can investigate contraventions of legislation that is not involved in the running of Organ and Tissue Donation.

- This body needs to be able to investigate all legislative contraventions and be independent of the contravener and able to take complaints and respond in a timely effective way.

Q46.

16.2 We have been guided by the following aims and principles:

- improving access to human tissue in Australia;
- providing respect for persons and the human body;
- ensuring equitable participation in and access to donation and transplantation systems; and
- promoting and upholding public trust.

Let us rearrange the above in some order.

1. promoting and upholding public trust.
2. providing respect for persons and the human body;
3. improving access to human tissue in Australia
4. ensuring equitable participation in and access to donation and transplantation systems;

Without the public contribution we do not have Organ and Tissue Donation. Sadly, consent rates are low and are not showing any signs of increasing to past rates. Trust in the system needs to be improved. Any laws around achieving this need to be elevated and implemented accordingly.

Q47.

Enough to do at present.