Donor Families Australia's (DFA) response to Australian Law Reform Commission's Issues Paper 51 May 2025.

Introduction

Thank you for your continual inclusion of Donor Family voices in this vitally important process of addressing the current shortfalls in the various legislations within the Federal, States and Territories legislation on Human Tissue. This is critically important work to humanise and harmonise organ and tissue donation practices in Australia. DFA is the only organisation in Australia dedicated to advocating and supporting Organ and Tissue Donor Families in Australia. DFA has over 1 000 members nationally as mentioned in a previous submission and at an interview.

Consultation with Donor Families is something that is not done well around Australia. Typically, when laws around Donation are changed Donor Families Australia find out about this as an afterthought or when it is too late to have proper input. Recently the Organ and Tissue Authority held a Community Forum that hosted over 250 Donor Families, Recipients and members of the community. This Law Reform process was well under way before the community forum and DFA attendees were surprised and disappointed when they found that not once did the OTA mention the review to the delegates or let them know that they could contribute to help develop future legislation.

Recently the National Health and Medical Research Council (NHMRC) posted on its website the new Ethical Guidelines for cell, tissue and organ donation and transplantation.' A review process that had been ongoing for around ten years. Importantly, these Guidelines will help inform the development of laws that regulate organ and tissue donation. Again, at the OTA's 'so called' Community Forum, this critical update was not mentioned at all despite the impact the guidelines will play in the experience of Donor Families and Recipients whose lives will be impacted by these developments.

It is the strongly held view of DFA members that [redacted] the input of Donor Families and Recipients even when decisions are being made about regulation and practice that directly affect them. So again, DFA thanks the ALRC for its inclusion of Donor Families, Recipients and the Community into this review, and for valuing our input. Ultimately it is the Community that controls this very important life saving/life improving process and the regulators and associated organisations are accountable to the community.

In the response that follows, the DFA response, as a group is presented. I (the author, and Chair of DFA) will submit my personal response to the first 2 questions separately and there are individual submissions from other Donor families who will respond to those questions.

Question 3 and 4e.

When we think about reforming human tissue laws, what principles should guide reform?

To have an Organ and Tissue Donation system that –

- respects both the deceased Donor and their Family, and the Donor's Recipient/s and their Family/ Families.

- Recognises the life saving and improving community contribution of the deceased Donor and their Family.

- Is reflective and mindful of the 2025 NHMRC *Ethical Guidelines for cell, tissue and organ donation and transplantation* as recently published.

- Eliminates any deceitful action from the guardians/ gatekeepers of Organ and Tissue Donation as pointed out by the Ethical Guidelines.

- Ensures all Families have been given all the information and support that they need to make a legally valid consent to donate or decline donation is provided. This should include consideration of rules regarding how the donor can be represented, laws regarding anonymity requirements and expectations regarding contact between donors, donor families and transplant recipients should also be discussed (Ethical Guidelines page 71). That includes the discussion around the respective legislations so that the Family is aware of any potential for fines and penalties. It is hoped that under the revised laws these requirements will be appropriately and compassionately be reviewed to meet community expectations.

- The Donor Register is recognised for what it is only a guidance tool, i.e. "the self-directed nature of joining the registry means that it is not possible to ensure that all those who register have made a fully informed, voluntary, and competent decision to donate". (Ethical Guidelines page 83). It follows that only the Next of Kin (NOK) can provide the information necessary for a legally valid consent to donation. The campaigns of DonateLife where they state it only "Takes a Minute" reinforce this. It must be mandatory that people are fully informed, make the decision voluntarily and are competent to make the decision.

- Donation and transplantation activities and decision-making should be transparent and open to scrutiny, (Ethical Guidelines). A feedback/ complaints mechanism should be publicly available to enable positive and negative feedback.

- The deceased Donor has a right to be heard. That right should fall back onto the NOK to take up. The NOK should own their loved one's body and information unconditionally. This right now, is presumed by NOK. The NOK are currently not told at the time of giving consent that once they give consent, they forfeit control of their loved one's name and information. This DFA believe could be perceived as being deceitful on the part of those in charge of the process and in direct contradiction of the Ethical Guidelines.

- Given the community nature of this therapeutic intervention of transplantation, whenever laws or policies affecting the community and more specifically, Donor Families are being considered, extensive consultation must be carried out. Current practice is to actively block any involvement of Donor Families when important laws and policies are put in place other than carefully selected individuals who represent their own experience and not that of the representative, wider Donor Family experience.

- Transparency and honesty is required in all areas, not just a judgement about what they feel we are capable of handling (NHMRC Ethical Guidelines 2025). So, where staff are worried that the family member is too emotional to understand the consent process they must stop, not change the information they are going to give- or fail to provide information. If we are to truly make an informed decision and one we can comfortably live with staff need to be well educated with humility, empathy, compassion and cultural safety. People making donation decisions should be respected and given all the facts as part of an education process prior to donation, and not at the time of a donation request being asked to understand a complex process- which many health professionals don't understand and be expected to provide informed consent- without regrets.

- Laws should be harmonious across Australia. Whichever State or Territory we reside in should not dictate our rights and how we are treated or discriminated against- we should be able to expect the same care and respect for the donation decision and ongoing care in every state and territory, and not be concerned when making decisions interstate in the case of unexpected death, that the law may differ and we need to find out what that difference is.

- Accountability must be a very strong aspect of these laws. If the relevant government departments, institutions and hospitals are not held to account for following the laws correctly (rather than interpreting them to meet their own needs) then the community will not have their rights protected.

- The priority should be to protect the rights and dignity of the Donor and Donor Family to the right of a peaceful death- which can be achieved if care and respect is shown, despite the reality of unexpected trauma.

- If we are to increase donation rates, we have to better educate the community about the process of donation (prior to being in this decision) and how this will impact their loved one's end of life, and their family grieving process. As a society we do not readily discuss death and dying. The OTA/DonateLife need to be open, transparent and honest and provide all the information in a accessible, transparent manner. [redacted] People really have no idea what they are actually signing up for when signing the AODR. Ambushing families at a time of great stress and grief is not acceptable by taking only the information on the AODR as informed consent. The Register is not the easy panacea for increasing donation that people think. It is lazy governance.

- Does the qualification of criteria for the Transplant List meet the needs of all potential recipients or could it be done differently? DFA is aware of organs that were wasted because there was not a match on the list. What if the match was not yet on the list but someone very close. This could have been their chance. In US Donate Life there is a saying, *'Every organ, every time'*- it is about being accountable for the gift of donation and responsibility of saving lives.

Question 5 Priority Issues –

1. Who should be able to authorise tissue donation when a person dies?

"The Designated Officer can provide authorisation for the removal of tissue **if it is known that the person wanted to donate their tissue**" (Issues Paper point 65). This point is accepted by DFA but with the provisor that the designated officer cannot know what the deceased Donor wanted based on the Register alone. The Donor Register should not be taken as being the only source of knowing what the Donor wanted. The Ethical Guidelines make it very clear that the Register cannot be used as a legally valid consent. If the designated officer said yes to retrieval based on the register alone they would be contravening current law and the Ethical Guidelines and the views of DFA.

The discussion around Families overriding the Donor based on the Registration alone is a troubling one given the Ethical Guidelines make it clear that the Register has too many flaws for it to be used on its own. The ethical guidelines also mention that the Registration should be current, and the discussion should be current. As it stands the Registration data base still includes those given when the drivers licence was used over 15 years ago. Since then, the potential donor could have changed NOK and possibly changed their mind but forgot that they are Registered.

From personal experience DFA has heard "I could not imagine the pain that would be caused by the designated office telling me that they have retrieved all possible organs and tissues from my 19-year-old daughter without first discussing the prospect with my wife (mother of the deceased Donor), myself (father of the deceased Donor) and the Donor's siblings". Not only would that cause irreparable damage to the Family unit, but it would be placing the staff in a very undesirable position of creating trauma. Staff mental well-being needs to be considered here as well, moral anguish is a real risk in these situations. Australian doctors and nurses would not want to be placed in that position where they need to tell the Family what they have done without first seeking their consent to do so.

"The practice of deferring to the wishes of the senior available next of kin is not required by the HTAs or other legislation" (Issues paper point 67). This is a very dangerous position to take. The designated officer would be left open to legal/civil action taken against them. The Ethical Guidelines make it very clear that the designated officer cannot possibly be sure of the deceased Donors wishes by the deceased Donors Registration alone. The only way of confidently knowing the deceased Donors wishes is to consult with the NOK.

The only people who can possibly give a legally valid consent is the NOK. They are the only ones who could possibly know what their loved one wanted. Any deviation from this principle could seriously damage trust in the system. Potentially the Australian public could react negatively to this change of direction thus putting at risk many lives.

The Importance of Public Trust in the framework – *DFA* is aware of those who will not sign up to the Donation Register as they do not trust the government and the law and families and individuals are fearful they will be bypassed in regard to gaining consent to donation. You do not need to be on the Register to donate, which is well known by many, but creates confusion for others- and needs to be made clear.

DFA have heard from Donor Families who have a lack of confidence in an organisation (OTA/DonateLife) that should have been there to protect and support Donor Families. These Families have told us that would NEVER have agreed to donation if they knew they were giving up the basic human right to say the name of their loved one and share that they were a donor, to own their loved one's information and to speak freely. This deception has had long lasting implications. The recent amendment to Federal Legislation sought only to protect the OTA and other administrators, despite clear information that families could also be supported. Please see attached DFA Senate Submission.

Why is there no mechanism of accountability? Eg: The DF/Rec letter writing procedure policy that was jointly worked on with DFA and agreed to by OTA/DonateLife and published on their website [redacted] This failure comes at great cost to both Donor Families and Recipients who put so much time and emotion into their letters but never know whether they have been received. **The family SHOULD NEVER BE BYPASSED.**

Whilst the Register is a great tool it does not meet the criteria for informed consent as per the NHMRC 2025 Guidelines. It may not be current; it's unlikely a medical professional was present to guide them through the process. The self - guided nature does not confirm that proper and adequate information has been reviewed.

No family or medical professional should be placed in a situation where they are arguing over donation/consent at the time of a loved ones' imminent death. Moral distress as it appears in the NHMRC 2025 Guidelines must be a consideration. "Moral distress may be linked to burnout and staff turnover, and to moral injury. Prevention of moral distress is a key component of care for patients, their families and health professionals". This area of medicine can be challenging to work in and requires a special set of skills learnt over time. If families are to be cared for properly it is imperative that we maintain these very valuable members of staff and care for their mental health.

2. Who should be authorised to remove tissue?

- The OTA/Donate Life website states, as at 4/7/25, "Organ and tissue donation surgery is performed like any other operation - in the hospital by a surgeon and their team".

As pointed out in the Issue Paper (Point 71) Not all tissue retrieval is done by surgeons and their team. The Issue Paper has omitted that WA is a state that has legislation that permits tissue retrieval to be done by non-surgeons or medical university educated staff.

[redacted]

If the OTA is to describe details regarding 'by whom' and 'where' in its communications (and as is required by the Ethical Guidelines) it would then need to be consistent discussing tissue retrieval. That is it is performed by a non-medically trained staff member with their team of non-medically trained staff and that the procedure (operation) is conducted in the hospital basement on the mortuary table- which apparently is the truth. At present tissue Families are not told this at the time of providing consent to donation. The Ethical Guidelines make it very clear; the Family has a right to know. Another example of unethical deceptive behaviour.

[redacted]

[redacted]

[redacted] DFA explained that the person in the street would fairly assume 'trained surgical staff' meant a surgeon. The [redacted] indicated that he was content with the wording and saw no need to change it. DFA was not happy with the response, but it further helped to explain the approach used by the tissue banks. DFA took this issue up [redacted] Consequently, the [redacted] has now changed the wording [redacted]

[redacted] does not require the staff involved to have a tertiary education. All training is done on the job provided by others that have been taught in the same way. DFA again applied the 'person in the street' test to the above wording. When you look at "specially qualified" that is another way of saying no medical qualification is required by this person and "highly trained team of health professionals" is another way of saying taught on the job. DFA would suggest that this wording is equally deceptive and therefore unethical and perhaps a cynical response to DFA's original query [redacted] Families of deceased Tissue Donors are not told by whom i.e. name and qualification or where their loved is to have their procedure at the time of being asked to provide consent. If they were told the truth, [redacted]

Organs and Tissues should only be removed by a medical practitioner. Their qualifications must be provided to Donor Families at the time of making their decision. Should a family wish to view their loved ones' body after donation, it's imperative that the removal of Tissue be done in a skilled manner with specialist professional recognition so as not to negatively impact the Family and community trust. This must be consistent across all States and Territories.

Trust and respect are two important influences in Organ and Tissue Donation. When either or both are lacking you will not get the best result for those needing a transplant.

3. How should we ensure potential donors are identified in hospital?

This must begin with comprehensive education of donation/transplantation to our potential new medical and nursing professionals during their education at university. This should be continued in the hospital setting and any setting where donation is possible in conjunction with other skills development. We need to normalise "routine referrals" at the end of life for all people who die and not just in the ED or ICU to capture every potential donor across the whole hospital, and to honour those who wished to donate but couldn't and their families.

4. How should steps and interventions that occur before death be regulated?

The issue of who owns the deceased's body and information is important. The only people who are able to know what the deceased wanted are the NOK- (not the designated officer). Once this is clarified consent for procedures and information would come from the NOK. Investigative steps such as reviewing medical records, possible screening tests and treatments that may be necessary to help donated organs work in the recipient, should be discussed with the NOK as they would be with a patient in the hospital setting.

5. How should donor and recipient information be handled?

Just like all medical information that relates to an individual that information is confidential and should not be passed on without the consent of the person or their guardian to whom it relates. Medical personal should always confirm with the owner of the information as to whether that information can be passed on. At present the confusion is no one currently owns the deceased Donors information. That is a point that is not passed onto to the NOK during the seeking consent for organ and tissue retrieval processes. No one lets the NOK know that when they leave the hospital after giving consent, they have effectively handed over all ownership rights to their loved one's information. The Ethical Guidelines makes it clear that hospital staff need to pass on this information, at the time of seeking consent, for it to be a legally valid consent.

IF the law remains where the NOK has relinquished ownership of their loved one's information when they consent to retrieval you will have a continuation of Families contravening the law as they currently do. DFA has a letter from [redacted] agreeing that Families are contravening the law when they speak about their loved one but stated that [redacted]

DFA is not aware of any prosecutions around the country and yet politicians, government departments and community members have been contravening the HTAs for decades and in the case of politicians and government departments knowingly. Importantly however, veiled threats are used at times to silence families by institutional managers and leaders and to suggest that the individual/ family are contravening law and at risk of penalties. Perhaps a principle should be that the HTAs be taken seriously. Should the Health Department be the best department to police this legislation? As with other privacy laws the owner of information has the right to pass their information or give consent for others to pass their information on to others. That should also apply to the owners of information such as Recipients and in the case of the deceased, their NOK. As with all privacy rights this must be unconditional. This is a basic Human Right and a respect for legacy and should not be withheld from anyone. **Let the deceased be heard**.

Where Recipients have given consent for any of their information to be passed on to the Donors Family that should happen. Staff passing on the information should be comfortable that the Recipient is aware of what are possible ramifications and then pass on. The same should apply for the Donors Family. Where you have both parties consenting to meet that should be enabled by the relevant government department. This is a matter of Human Rights of freedom of association and should see the paternalism around this topic dropped. Fears that Donor Families may be stalkers and have inappropriate behaviours are deeply disrespectful and regardless, there are other laws in place that address ‘threatening’ and ‘stalking’ behaviour for all community members.

“Health professionals must strive to avoid paternalistic decision making, in which their own personal beliefs regarding the proportionality of risks and potential benefits in a particular case are valued over those of the individual patient who is best placed to evaluate this in the light of their personal values and preferences” Ethical Guidelines page 110.

“…when the relevant people involved agree on the disclosure or exchange of specific information, then information may be shared freely without breaching privacy or confidentiality” (Ethical Guidelines page 132).

6. How should tissue removed in post-mortem examinations be used?

At ALL times the Families consent should be sought. If you are not sure if consent is needed that means it is. Public Trust is essential. You cannot go wrong if you have sought consent, you can go badly wrong if you have not sought consent. It is not possible in this paper to know or respond fully to this question, other than to state, that if the need and use of the tissue is fully explained- ideally in public awareness / education campaigns so the information isn’t new, all therapeutic possibilities should be able to be considered. **Donor Families’ wish to support their Donor loved ones in their wish to ease the suffering of others, is a gift of humanity, but they need to know and understand that the gift isn’t abused.**

7. How should trade in human tissue and tissue products be regulated?

DFA asked the Health Department of a state, ‘who is regulating the cost recovery for Tissue Banks as stated in the legislation?’ They responded, ‘the TGA’. DFA furthered the conversation with the TGA who indicated that it is the state’s responsibility. Even though a cost recovery clause may be in current HTA’s, that even though a cost recovery clause may be in current HTAs, it means nothing as it is not being regulated. DFA spoke to a CEO of a Tissue Bank who said the clause means nothing to them as they are a not for profit. Clearly a clause in the legislation, that is unregulated, apparently, ‘without any teeth’. DFA would like it to be made very clear who will be accountable for the regulating and how; and is the regulation applicable to ‘not for profits’ tissue banks? It is also distressing to see donated human tissue described as a ‘product’ and for the TGA to have it under the ‘Good Manufacturing Code’. **Please be sensitive and review and improve the terminology and language used.**

The very heading used in the Issues Paper – ‘**tissue products**’ demonstrates the dehumanisation of the gift given by a deceased Donor Hero. When discussing this topic, it is important that we remember a deceased person generously donated some of their body not a **product**. **Product** implies the commodification of the donation. Language is important. The issue of Trust is at the forefront here, please note: Ethical Guidelines page 48.

On the question of should advertising be allowed with Tissue Donation. **NO**. Again we are talking about someone’s generous donation of themselves, we are not talking about a product.

No matter how much the Tissue donation is modified and transformed it will always be someone's donation and someone's loved one, never a product.

8. What, if any, other issues should we be focusing on in this Inquiry?

DFA advocates that there should be safeguards put into place to protect Donor Families during the decision-making process, to make it easier for them to say yes. It must be recognised that they act of donating their loved one's organs and tissues for many families is a sacrifice, in the way the process is currently approached. It does not need to be like this, and if compassionate care with transparent, appropriately worded information, empathy and supportive care was provided to families we believe many more would agree to donation knowing their loved ones as they were respected.

In one of our members case, *"they had been awake for well over 24 hours"* (receiving the call very late at night and not having been to sleep from the night before)- including 5 hours of travel to and from country Victoria. Were all the staff made aware of this or considering these aspects in the way they approached the family? Have the family had access to food, fluids, their medications if needed- access to their loved one, and most importantly clear information regarding their loved one and their situation?

Regarding sleep alone, and not considering all the other challenges faced by the family, "*this lack of sleep can cause difficulty concentrating, impaired judgement and the similar effects to those of being legally intoxicated. I would be advised not to sign any contract under these circumstances; yet I was expected to absorb new information, understand it and be happy with it at a time of great stress and in brain fog. Does the lack of capacity due to sleep deprivation open the grounds for consent to be challenged? We felt like a rat on a wheel with no way of getting off".*

9. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

Unfortunately, we do not have time to complete this section

10. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

Unfortunately, we do not have time to complete this section. Thank you for the opportunity to provide feedback. We look forward to supporting the review and continuing this critically important work to support Australians wishing to help others through organ and tissue donation for transplantation.

Sincerely,

[redacted]

Bruce McDowell,

Chair, Donor Families Australia

7th July 2025 Email: admin@donorfamiliesaustralia.org

Donor Families Australia INC

Submission

Senate Committee for Community Affairs Inquiry:
Australian Organ and Tissue Donation and Transplantation Authority Amendment (Disclosure of Information) Bill 2023 (Cth)

Board of Donor Families Australia
https://www.donorfamiliesaustralia.org/

Contents

This submission was authored on behalf on the Board of Donor Families Australia
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Preface

Thank you for the opportunity to provide a submission to the Senate Committee Inquiry into the proposed legislation.

Please note:

- DFA were not provided Terms of Reference for this inquiry.
- DFA only discovered this legislation was being presented to the House of Representatives a week before it was passed.
  DFA had received no notification or consultation to enable us to provide advice regarding this legislation.
- DFA have received only a four-business day extension to enable a submission.
- DFA have not had the opportunity to engage widely and consult with our 1000 plus membership when drawing together the evidence, we may have inadvertently missed voices and views, for which we apologise.
- DFA provides evidence that the proposed amendment and its development and passage provides further evidence of a continuing lack of consumer collaboration and consultation in delivery of the national organ donation program.

The evidence we present represents the 10 years of experience gained as our volunteer organisation has worked tirelessly without government funding to provide support, care and information to donor families and others touched by organ and tissue donation decisions. DFA are passionate in our desire for the practice and representation of organ and tissue donation to be done well in Australia. DFA seek to maximize our declining consent rates. DFA believe this can be done by providing excellence in care and support before, during and after the event for donors and decision makers. DFA believe Australia can lead the world in donation for transplantation. DFA wish to collaborate with national and jurisdictional institutions and healthcare providers to co-create practices and care that limits fear, offers compassion and makes it easy for people to agree to deceased donation. DFA believe organ and tissue donation should be a part of normal end-of-life care in Australia.

We commend the Government for their willingness to progress review and harmonization of the Human Tissue Act/ Transplantation and Anatomy Acts, but if amendments are to be made to the Act/s, it is essential that these amendments are appropriate, transparent, acceptable to the community, sensible and importantly, create trust and do no harm.

The purpose of this submission from Donor Families Australia is to share our concerns regarding the unintended consequences to donor families and our support community if this proposed amendment is passed in its current form. Importantly, we also foresee unintended consequences that could negatively impact potential recipients and reduce Australia’s already poor consent rate and organ and tissue donation rate.

Acknowledgement

DFA acknowledge and pay respects to all deceased and living organ and tissue donors, their families and communities who support them. DFA also acknowledge and pay respects to the people who receive or need the gift of organ and tissue donation. DFA offer our love and support to all these communities, connected in such a unique and powerful way, these shared experiences are our gift to humanity.

Philippa's Story

Many in our community are unaware of the process of organ and tissue donation until faced with what is often an unexpected crisis and the impending - or already revealed, death of their loved one. In this vignette, Executive Board member and Secretary of Donor Families Australia Inc., Philippa Delahoy, uses parliamentary privilege to share the name of her husband, and her reflection of donating her husbands' organs. The sharing of stories requires revisiting grief but may also help with the hope that the information will benefit others – a hope that may provide healing. We thank Philippa for her generosity in helping others understand.

A donor family experience with the process of organ and tissue donation

My husband Scott was a fit, healthy 44-year-old when he contracted swine flu. He was admitted to ICU with double pneumonia and placed in a drug-induced coma to be intubated and placed on ECMO (a machine that oxygenates the blood, externally). Tragically, 13 days later, Scott suffered a massive brain haemorrhage that was incompatible with life; this occurred at **approx. 11am**.

I want to share what happened next to the Senate Inquiry so that you can understand the lived experience of consenting to donation and perhaps understand a little of why the donor family community is so important to those who have shared this experience. Organ donation isn't as simple as signing up to a register, there is so much more to this process and so many steps along that way that are too overwhelming for families to continue with consent.

Around 6pm, two donation co-ordinators arrived at ICU to begin the consent process. The consent process consists of many forms to be completed.

Around 8pm, the two co-ordinators and I started to complete the forms. The forms require consent to be given for every organ and tissue type. I recall at one point being asked whether Scott's thigh bones could be donated and for a split second I thought, but how will he walk…such was the level of disconnect between my still healthy-looking husband and the fact that he was brain dead. I was also asked if he had any sexually transmitted diseases, obviously this wasn't a concern, nevertheless it was confronting; can you imagine the same question being asked of a parent consenting for their teenager?

In between these process meetings, I held a bedside vigil with Scott as family and friends came to say goodbye and to sit with me in my grief. During one of these times, the donor co-ordinators came into the room to ask if they could measure Scott to estimate the size of his organs for potential recipients. After I agreed, they proceeded to take out a tape measure and record his measurements; all the time that Scott was still looking fit and healthy.

Finally, **around 3am** the following day, I was told that recipients had been matched and that the donation and transplant teams were in place. Unfortunately, the team decided to wheel Scott away while I was in the bathroom and I had to run down the corridor to keep up with Scott's bed.

In the operating theatre, I sat with Scott holding his hand as his life support was switched off. I was horrified to see the colour drain from his face as his heart slowed and eventually stopped. This took a torturous 5 minutes and I wanted to shout that the Medical team had made a mistake, how could be have survived 2 minutes, 3 minutes, 4 minutes without life support? Eventually, his heart stopped beating, I kissed his now blue lips for the last time and left the operating theatre into the arms of my parents. I'm often asked why I sat with Scott when his life support was switched off and my simple answer is that I didn't want him to leave this earth alone.

Senators, if for a second, you can imagine that instead of Scott, this is your loved one, wouldn't you want to meet, commune, share stories and support people who had been through the same experience? Please find it in your hearts to stop this amendment and put donor families at the centre of organ and tissue donation where we belong.

Background

This legislation is being rushed through the parliament in direct response to legal advice received by DFA in July 2021. DFA brought this advice to the attention of the Commonwealth and OTA. DFA deeply regret that to date, we have been actively excluded, omitted, or silenced from consultation and engagement by the OTA and Commonwealth regarding this proposed amendment to legislation and other matters pertaining to organ and tissue donation practice. Since learning of the proposed 2023 amendment that is now under review, DFA sought further legal advice[1] that confirmed that the legislation would provide more power to the OTA and its agencies and continue to silence and threaten bereaved families of donors, and recipients. This directly impacts DFA and the support that is provided to Australia's donor families and the positive work of educating, role modelling donation and garnering support for organ and tissue donation in Australia.

DFA sought legal advice in 2021[2] regarding the application of legislation that pertains to organ and tissue donation in Western Australia (WA). This followed an extended history of people who had donated their loved ones' organs and/or tissue experiencing threats, intimidation, bullying and paternalism from Organ and Tissue Authority personnel and some DonateLife Agency and hospital staff. These misuses of power have been experienced most frequently in the context of bereaved people who expect to have the freedom of speech to use their deceased loved ones' names in sharing with others that their relative donated organ/s and/or tissue[3].

The legal advice made clear that DFA, OTA and many bereaved organ and tissue donor family members across Australia along with their friends and communities were breaching WA legislation- and potentially other state and territory legislation. This risk has implications for organisations named after organ and tissue donors such as *Zaidee Foundation, Hookes Foundation*; and for political leaders such as Prime Ministers- especially Prime Minister Rudd, who spoke about many donors by name and engaged with many donor families at the launch of the OTA. Other examples include the use of donor's names by Health Ministers federally and at a jurisdictional level, and at services of remembrance hosted by DonateLife Agencies.

To be explicit, wherever people share stories that include the names of donors they are at risk of being penalized depending on their jurisdiction. This legislation extends to individuals sharing to friends, families and in all the places they work and play that their loved one was a donor; in conversations between bereaved people following a death, donor families comforting each other over a cup of tea, the media reporting on a story from a family and DonateLife Agencies across Australia are breaching or potentially breaching the legislation. Each state and territory have different Human Tissue Acts/ Transplant and Anatomy Acts, the varied legislation regarding donation has added to the confusion.

In July 2021 DFA met urgently to consider the implications of the legal advice on the ongoing work of the organisation, recognising DFA were (and continue) to break the law, as do all the other people and organisations listed and many more. The DFA Committee agreed that as a matter of urgency DFA were responsible to alert key people and organisations

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[1] Advice by Lavan 23 June 2023 (Advice regarding the proposed amendments to the Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth) (OTDA) and the implications for Donor Families Australia (DFA) and families of deceased donors and recipients).

[2] Advice by Lavan 30 April 2021 (a letter of advice with respect to legislation surrounding the ability of organ donor families (next of kin of minor/adult deceased donors) to disclose or give to any other person any information or document whereby the identity of "a person" may become publicly known regarding the Human Tissue and Transplant Act 1982 (WA), (Appendix 1)

[3] DFA chronology of significant events (Appendix 1 & 2)

responsible under the legislation[4]. We agreed we should seek to collaborate to resolve the issue; request a national moratorium on prosecution for all involved and then advocate that states, territories and the Commonwealth act with urgency to harmonise and humanize the legislation to meet community human rights expectations to enable the freedom of speech for all bereaved organ and tissue donor families in Australia. We approached Dr Anne Webster (MP) instigator of the 'Parliamentary Friends of Organ Donation' for guidance and help[5].

Following this correspondence there ensued many efforts to connect with the Federal Attorney General, the Health Minister/s, the OTA and Commonwealth/ Jurisdictional agencies to enable DFA to collaborate as healthcare consumers[6] to support legislation at a Federal and State/ Territory level that would meet contemporary expectations and enable those most impacted by the decision to donate, freedom of speech and association. A chronology of the major events in the history of DFA, and the correspondence we have engaged in regarding this, and other practices and policies related to the experience of DFA is listed in **Attachment (2).**

Problem

We have sought clarification from the Minister's office and have had a meeting with an official from the Department of Health. On both occasions we were informed that this amendment only applies to the activities of DonateLife and the OTA, however our independent legal advice contradicts these reassurances. DFA understand that this amendment does not provide any relief for families of donors to speak freely. Instead, it provides additional powers to the Organ Donation Authority and its Agencies. **At no stage in the effort to have this legislation amended has there been any consideration of the needs of families touched by donation decisions, instead, just efforts to protect and give additional power to the OTA and its agencies.**

The entire process of developing this amendment has been rushed, without appropriate consultation and does not meet the standard expected for good governance. These actions and the implausible denial of impact to Donor Families has increased confusion and despair within the donation community. Many have lost trust, and believe that it is impossible to have credible, authentic consumer voices heard in this sector of healthcare practice, policy, and legislation**.**

DFA have been advised that as an independent organisation that it will not be able to publish or disseminate information that hadn't already been published by the OTA or a DonateLife agency (secondary publication). The implications of this advice for DFA and all families of deceased donors and recipients is very distressing.

1. Most Donor Families will continue to be prohibited to say their loved one (by name) was a donor.
2. Families who are involved in events as mentioned in the proposed amendment lose their right to the material they have contributed to, handing all intellectual rights for the information they have shared to the OTA/ or Agency. There is no mention of a withdrawal of association if they later regret this decision or the ability to put a subsequent stop by the OTA and its agencies in using that material.

This issue is of significant concern to the wider community with a 2022 petition garnering huge support for legislative change to enable families to have this freedom to control their loved one's information including saying their name in

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[4] Email (6 July 2021) regarding DFA consultation and draft letter to Dr Webster (MP)

[5] Letter to Dr Anne Webster, MP, Member for Mallee (Appendix 3)

[6] https://www.safetyandquality.gov.au/our-work/partnering-consumers/australian-charter-healthcare-rights

relation to donation.[7] In having said 'yes' to donation, families have, unbeknown to them, handed over control of their loved one's information to the government without knowledge, consent or understanding.

The use and management of Donor information has remained a contentious and troubling issue for Donor Families for many years. There is great confusion in the donor and recipient community about what families are allowed to say and do, with many examples over time of redacted letters, lost letters, callous and hurtful approaches, and statements by senior administrators to families in hospitals that they cannot talk to the media or anyone else about the donation and a general paternalistic approach of control, silencing and removal of grieving families' freedoms of speech and association.

In the current and proposed legislation, by law, families are not permitted to let each other know, or their families or neighbor's or communities speak of their loved one's donation and share their name as having been an organ or tissue donor. Whilst at the same time there is no preparation by authorities of potential donors and their families that freedoms of speech will be impacted when they consent on the Australian Organ Donor Register if at the time of death their families authorise donation of their loved one's organs or tissues.

1. This amendment seeks to restrict the use of our loved one's name and information/ story to four activities **for the purposes of the OTA and DonateLife only.** As clearly stated in the explanatory notes of the amendment, this provision does not allow donor families to tell our loved one's stories for activities beyond the remit of the OTA and DonateLife.

2. Donor Families Australia is a not-for-profit organisation that is independent of the OTA and DonateLife and as such we have our own activities where storytelling is an important element of our support activities; activities that are not listed within the remit of the OTA and DonateLife.

3. If the amendment continues in its current form, we fear that Donor Families Australia will no longer be able to provide support to our 1000+ strong membership.

4. We fear that our social media sites, our website, our newsletter, our anniversary emails to donor families that are so meaningful to them, our marquee event 'Donor Heroes Night' and our consumer lead, co-created conference will be found to contravene the amendment. Clearly this is against the Charter of Health Care Rights, freedoms of speech and is also deeply unethical.

5. If Donor Families Australia cannot provide these services and face to face and online places of refuge, love and care, who will provide the support, comfort and community to donor families? Many families receive limited support from the funded programs associated with the OTA,/ DonateLife agencies but this is insufficient for many families and individual's needs. There is clear evidence that shared support between people who have had similar experiences provides long term positive outcomes. As a caring society, we can point to many support organisations of consumers with similar experiences; it is critically important to donation to provide positive independent support in the community for donor families. To be able to support one another, after losing precious family members in often sudden and tragic events helps in the healing process of finding a path through grief. It is a sad omission that Donor Family support in collaboration with Donor Families has not been listed as one of the approved activities of the OTA and its agencies clear that the Authority or a Donate Life Agency does not have support as one of its activities as it is not specifically listed in the amendment to the legislation.

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[7] 'Let organ/tissue donor families "say their loved ones' name' Started July 2022.

6. At a time of unbearable pain and despair, donor families thought of others and consented to donation, now Donor Families ask for nothing in return other than the common respect and agency afforded others.

7. Donor families should be able to freely tell the stories of our loved ones within our community, without the approval of the OTA or a DonateLife agency and without connection to the OTA and DonateLife activities.

8. It is through storytelling as a community that donor families grieve and heal, that our loved ones live on and that their life-changing gift can be celebrated and become something that all aspire to do following their death. In the United States there are parades to remember donors and their families, a National Donor Memorial, and a National donation Medal. None of this is possible if the donor family is unable to say the name of their loved one in relation to organ donation. It is not surprising our donation rates are so low. **It should be noted that the US donation rates reached their highest levels ever in 2022- despite the impact of Covid-19.**

Finally, this amendment will further adversely impact a specific cohort of our donor families, those that live in the Australian Capital Territory (ACT). In a progressive and transformative move, Donor families in the ACT are currently able to share their loved ones' donation with the Registrar of Births, Deaths and Marriages so that the organ and tissue donation can be acknowledged on the death certificate; an act that costs nothing and yet leaves a permanent legacy of organ donation. The proposed amendment in its current form will outlaw the sharing of the organ and tissue donation information about the individual donor with the Registrar, as this is not one of the four activities sanctioned by the OTA and DonateLife and is not within the remit of the OTA and DonateLife as it is a supporting Donor Families activity.

This toxic setting is the context of Australian organ and tissue donation today. Several states are undertaking inquiries as to why donation rates are so low, and one must only assume that the continuing silencing or Donor Families and withholding of community and professional education about organ and tissue donation is impacting Australia's donation rates. There have been many reviews into organ donation in Australia, and the problems mentioned in this submission have been raised previously, and yet there remains an extraordinary inertia and complacency regarding the impact of this critical problem for those in need of transplant. In a 2015 Review into organ donation and transplantation program instigated by Assistant Minister of Health, Fiona Nash [8] it was recommended that DFA recommendations be considered regarding harmonization and humanizing of legislation and processes to enable credible critical review of practice to support improvements, with a comment that it was impossible to find the complaints process.

Evidence that points to failures in providing appropriate care and support for donor families, include the time taken to facilitate organ donation extending from the time death is confirmed until retrieval surgery (time spent for families and hospital staff caring for a deceased person in an Intensive Care Unit. The data demonstrates these times have extended from an average of 22.7 hours in 2018 to 28.5 hours in 2022 in Australia [9] Of note, in 2008 (prior the OTA) the median time was 15.3 hours [10]

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[8] Review of organ donation and transplantation program https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id:%22media/pressrel/3858024%22

[9] Time from brain death to donation, Australia (2018-2022) https://www.anzdata.org.au/wp-content/uploads/2023/05/s03_pathway_2022_ar_2023_v1.3_20230523.pdf

[10] Time from brain death to aortic cross clamp 2003-2008 (2008) https://www.anzdata.org.au/wp-content/uploads/2009/01/2009Pages37-55.pdf

Recommendations and Conclusion

DFA is not satisfied with the current proposed amendment. It is confusing and does not meet community expectations or standards. We seek an inquiry into the way the legislative change has been developed; we demand appropriate widespread community consultation with Donor Families and others impacted by existing legislation relating to organ and tissue donation to bring them in-line with the 21st Century and expectations of transparency, freedom of speech and association and humanity.

The amendment to the Human Tissue Act in the ACT was developed with authentic community consultation with Donor Families Australia and we thank Tara Cheyne MLA for her ongoing support of donor families throughout Australia and for her willingness to assist other States and Territories with changing their legislation relating to organ and tissue donation.

DFA has presented compelling reasons to challenge the amendment and all existing nation legislation pertaining to organ donation. Our position is supported by the attached legal advice. We recommend that the Committee reference the recent changes to the legislation pertaining to organ donation in the ACT. There they acknowledge the rights of the families of deceased organ and tissue donors, and recipients the right to ownership /control of information by families of deceased loved ones and freedom of speech.

Before legislation had even passed the Lower House, for the sake of credibility, transparency and trust, there should have been a proper and respectful consultation period with those that the legislation has been designed for. We urge the Committee to consider, how would each one of you respond and feel if you were told following the organ donation of a loved one (that is a complex process that lacks community transparency/ education) that you were not allowed use the name of your loved one in relation to organ and tissue donation. This is the reality for many Donor Families of Australia.

Please accept our concerns and recommendations and we trust that with your support and review of the amendment, new wording will provide clarity to Donor Families and a revised amendment will harmonise the legislation across the country without harming the rights and well-being of donor families. No other bereaved families are so restrained in their human rights.

DFA believe ‘Enough is enough!’ The Australian public would be understandably distressed to know that bereaved people across Australia are silenced and treated in this way. In signing the Australian Organ Donor Registration form, we are certain many would be horrified to realise they would be waiving the rights of their family members to talk about them after their death as being a donor. In addition to this submission, we will also be presenting a complaint to the Australian Human Rights Commission.

Appendices

APPENDIX 1 Chronology of significant events (Part 1)

Date	Event	Comment	Evidence
15/12/2012	Opening of the Donor Awareness Fountain in Geraldton WA by Donor Family Australia (DFA)	Honouring our Donor Heroes, Creating Awareness for Organ and Tissue Donation.	*Donor Awareness Fountain Geraldton WA*
15/1/2013	Certificate of Incorporation	Organisation becomes Inc.	RegistrationNo.A10166 Incorporated in WA
20/1/2013	Committee meets for its first meeting	Joining of Donor Families right around the country.	Available upon request.
9/4/2013	Panel Media Sydney Town Hall Sydney	Prior to ABC's 4 Corners programmed being aired. DFA was part of the panel for the Media Conference with Sharelife Australia. DFA message was that Donors are heroes.	Available upon request.
10/5/2013	First DFA Newsletter	Connecting Donor Families. Newsletters are produced ongoing to keep Donor Families and the wider community up to date with issues that impact them. These newsletters provide support to help families in their grief and honour their Donor Hero loved one.	https://www.donorfamiliesaustralia.org/_files/ugd/8a154b_8a858ecdc8a44343837b8f991acd445a.pdf
30/9/2014	Donor Family Dinner	Grouping Donor Families together for peer support.	The Honey Bar Clarendon St South Melbourne
03/10/2014	Commenced sending Anniversary emails to Donor Families	Supporting families on the anniversary of their loved ones passing. These emails are sent to all members on their loved ones anniversary.	Available upon request.
1/07/2015	Ernst and Young Review	DFA executives and Members attended the various sessions held across Australia to provide a voice for Donor Families and their loved ones.	Available upon request.

22/11/2015	First DonateLife National Thank You Day	DFA initiated with the Minister of Organ and Tissue Donation Fiona Nash MP public acknowledgement across the Australian community of the generosity of organ and tissue donors and their families, and the impact of their decisions on the broader community .	DFA Chairman went to Canberra to contribute to the discussions of the National Thank You Day. Launch attended my Minister Wyatt. Available upon request.
1/01/2016	OTA leaflets distribution to local community	Geraldton MLA, Ian Blayney, made a commitment to make 2016 the year to promote Organ and Tissue Donation after discussions with DFA Chairman	OTA leaflets were placed in every letter leaving Mr Blaney's office, providing constituents with facts on organ and tissue donation, and the process for registering as a donor. He encouraged other politicians to follow his lead. *Hon MLA Ian Blaney with DFA Chairman at announcement.*
01/01/2016	Newsletter reaches a circulation of over 6,000.	Community has embraced the Newsletter	Available upon request.
01/05/2016	DFA attends Launch of Ernst and Young Review in court yard of Parliament House	Chairman of DFA stands beside Minister of Organ and Tissue Donation representing Donor Families	*Fiona Nash MP at Launch of EY Review*
15/11/2016	ACNC Charity status	DFA became a Not for Profit Charity as registered with the ACNC	
26/7/2016	National Donor Family Dinner	Melbourne	Available upon request.
18/10/2016	DFA National Strategic Planning Weekend workshops , Sydney. Special guest OTA CEO Felicity McNeill	Two days of face to face around the conference table formulating DFAs Strategic Plan. Report Available upon request.	*DFA Executive Committee with CEO of OTA at Strategic Planning Weekend.*

20/11/2016	DFA organises Thank You Day events around the nation.	DFA held picnics in states and territories. All were well attended by the community.	Available upon request.
17/3/2017	Attended Community Consultative Forum Melbourne on the topic of Consenting adults meeting.	DFA representation on the importance of consenting adult donor and recipients being able to meet.	Available upon request.
16/9/2017	National Donor Family Dinner	Melbourne	Available upon request.
9/3/2018	DFA committee members attend meeting with OTA CEO Lucinda Barry on the topic of letter writing.	Meeting held in room at the Sydney airport. DFA provided recommendations and proposed changes that needed to be made to the process to address problems of lost and missing letters between donor families and recipients. Also, to address issue of misuse of letters, heavily redacted and misuse of authority in managing personal information	Available upon request.
7/12/2018	Contribute to the 2nd Ernst and Young Review	DFA consultation presents Donor Families points of view for the review.	Available upon request.
10/12/2018	National Donor Family Dinner	Melbourne	Available upon request.
26/1/2019	DFA Executive Committee member Dr Holly Northam receives OAM for work done in Organ and Tissue Donation.	DFA was very proud of its inaugural committee member in being awarded the OAM for services rendered.	*Dr Holly Northam received OAM for her contributions to Organ and Tissue Donation.*
28/1/2019	DFA is an inaugural member of the OTA's Community Engagement Group	DFA joins other pro-donation groups and individuals to help contribute the community's perspective on Organ and Tissue Donation.	Available upon request.

2/3/2019	National Donor Family Dinner	Newcastle	*Donor Family Dinner Newcastle NSW*
23/5/2019	ACNC Deductible Gift Recipient status	DFA becomes an ACNC DGR	
4-5/10/2019	DFA Conference over 2 days at the University of Canberra ACT	The Conference brought together a wide range of community representation with a wide range of views. Was highly successful.	*DFA Conference Canberra*
19/2/2020	Tara Cheyne MP ACT introduces Acknowledgement of Donation on the Death Certificate in the ACT.	As a result of Tara's presence at our conference she was able to present to the ACT Parliament a new way of creating a legacy and helping donation awareness.	Available upon request.
26/2/2020	DFA committee members attend launch of Commonwealth Parliamentary Friends of Organ and Tissue Donation.	The Chairman addressed the gathering on the good work that was being done by the ACT Parliament on Acknowledgement of donation on the death certificate. This was a conference initiative.	Available upon request.
23/4/2020	Launch of Ernst and Young review	In it is Recommendation 26 provides that: States and territories establish a nationally uniform process for arrangements for donor families and recipients over the age of 18 to be identified to each other based on the principle of mutual informed consent	Available upon request.

18/5/2020	Inaugural Donor Heroes Night.	Community is invited to leave their porch light on in honour of our Donor Heroes. This is now a annual event. With the most recent having over 200,000. Very successful event not only honouring our Donor Heroes but raising awareness in the community.	*Inaugural Turn on your Porch Light for a Donor Hero*
9/9/2020	Kurri Mongrels Bike Association ride for Donor Families.	This bicycle club rode through the countryside to promote Organ and Tissue Donation and raise much needed funds for DFA to do the work they do.	*Bike ride raining awareness of Organ and Tissue Donation and raising funds for DFA .*
25/9/2020	DFA works with the OTA on the letter writing policy.	[redacted] During the process the OTA lets DFA know that it is against the law for Donor Families to include the first name of their loved on in a letter.	Available upon request.
N.B. Chronology of Significant Events Part 2 follows on from this document.			

APPENDIX 2 Chronology of significant events (Part 2, Dec 2020 to date)

Date	By whom	Reference	Relevant points to highlight
14/12/20	OTA CEO	Letter page 1 and 5	DFA (Donor Families Australia) consults with the Organ and Tissue Authority (OTA) in relation to letter writing between Donor Families (DF) and Recipients. OTA CEO writes to DFA as to why families cannot include the first name of their deceased loved one in their letter to the Recipient. • CEO states all jurisdictions prohibit health professionals from disclosing identifying information. • CEO does not want health professionals to be exposed to fines and penalties. • CEO points out that only the donor can give consent for health professionals to pass on information. • CEO confirms that DFs do not have control or ownership of their loved one's information as they do of their loved one's organs and tissues.
30/4/21	Lavan Legal Services	DFA seeks legal opinion in relation to OTA CEOs letter (Appendix 1) of the 14/12/20.	The Chairman of DFA approached Lavan legal services in Perth WA for legal advice on disclosure of information within the Human Tissue and Transplant Act 1982 (WA). • Lavan states that only the deceased donor can give consent for their information to become publicly known. • The state government organ and tissue transplantation process currently acts outside of the law in WA. • The state government is currently acting unethically in not letting families know that they are unable to talk about their loved ones donation publicly. • The state government is currently acting unethically by knowingly contravening its legislation. • "From a legal perspective, there are no requirements in the HTTA that donors and/or their families/next of kin must be informed of their rights after consenting to organ donation. Consent can only be given if medical advice (not legal advice) has been given. From an ethical perspective, this is certainly an issue which we can understand could be close to the heart of many donor families".
21/5/21	Meeting with WA local Labor Member Geoff Baker	Follow up email of thanks 22/5/21.	• First presentation of Lavan's advice to the state government. • Asked for the legislation to be amended to allow for the next of kin to be given the authority to give consent for their loved ones information to be made publicly known.
22/5/21	DFA	Copy of WA legislation with example of possible amendment.	Included with Geoff Baker's email how the legislation looks today and how it could be amended to give next of kin the authority to make their loved one's information publicly known.

Donor Families AUSTRALIA

Date	By whom	Reference	Relevant points to highlight
11/6/21	CW Dept of Health	First reference to DFA's legal advice by Comm	Acknowledgement from the Cth Dept of Health that DFA has legal advice as to disclosure of information
22/9/21	Notes taken by DFA for DFA	Notes taken of meeting with DFA, CW Dept of Health and OTA	• Three organisations discussed Lavan's legal advice. • CW Dept Health advised DFA would be consulted along the way of any progress made re amending legislation. • OTA confirmed that SA and the NT have the same legislation as WA and acknowledged that it was a problem. • DFA had written to a Federal politician including Lavan's advice. DFA was told this letter was referred onto the Attorney General of Aus. • DFA referred to the Charter of Health clients. In it is mentioned that health consumers have a right to be treated within the law. • Cwth Dept of Health suggested that we need to work with all states and territories to have a uniformed approached. DFA said this does not help DFs who wish to act within the law now. • DFA mentioned that the OTA in the CEO's letter showed a duty of care for its health workers but who is showing a duty of care for Donor Families?
4/10/21	DFA	Notes taken from meeting with [redacted] [redacted] MP	• MP's approach was to play down Lavan's advice and kept saying DFA was overreacting. The Member was ok with DFs and government departments to continue breaking the law. • He made it clear that he was not going to take this any further.
3/11/21	North Metropolitan Health Service WA	Cancellation of Remembrance Service	• Letter explaining cancellation of WA Service of Remembrance. • The reason for cancellation – Due to unforeseen circumstances. Have not let the public know why the service has been cancelled. • Have advertised a Memorial Service in Bunbury because it is a PRIVATE EVENT.
8/11/21	OTA Update to the Community Engagement Committee	Page 2	• Acknowledgement of meeting with DFA and Com Dept of Health regarding legal advice from Lavan. • OTA said there are concerns about the implications this has for donor families who publicly share that their family member became a donor to help raise community awareness about donation or to commemorate their loved ones in remembrance services. • The OTA says it will keep everyone up to date with any developments.

Date	By whom	Reference	Relevant points to highlight
			• OTA will not share any new DF stories on website until advised otherwise.
15/12/21	National Health and Medical Research Council (NHMRC)		• DFA contacted the NHMRC so as to confirm whether ethical standards are being breached by government departments. • Advising DFA that ethical standards for organ and tissue donation will be reviewed at the end of 2022.
23/1/22	DFA to Minister of Health SA Mr Wade		• DFA lets the Minister know that Lavan's legal advice is applicable to SA as legislations are identical.
8/3/22	Minister Wade's response via Health Dept SA CEO Dr C McGowan		• Dr McGowan advises DFA that Donate Life SA is not a state government dept. He quotes the Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth) as if to say Donate Life SA responds to this legislation. • To the question of whether the SA health personnel should be telling the deceased donors next of kin that they could be fined up to $20 000 if they make their loved ones donation story public Dr McGowan says there is no legal requirement for them to do so. [redacted]
14/3/22	WA Minister for Health to DFA		• Assurance of legal transfer of deceased donor information away from the hospital environment to other government depts. (DFA is not convinced that hospitals are legally making the deceased donor's information available to other government departments as no one has given consent for this information to be passed on.) • "Donate Life WA will in future include information about the prohibition on public disclosure during its work with donor families until such times that the legislation is amended". (To DFA's knowledge Donate Life WA has never done this [redacted] • "It has not been routine practice for Donate Life WA to inform families of the specific requirements of Section 34 of the WA HTTA as there is no legal requirement upon DLWA to provide this advice". There is not mention of ethics by the Minister. [redacted]

Date	By whom	Reference	Relevant points to highlight
16/4/22	DFA to Minister Health WA Donor Families	Participation at the World Transplant Games (WTG)	• The WTG will be conducted under WA law and as such those organising and sponsoring (WA and Federal Gov) will be knowingly contravening WA legislation. • DFA recommends the amendment of WA legislation to coincide with the Games. • DFA provides the Federal Tissue Act clause 58 as its example of how the WA legislation should read. The Federal Act allows for the OTA CEO to seek consent from the partner of the deceased to make their information publicly known.
27/6/22	DFA	Notes from Minister Sanderson's WA Officer Phone Call.	• [redacted] • DFA said DFs not owning deceased loved one's donation information is violation of their human rights. Shows a lack of respect on the part of the government. • Told WA government does not want to amend law as it would allow consenting adults, DFs and Recipients to meet. [redacted]
7/7/22	WA Health Minister to Mr McDowell	Response to World Transplant Games Contravening Legislation	• "I appreciate your valid concern that risk of prosecution may prevent donor families from speaking about their deceased relatives donation". • "Individuals won't be prosecuted for the disclosure of personal information where consent has been provided by the next of kin". Therefore Donate Life WA won't be prosecuted for presenting a Donor Family at its remembrance service. [redacted]. • This letter is meant to provide reassurance to the next of kin that they will not be prosecuted. For myself and my wife this letter comes as a shock. It confirms I am committing an unlawful act every time I speak about my daughter's gift. My wife and I were not told this at the time of giving consent for retrieval.
20/7/22	DFA	DFA Media Release	• "Donor Families seek law change in WA to celebrate the lifesaving gifts of loved ones".

Date	By whom	Reference	Relevant points to highlight
			• Media release circulated amongst WA media for media conference at Lake Monger in Perth. • Media represented by Channel 9, ABC, Channel 7, various radio channels and the West Australian. • DFA did a live radio interview and featured in a live segment on Channel 9 news. • Curtin University picked up the story for its radio.
26/7/22	DFA	Change.org Petition	• "Our daughter is a donor hero, yet we have no legal right to say her name when sharing her donation story". • Shared photo of Karen and Bruce with their daughter's photo turned around demonstrating the restrictions of the current law by not being able to make the loved one publicly known. • 17 639 have signed DFA's petition.
6/9/22	ACT Health Minister Rachel Stephen-Smith MLA	Amendment to the Tissue Act in the ACT	• "The ACT Government considers the need to address the identified legal concerns, too important to postpone and has chosen to move ahead now". • "I will be moving a Government Amendment to the Bill to further amend the Act to allow the sharing of donor information with the consent of family. The amendments I will move avoid the existing narrow terms to ensure relevant family members are able to consent to the disclosure". • The Minister confirms that without this amendment donor stories at remembrance services cannot be shared. • "As you may be aware, the disclosure of information section of the Act currently makes it an offence for DonateLife ACT staff to share information about donors where there is a risk that the identity of a donor may become publicly known".
9/9/22	DFA to ACT Health Minister Stephen-Smith		DFA appreciates the progress made by the ACT in leading the country in reform within organ and tissue donation
28/9/22	WA Attorney General Mr John Quigley MLA		• "It would not be appropriate for the Registrar, Births, Deaths and Marriages to knowingly contravene legislation by including a deceased's donor status on a document that may be made publicly available". • The Attorney General states it is not appropriate for his government department to knowingly contravene legislation, but for some reason it is ok for other government departments to knowingly contravene legislation. • The Attorney General is acknowledging Lavan's legal advice.

Date	By whom	Reference	Relevant points to highlight
2/11/22	Proposed Amendment to the Birth,Death and Marriage Registration	Tissue Donation Statement Amendment Bill 2022	• Nicola Centofanti MLC introduces a Bill for An Act to amend the above mentioned Act. • Nicola Centofanti MLC is hoping to introduce Acknowledgement of Donation on the Death Certificate in SA.
24/11/22		Amended Legislation in the ACT for Disclosure of Information	• ACT amendment to Transplantation and Anatomy Act 1978 – Section 49 (4) (c) (iv) • With the consent of - if the relevant person is a deceased person to whom subsection (1) (a) applies—the relevant person's next of kin or legal personal representative; • Is passed in the ACT Parliament 24/11/22. • In the ACT Donor Families are finally respected.
24/11/22		Hansard ACT for the amended legislation.	• "The changes will allow for DonateLife ACT, with consent, to share stories of individuals and their loved ones at its organ donor remembrance ceremonies such as the annual DonateLife ACT Service of Remembrance and Thanksgiving. The changes will also allow for DonateLife ACT, with consent, to help raise awareness of organ donation through other activities where stories of individuals and their loved ones are shared". • Consistency with Human Rights – "The amendment acknowledges that everyone has the right to recognition as a person before the law, is equal before the law and is entitled to the equal protection of the law without discrimination. By increasing the exemptions to the restrictions on the disclosure of information in section 49 (4) (c) of the TA Act, living adults, children, legally incompetent people and deceased donors are all recognised as being equal before the law and they and their families are afforded the same rights to disclose information. Prior to the proposed amendment, only living donors and adult transplant recipients were able to consent for their stories to be shared. This discriminates against the families of children, legally incompetent and deceased donors, as they are not provided with the same rights to share their loved ones' stories".
22/12/22	Chief Minister NT Natasha Fyles		• "I am supportive of donor families being able to commemorate their loved one's donation. The Northern Territory is currently examining legislative options that would allow families to speak publicly about loved ones who have

Date	By whom	Reference	Relevant points to highlight
			generously donated their organs. In addition, options to allow government employees to share donor stories, with the consent of families, is also being considered".
22/12/22	Nick Steele Qld Hlth on behalf of Yvette D'Ath MP Minister of Health		• In his letter Mr Steele confirms Qld's opinion that Donor Families making their loved ones information publicly known at Donate Life Qld Remembrance Services is not prohibited by Qld's Act. • Qld's Act is the same as the ACT. The ACT has already put in place legislation to specifically allow Donor Families speaking at Donate Life ACT Remembrance Services as prior to the amendment it was unlawful to. • Enquiries to Mr Steele's referred officer confirmed that the OTA had told Qld Health that it was ok for Donor Families to speak at their Remembrance Service in direct conflict to the ACT experience. • The referred officer agreed that Donor Families in Qld do not own their loved one's information as the family is not authorised to give consent to the hospital staff to pass the donors information on. • The referred officer agreed there were potential ethical issues with Donor Families making their loved ones publicly known at a Qld health function.
5/1/23	WA Health Minister Sanderson		• "Hon Stephen Pratt spoke recently in the Legislative Council of attending DonateLife WA Service of Remembrance last month, and he acknowledged the moving speech made that day by a donor family member regarding her child s generous gift". Minister's letter confirms Mr Pratt's MP appearance at the Donate Life Remembrance Service where Donate Life WA knowingly contravened legislation. • Minister reaffirms that DFs will not be prosecuted for knowingly contravening legislation. This is little comfit to families who have no idea that they are breaking the law as DFs were not given all the information they needed to make an informed consent.
20/1/23	Premier of Tasmania		"The Tasmanian Human Tissue Act 1985 currently prevents the disclosure of information of donors, even with appropriate consent of the next of kin, to donor families or recipients, which would allow for families and other persons to celebrate the significant contribution of donors and organ donation more generally".

Date	By whom	Reference	Relevant points to highlight
20/1/23	National Health Medical Research Council (NHMRC) – Director Ethics and Integrity		• "Legislation and ethics guidelines are related, but independent of one another. All NHMRC ethics guidelines require adherence to relevant laws and ethics guidelines may either extend the requirements in legislation (by providing more detail about what is required) or may defer to legislation, where relevant". • "Ethical standards are critical in the practice of organ and tissue donation and transplantation and in the development of related policy and clinical guidelines".
29/1/23	DFA to Nicola Centofanti MLC SA		• This letter points out to the MP the similarities between WA and SA laws in relation to disclosure of information and references letters from the CEO of Health in SA and the Attorney General of WA. • DFA supports the MP in her endeavours to introduce amended legislation to allow acknowledgment of donation on the death certificate. • It pointed out, that from the WA experience their tissue Act would need to be changed to reflect the ACT amendment before the acknowledgement could be passed.
14/3/23	Hon SA Health Minister Picton	Response to DFA letter	• Minister acknowledgement that SA Human Tissue Act does not allow for Next of Kin to publicly disclose information about the deceased donor. • Minister is waiting for a Federal review. • Minister has written with pen he is willing to take action if review is too far away.

N.B. All references cited can be provided on request.

Donor Families
AUSTRALIA

2024 NHMRC Ethical Guidelines for Organ & Tissue Donation

A report of DFA Community consultation and feedback undertaken in July 2024.

This report describes the process undertaken and key findings from consultation process used by DFA to seek feedback and evaluation of the draft NHMRC Ethical Guidelines for Organ Donation and Transplantation.

Donor Families AUSTRALIA

Consultation Report re draft NHMRC Ethical Guidelines for Organ and Tissue Donation

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Appendices

Introduction

Thank you for the opportunity to bring the voices and views of representatives of Donor Families Australia (DFA), as a key stakeholder, to this document.

The past has told us that those providing the service do not necessarily follow ethical guidelines. We have witnessed this by their reckless abandonment of state and territory law. We have also seen amendments to federal, state and territory legislation that doesn’t always meet the intentions of the ethical standards. What guarantees do we have that the OTA and the various DonateLife offices will use the ethical guidelines as a means of carrying out their duties? DFA acknowledges that the guidelines have an important role in ensuring best outcomes for donors and their families and recipients. We strongly believe that a process needs to be introduced to ensure the guidelines are implemented. We suggest that:

- there needs to be a form of accountability for those in charge of carrying out organ and tissue retrieval such as an accreditation process as undergone by hospitals throughout the country. This accreditation process would use the ethical guidelines as its basis of assessment to provide best practice and;
- DFA be part of this process to ensure the best possible service is provided to the community.

We would welcome the opportunity to discuss further any issues raised in our Report.

[redacted]

Bruce McDowell
Chairman

Acknowledgement

Thank you to Donors and Donor Families

The launch of Donor Families Australia in 2013 provided a wonderful opportunity for Donor Families to improve community acceptance of organ and tissue donation and the care of families who make organ and tissue donation decisions. The generosity of donors and their loved one's transforming the lives of others, both at the time of the donation decision and long afterwards, because donor families are the best advocates for organ and tissue donation.

Many health care professionals have been fortunate to have witnessed the courage and kindness of families who have made donation decisions at times of great sorrow. The members of Donor Families Australia continue to provide energetic inspiration, advocacy, guidance, compassion and care to ensure Australians receive the information and support they require to make donation decisions they never regret.

Many in our community are confused about the process of organ and tissue donation. DFA provides opportunities for discussion, education and collaboration about a range of matters that impact on Australian donation practices including the need to properly care for and acknowledge live donors, tissue donors and their families as well as organ Donor Families. The gift of donation is truly extraordinary and builds our humanity.

If Australia is to achieve equivalence with international leading practice it is important to make organ and tissue donation normal. A conversation about donation should be a part of expert end-of-life-care for every Australian. Understanding the donation process and knowing loved one's wishes are just so important to helping to save lives and providing meaning from what are often tragic circumstances of unexpected death. This is because most people wish to help others and to honour the wish to donate. Despite this, many families never have the opportunity to have those wishes properly considered because either donation isn't mentioned, or the person conducting the conversation at the time of death lacks the knowledge and skill to properly support the family making those decisions. Donor Families Australia helps to identify and fill these gaps. Donor Families Australia has also become a place where recipients and their families are also honoured and respected- and the complex relationship and experience of organ and tissue donation for transplantation becomes real.

Thank you to the founding Donor Families and especially Bruce, Karen, Leanne, Rick, Philippa, Graham and Elayne for the honour of allowing me to contribute to Donor Families Australia and to all the subsequent members. The benefits gained by our society from your decisions are incalculable, but include leadership, selflessness and charity in caring for those in need- and love for humanity.

Holly Northam (Compiled report)

[redacted]

DFA Contribution

Board of Directors

Bruce McDowell, Donor Family, Western Australia, Chair

Bruce, his wife Karen and their two sons became a Donor Family in 2008, [redacted] Consequently, Bruce and Karen were brought face to face with the poor donation rates in Australia. It became their mission to raise awareness of the importance of organ and tissue donation and the need to support and advocate for Donor Families. Bruce went about raising funds to build a Donor Awareness Fountain constructed on the Geraldton Foreshore. This Fountain was a Memorial to show gratitude to Donors and to help raise organ and tissue donation awareness within his community. He was awarded the Rotary Paul Harris Award for his work in organ and tissues donation awareness.

Bruce holds a Masters in Accounting, Bachelor of Health Administration and Teaching qualification. He worked eighteen years with the Health Department of WA in various Hospital Administrator roles throughout country WA and managed an Indigenous Medical Service before moving into his own accounting practice as a CPA. This wealth of experience gained has given him good insight to how Government policy and systems work especially within Health.

Bruce brings to Donor Families Australia a lifetime of community service and advocacy. Whilst living in Geraldton Bruce provided service to many community groups including roles as a Director for the Geraldton University, Executive member of the Geraldton Palliative Care Board, Executive member of Community Disability Employment Agency, and Executive Member of the Geraldton Catholic Cathedral Restoration Committee.

He served as the inaugural Donor Family representative on the WA DonateLife Advisory Committee, along with being the Donor Family representative on the Biotherapeutics Association of Australasia, he was an inaugural member of the Organ and Tissue Authority's Community Engagement Group along with becoming an inaugural member and Chair of Donor Families Australia. A position he has held for eleven years.

Graham Harrison, Donor Family, New South Wales

The death of Graham and Elayne's ten-year-old son Ben following surgical complications in 1993, resulted in their decision to donate his organs and as an outcome, Graham became heavily involved in the promotion and improvement of the organ donation and transplantation systems. Over the years Graham has been involved with ACCORD, Australians Donate, Transplant Australia and more recently, ShareLife Australia. However, it is through Donor Families Australia that he sees donor families' voices grow collectively, to the point where they will be involved in all aspects of improving Australia's organ donation and transplant systems. He is particularly interested in donor family support at the time of donation and the years that follow.

Leanne Campbell, Donor Family, Victoria

In 2009, Leanne and Rick's twenty-one-year-old son Brett was tragically killed in a freak accident whilst holidaying with friends. Brett had made his wishes known in regard to organ donation and so his parents consented; his gift saved three people's lives. Leanne is passionate about supporting donor families. She is a volunteer with DonateLife, the Donor Family Representative for Transplant Australia (Victoria) and a support group leader with The Compassionate Friends Victoria.

Barry Mewett FCPA, FIPAA, Donor Family, Australian Capital Territory

Barry became deeply involved with organ donation following the sudden and unexpected collapse of his wife from a massive brain haemorrhage. He and his family agreed to donate multiple organs from his wife. The DonateLife organisation in Canberra provided support as Barry and family tried to come to grips with this loss, including facilitating contact with a recipient. He has been given the opportunity to tell his story at DonateLife remembrance services. Barry joined Donor Families Australia a few years ago to contribute to the interests of Donor families, including supporting initiatives with ACT Government to allow families to publicly recognise donation on death certificates. Barry believes much more should be done to support consensual contact between donor families and recipients. Barry has extensive working career in Government, experience in the development of a major consulting practice to Government and as a member of the University of Canberra Council, including leadership in risk management and finance.

Darryn Wilson, Recipient

In 2019 Darryn received the gift of life through a liver transplant, since his transplant Darryn is living a very productive life with his family, being involved in grass roots community sport as well volunteering with Donate for life.

Darryn discovered Donors Family Australia through a desire from his donor's family willingness to connect, Darryn is now an active member of Donor Families Australia with a vision to help bring awareness of donor recipient's stories and increasing recognition of consensual connection between donor families and recipients

Jackie Robson, Donor Family, South Australia

In 2016 Jackie's husband and father of their 3 children died very suddenly of a catastrophic brain haemorrhage. Pete's organ donation saved the lives of 3 people. Jackie is passionate about supporting and giving a voice to donor families and improving donation rates in Australia

Jackie has a Bachelor of Education and Montessori Diploma. Jackie spent many years overseas where she met her husband. Coming back to Australia Jackie taught in various Montessori schools and was instrumental in creating the first Montessori stream in a public school in Victoria. For 12 years Jackie was Principal at a Montessori Centre before retiring.

Philippa Delahoy, Donor Family, NSW

Philippa is a donor wife, following the sudden passing of her husband Scott in 20122.

Scott's kidneys freed two young people from a lifetime of dialysis and his corneas went to medical research. Scott, a huge sci-fi fan, would be amused by his organs living on long after him.

Philippa became involved in Donor Families Australia in 2017. With her background working within Pfizer, Philippa brings a wealth of knowledge about media communications and is an invaluable member of the Board.

Holly Northam, Advisory and advocacy, Australian Capital Territory

Dr Holly Northam OAM, PhD, Senior Fellow of the Higher Education Academy is an Associate Professor at the University of Canberra. Holly is a Registered Nurse, Midwife, and Churchill Fellow (2006, Organ Donation). Holly's work centres on giving voice to those vulnerable to silencing and oppression by poor clinical practices, policies and legislation and identifying health care strategies to enable people to flourish. Holly's PhD study explored the decision-making experience of bereaved families who made organ donation decisions on behalf of a loved one and identified factors that influenced families to agree or decline donation. With over 30 years of clinical experience, amongst her previous clinical roles Holly was an organ donor co-ordinator and manager of the ACT Organ and Tissue Donation Service. Holly was a Director on the Board of ShareLife Australia and is a founding member of Donor Families Australia. Holly has fought hard to ensure Donor Families have a voice and are heard. Holly has a passion for equity and social justice in healthcare and has a conjoint appointment with the Congress of Aboriginal and Torres Strait Islander Nurses and Midwives where she is the Director of the Leaders of Indigenous Nursing and Midwifery Education Network.

Donor Families Australia Logo

Designed by Kiri Northam for Donor Families Australia, December 2012.

Logo design Copyright © Donor Families Australia 2013

Donor Families
AUSTRALIA

About The Design

The heart shape was chosen as being the most recognisable and emotive organ. Following the concept of two lives connecting, I experimented with the placement and connection of two hearts. I settled on the rippling hearts to signify the impact organ donation can have on families and the community; the butterfly effect that one good deed can achieve. The angle of lean helps to emphasise vulnerability and creates a more accessible visual.

The gold and green colour scheme was chosen to underline the organisation as a national body. The gold hearts are used as a metaphor for generosity and to be completely abstracted from the actual organ, to avoid any negative connotations. The green was chosen as a calming complementary colour to be used to help identify the brand.

Consultation Plan

1. Objective: Within a three-week period communicate to the community who is part of DFA the opportunity to authentically consult and offer feedback mechanisms.
2. All members of DFA to be approached to ensure their voices are respected and heard if that is what they desire.
3. A feedback form was developed (Appendix 2) based on member experience and disseminated via email, social media platforms and word of mouth to members of Donor Families Australia. The opportunity to participate in two online consultation webinars was offered to all members of Donor families Australia.
4. All submissions had to be received by July 14 to meet NHMRC timelines.
5. Data was collated and analysed for themes and trends. Outlying views are also presented.
6. Based on the feedback received, conclusions were drawn, and recommendations developed actions to address consumer concerns.
7. A comprehensive report outlining the consultation process, findings, and recommendations was collated and is presented here.
8. The report will be shared with those that participated and others who are interested and will be made available on the DFA website.

Consultation Response

We are grateful for the opportunity to provide this response. But note, this is like previous experiences of having Donor Families voices excluded- maybe by omission or commission by organisations that facilitate and guide organ and tissue donation activity in Australia. We consider that not being included is deeply disappointing and believe that inadequate consultation and acknowledgement is an unethical omission in the public process of consultation. The letter that we sent to the Assistant Minister regarding these concerns is available (Appendix 1).

We believe there is an **over-arching conflict of interest** involved in the review of the ethical guidelines. This review should have been undertaken with the OTA as a stakeholder and not as a collaborator. This process has deeply undermined the credibility of the draft guidelines and the oversighting bodies.

This is one of many submissions from DFA over many years. DFA is a not or profit organisation entirely run and supported by Donor Families and a few committed supporters. **We receive no government funding as an ethically based decision to ensure transparency, independence and to build trust within this community by limiting concerns of conflict of interest.**

Please note Appendix (5) our recent submission to the Senate Committee for Community Affairs Inquiry: **Australian Organ and Tissue Donation and Transplantation Authority Amendment (Disclosure of Information) Bill 2023 (Cth)** for more information about who we are and why this response is important to Donor Families and for donation in Australia as a whole.

This submission is prepared specifically from consultation with members of Donor families Australia. We are aware that other community members were interested in contributing when they became aware of the review. DFA made the decision that given we were provided with a specific extension to enable a response, and considering the tight time frames for consultation it was seen as beyond the capacity of DFA to include additional individual feedback. We have included another organisation, the Australian based committee of the International Coalition to End Transplant Abuse in China prepared by Professor Wendy Rogers- an author of the original guidelines. Similarly to DFA, that organisation was not made aware as a stakeholder of the public consultation process. Given the support and affiliations between DFA and the International Coalition to End Transplant Abuse in China we are pleased to include their feedback (p.35).

Following several meetings and consultation within the DFA Board the Feedback letter and form were developed (Appendix 2). The Feedback form was disseminated through the DFA membership via email and on social media platforms. Given the sensitivity of the topic and the concern that some members would not manage to complete survey platforms well the Feedback form was sent out as a 'word' document to enable greatest participation.

The letter of invitation to participate in the consultation email and included on the form included an invitation to participate in a webinar to provide feedback if preferred. Two times were offered to ensure opportunities for our membership who live across the range of Australian time zones. One was scheduled for 7 pm AEST and the second at 7 pm for West Australians. The first was well attended and the participants provided approval for the discussion to be recorded and shared as part of our feedback.

Respondents were required to return the forms by the 14th of July to enable collation of feedback. DFA received 19 written responses using the feedback form (15 Donor Family and 4 recipients) and 9 participants in the webinars (6 Donor Families, 2 recipients and 1 community member).

	Donor Family	Recipient	Community member
Feedback Survey	15	4	
Webinar	6	2	1

We received emails and calls of interest and for some families it was too hard to revisit the experiences to provide comment.

Webinar recording- shared with participants recorded permission [redacted]

Transcription available upon request.

Summary

Themes

"Sorry if I come off as emotionally charged at times. I guess when people are trying to tell a mother what she should be or not be doing about her own child it hits a nerve… All I can do is try and be a part of the fight for the rights of donors and recipients" (Donor family Email.)

- **Lack of clarity and consistency** re referencing legal requirements and their relationship to ethical practice: "I believe all legislation should be uniform throughout Australia" its impact for ethical experiences.
- Poorly written ethical guideline document: *"If the authors are unable to write a short, simple set of guidelines available to the "man in the street", the entire exercise will be a waste of time and effort".*
- **Frustration** from **lack of engagement, poor communication** and omission of **consultation** from the institutions.
- Anger regarding **paternalism** and a belief that **human rights** are impinged by ethical failures in practice and regulation.
- Anger regarding the perceptions that **conflict of interest** between respect for the deceased and the need for organs and tissue are enabled and unchallenged.
- **Distress that beliefs and trust** in professional practice are **not reciprocated** with **respect for decision makers and deceased,** and that the guidelines need to account for this.

DFA provided a space for final comments that received extensive commentary that point to an overall total anger and frustration that their voices are not heard and Donor Family and Recipient good will, altruism and compassion to act with humanity regarding efforts to make things better for others, are subverted with institutional ideas of mistrust, oppression, silencing and dismissal. Issues all relate to the lack of transparency regarding information, informed consent, communication, human right of association, dignity of the deceased and respect. Frustration at over-riding paternalistic approaches that disempower and contribute to distress and grief as discussed by the respondents below and throughout the consultations, and these are the messages that so many of the community wished to deliver.

- THIS IS LIKE HITTING A BRICK WALL... NOBODY LISTENS TO THE INDIVIDUAL OR GROUPS AND NOTHING EVER CHANGES. I HAVE ANSWERED THE ABOVE QUESTIONS SO MANY TIMES I HAVE LOST COUNT AND CERTAIN GOVERNMENT BODIES JUST DO WHAT THEY WANT ANYWAY SO WHAT IS THE POINT OF YET ANOTHER SURVEY.??? I AM IN CHARGE OF MY OWN LIFE AND WILL SPEAK OUT ABOUT MY HUSBANDS STORY IF I WANT TO AND MAKE MY OWN DECISIONS.
- There needs to be much greater transparency in organ donation in general in Australia. There is a high degree of control and power by medical practitioners and organ donation agencies involved in the organ donation process with very little regard to the emotional consequences for donor families and recipients post donation. Donor families and recipients are key stakeholders in this process and should be included in the decision-making process. Over time, we find new ways can be better than previous thought patterns and as such, allowing donor families and recipients to meet is an example of realising the benefits outweigh the perceived negative consequences (which have been demonstrated to occur so rarely that they are negligible). If consenting adults can make the decision to donate their loved

one's organs at one of the worst times of their lives, they are perfectly placed to be able to consent to meet with the recipient of these organs (if they wish and research shows many choose not to meet). This connection with the recipient can allow the donor family to experience something positive emerge from their personal tragedy.

- The Organ/Tissue Donation and Transplantation System that deals with all aspects involving Donor Families and Recipients and their families, needs to be more humanised at the Bureaucratic level. There should be an advisory board of Donor Family members and recipients who will represent the community, chosen by their peers, advising and directing OTA senior management. OTA is there to serve Donor Families and Recipients and therefore should be accountable.

Examples of contemporary ethical challenges encountered by DFA

This is an example that is mentioned by some respondents who believe the practice and approach is unethical and who hope with ethical regulation these concerns may be addressed. This related to a letter received by the Chair of DFA (Appendix 3). It expresses the views that so many engaged in this organisation and beyond express, that families and the community are deliberately omitted from consultation when it is feared they will not agree with the proposed changes. "*Received this letter yesterday from the WA Health Dept Act Chief Medical Officer. I highlighted the paragraph that confirms the Amendments contradict the above paragraph from the guidelines.* "The legislation aims to support access to lifesaving and life-enhancing human tissue and tissue products for patients in need". *Who cares how the Donor is treated? Clearly the legislation doesn't when it has now downgraded the level of expertise needed to retrieve the tissue. Not one family was consulted for this legislation.* "

Please note ongoing advocacy regarding legislation review in Appendix (5) DFA's recent submission to the Senate Committee for Community Affairs Inquiry: Australian Organ and Tissue Donation and Transplantation Authority Amendment (Disclosure of Information) Bill 2023 (Cth).

Specific issues that need urgent ethical consideration and need to be addressed in the guidelines:

- Ethical harmonised national legislation.
- Conflict of Interest by the OTA.
- Transparency in the informed consent process and information at registration on the Organ Donor Register and upon the death of a person in the context of organ and tissue donation.
- The right of freedom of association and to be able to use the name of your relative.
- Information about the knowledge and skills of organ and tissue retrieval teams and the ethical positioning of their roles in relation to respect for the deceased.
- Critical need for trust building, transparency and humanity.
- Critical need for recognition of altruism, *deep hope* * and trauma informed approaches.
- Critical need for respect, acknowledgement, reciprocity and dignity for all involved before during and after organ and tissue donation.

* *Deep hope* is defined as: a layer of hope that underlies this experience and may continue to exist, or even thrive, during a time when the patient [and their family] has very few 'somethings' left to hope for (Coulehan, J., 2011, p. 144. Cited by Northam, H.L (2016).Hope for a peaceful death and organ donation. PhD Thesis. University of Canberra. p.xii).

Responses to DFA Questions

The key questions posed by DFA relating to the draft guidelines received excellent response rates. **Regarding question 1:** *Do you think families and recipients have a right to meet if they both are consenting*? Respondents who included Donor Family and Recipients responses provided 100% support to agree to this proposition best summarised by these statements:

> My thoughts are best expressed by Senator Linda Reynolds in the Senate Chamber on 10/8/23, “I'd like to finish with the words of somebody else who made a submission to this inquiry. It was Mr Brian Myerson, OAM. He expressed frustration with this bill's apparent disregard for recipients and their donor families—the other side of the coin. He said the bill continues to 'deny the rights and liberties of donor families and organ transplant recipients' and continues: These two groups have endured incredible hardships and suffering through sickness and death and are being denied the opportunity to divulge information about themselves and their loved ones as and when they wish. No liberal democracy should discriminate against these groups and should protect their basic rights such as freedom of assembly and free speech.” The right to meet independently should be an absolute right for anyone in this wonderful country and the rights of donor families and transplant recipients should be included in this.

And:

> Families and recipients should be able to make their own decisions on who they meet, it is a basic human right. We do not need an overbearing authority telling us who we can and cannot meet.

Regarding Question 2: *For those that have met: have you experienced any of the risks mentioned or any other occurrence that made you wish you hadn’t sought out your donor family/recipient*? We received 8 responses, with the comments by those who had met indicating satisfaction with the experience, for example:

> I have met the recipient of my son’s kidney and pancreas, and it was a beautiful experience.

And

> I have not met any recipients but have heard of many meetings of families and recipients. I do know that not all meetings are the same, but I have never heard of anyone saying they are sorry for having met.

In Question 3 respondents were asked: *Despite the risks mentioned do you believe it is the decision of both the consenting parties to meet as consenting adults, as a normal Human Right to choose who you wish to associate with? Or do you believe that the authority of a paternalistic system is appropriate in these situations - that is, a system that makes decisions for people rather than letting them take responsibility for their own lives*? This question stimulated emphatic responses from almost all the respondents**. For example,**

> Despite the risks it is absolutely a normal human right to make the choice of whom I associate with. It’s ridiculous to suggest otherwise.

And

> ABSOULTELY! Consenting Donor Family and Recipients, as a human right, should be able to meet if they choose. They are in the best position to decide what is best for them at the time NOT a government policy put in place that is based on questionable reasoning. It would be for most a great aid in the healing process for both parties. They are perfectly capable to decide when and how much they want to form a relationship with each other. Donor Families and Recipients have been asking for this for years and their request has been ignored. It's time for the policy makers to listen and learn from best practice from other countries.

Question 4 posed the question: Do you think the benefits of meeting outweigh any potential risks?

> Definitely. Like everything in life there are always risks. Humans can't continue to live in fear thinking the worst. Let's face it, I think I could easily say almost all people travelling this road have suffered in some way and would have no intentions to continue doing so. The meeting would be for a beneficial reason only and no 'rules' should ever be able to take that decision from anyone.

Most respondents commented on this question and the theme that was consistent in all the feedback pointed to mutually positive experiences and the desire to be able to connect if mutually agreed.

> My relationship with my donor family is one of the most precious relationships I have ever experienced. They continue to thank me for all I have done for them in coming to terms with their son and brother's death. Until I met them, I had this deep need to thank them face to face as writing it was not enough for me.

The next question (4b) probed to gain a greater understanding of if the community felt that the institutions had a ethical obligation to support donor and recipient connections. Most Donor Family members and recipients also responded to this question with shared agreement, one indicated they were undecided, but overwhelmingly the view was that:

> Yes, they should. This way it provides a safe way to communicate. If someone give consent that is what it should be. They should be able to do what they choose and have full support of the Organ Donations and Transplant organisations to do so.

Additional comment included suggestions such as,

> I think there should be a process established where parties can be linked to enable contact to be made. This would involve informed consent and perhaps counselling/support available to ensure there was no coercion or to manage any negative consequences that could potentially arise (research demonstrates this is an extremely rare occurrence in countries that allow contact). This process could be managed by the organ donation and transplantation organisations or by an independent third party.

Consensus concluding that:

> Yes, the donor and transplant organisation support through the whole process from start to finish, so why not follow if the parties wish to proceed.

In Question 5 ethical concepts related to trust, informed consent and paternalism presented as beneficence or non-maleficence were explored in the question: *Do you think DonateLife should tell all families, as part of the informed decision-making process, that they will not assist consenting Donor Families and Recipients to meet, and they will delete or redact any identifying information included in correspondence despite the correspondents' consent to share their information with the other?*

This question elicited many very powerful statements that pointed to great frustration and a lack of trust in the organisation that facilitates organ donation, which included (capital letters as submitted):

> IT DEPENDS IF DONATE LIFE WANT THE DONATION RATE TO DROP TO ZERO THEN INFORM FAMILIES THAT THE ABOVE WILL HAPPEN........ FAMILIES IN GRIEF ARE NOT ABLE TO UNDERSTAND ALL THAT IS HAPPENING AND ARE MORE LIKELY TO SAY 'NO' IF THEY HAVE DOUBTS AND TOLD WHAT THEY CAN AND CAN'T DO...... SO IN OTHER WORDS DO NOT INTERFERE WITH VERY PERSONAL CORRESPONDENCE OR THREATEN PROSECUTION.
>
> Yes, I received a card from one of the recipients of my daughter's organs. The card started with 'hello my name is ….' and a first name, this was whited out by Donate Life. I do not understand why, if the recipient wished to provide their first name (and only their first name), it should be redacted. I would have liked to have advised my name, and my daughter's, when I responded but I knew it would be deleted so I didn't, and it felt wrong, as if I was not wanting to include that information. I think that they should also prepare families for the likelihood that they will receive no acknowledgement of the gift from recipients. My family and I have struggled with the lack of acknowledgement. While I can understand someone wanting to maintain their privacy, I do not understand how you could not even send a note that simply says thank you. I was brought up to express thanks for small things, never mind something as life altering as donation, something that in my daughter's case saved two lives (and improved 2 others). We have had very little contact from DonateLife, and I have struggled with feeling that they don't need us now they got what they wanted, her organs. When I raised this with DonateLife, I was told I could contact the recipients. I shouldn't have to; our family has already given a lot.
>
> Yes. Fully informed consent means having all relevant information. DonateLife have an obligation to honour the process of donation and transplantation.

In Question 6 Donor Families were particularly asked to share their views with the question which is based on the experiences of donor Family members. *If you are a Donor Family: were you given any information as part of the informed decision-making process about the privacy laws in your state or territory? In some states and territories, you may be penalised and fined for telling others that your deceased loved one- was an organ and or tissue donor if you use their name.*

Responses ranged from*:*

> Yes, we were.

To: I was not told that I could not speak about my husband's donation without risk of being penalised. My husband's story has been widely used by DonateLife for promotion which means they have directly contradicted the law in WA. I always found it strange that DonateLIfe were so protective over the recipient information towards me and yet were happy to advertise my husband's story complete with details of time and dates which could potentially allow the recipients to self-identify (which happened with another donor family and recipient at an Honour ceremony held in Perth). This dual process is a contradiction which suits their narrative and control over the process but completely eliminates the donor families and recipients autonomy to decide if they would benefit from meeting. In all meetings of recipients and donor families in Australia, the benefits to both parties have outweighed any negative consequences and have assisted both parties in their difficult journey ahead.

In another experience a respondent reported:

> We were advised that DonateLife would act as the middleman and receive and forward information or letters between the 2 parties but they would not be able to provide info or personal details on either party.

And another experience:

> From my own experience, as I am sure of others, I was so proud of my loved one's donation and was so thrilled to share this one positive outcome from the trauma of losing my loved one. What purpose does such a draconian law in this situation. Surely telling others help to promote organ and tissue donation to the wider community. Of course, as part of informed consent, the families should be told they would be breaking the law if they talked about their loved one's donation. Again, it feels like "they got what they wanted" and families find out the impact of the consent afterwards. To further show Donate Life's disregard for donor families they recently introduced new federal legislation to cover them from using our donor stories but did nothing about clearing the way for donor families to tell their loved one's stories. Donate Life are so intent on controlling all facets of organ and tissue donation that they go to extraordinary lengths to control us and how and to whom we tell our loved one's story. This action is very hurtful and disrespectful.

Question 7 was focused on understanding Donor Family views regarding Decision making and consent and the clinical practice of retrieval surgery. This question was included due to recent communications regarding WA legislation (Appendix 3). It asked: *If you are a Donor Family, were you given any detail about who would perform the organ or tissue removal operation- what are their professional qualifications? Where the operation would be performed? What operation would take place for your loved one and what are the risks? In the same way as we are informed when we have our own operations.*

> Yes, but I was possibly in an unusual situation as I attended the operating room with my loved one and stayed during the withdrawal of life support.

For another family they believed coercion played a role:

> I was told that surgeons would be removing my husband's organs and that he would be treated with dignity and respect throughout the operation. I was also told he would be given pain relief which was a huge comfort to me at the time, but I have since been informed that this does not occur. I would not have consented had I not been assured he would be given pain control. I now feel the process was coercive and that it was a case of tell the family what they want to know to get the donation process approved.

Another family response:

> We were told nothing. We weren't even able to see our loved one prior to the retrieval. The only time we saw our loved one was at the Funeral Director's. We weren't told that to have corneas removed would leave obvious marks and having long bone removed would limit us to what we could dress our loved one in. We had no idea of even where our loved was, which hospital, what part of the hospital, who would be doing the operation, what qualification (if any) they had. Secrecy seemed to be paramount.

Some families expressed satisfaction:

> I was told about what would happen and wear but not about the professionalism of the surgeons. I just trusted the process.

Sadly, the overall view indicated disappointment and regret about how the process was communicated and its impact on the Donor.

> My loved one was a tissue donor. I spoke to a lovely Donate Life Co-ordinator who took me through a long list, and often confronting, questions. This consent was done over the phone. My loved one had died in a car accident and was taken to a major hospital. I was not invited to see my loved one before the operation. This omission still traumatises me today as I never got to say a proper farewell and just sit with my loved one prior to the donation process. When I did finally get to see my loved one their eyes were distorted and half open, her legs were obviously affected.... nobody prepared me for this. Donate Life's website tell us that it is a myth that the donation is visible, I can confirm this is not a myth it is true. I strongly believe that Tissue Donors Families, like Organ Donor Families, should be provided with a place to spend time with their loved one prior to donation being carried out. I was not told who was going to be operating on my loved one, but I assumed it would be a surgeon who I trusted to take care and show respect to my loved one.

Question 8 related to the emerging change for DFA in supporting families wishing to donate their loved ones organs and tissues. The West Australian (WA) parliament recently passed legislation to allow a retrieval technician to perform the retrieval of musculoskeletal tissue from our deceased loved ones. This is something that may already occur in most/ every state and territory. The Job Description for a retrieval technician does not include, as essential criteria, the requirement for a tertiary qualification within any medical/ nursing/

allied field. This suggests that If your loved one is to have tissue retrieved that the procedure may be done by someone without any medical qualification. The retrieval technician will be replacing a medical doctor, a Allograft Fellow, who is an advanced orthopaedic surgical trainee who spends 12 month undergoing specialist training in musculoskeletal tumour surgery and prosthetic reconstruction, as well as donor tissue retrieval processes. The WA parliament's rationale for passing this legislation is argued that the Allograft Fellow has competing demands on their time and may not always be available with the consequence that in the past that opportunities for donation have been lost. The Ethical Guidelines (p.40) state – "Respect for the dignity of donors - including potential donors - means that a donor should never be treated solely as a means to achieve the goal of transplantation for another individual. Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes unethical exploitation". All participants were asked, *Is the downgrading of the expertise of the person performing surgery on a deceased donor showing disrespect for the dignity of that donor? Has the goal now become about the transplantation for another individual and the donor now being treated solely to achieve the goal of transplantation for another individual? Do you think the WA government has upheld the ethical principles with this new legislation?*

This question also elicited significant responses from most respondents.

Some felt unable to answer:

> I am not aware of the details.

For others, the perception of harm to the deceased as a source of organs over-riding respect for the deceased body became a point of deep concern re the ethics involved and concern about the conflict of interest in retrieving the organs and tissues ahead of the respect for the deceased.

> The donor should never be treated purely as a source of organs, the donor was (possibly/in some Instances) someone's father/mother, son/daughter, sibling, grandparent etc. This donor is the hero in the story and should be highly respected until laid to rest.
>
> Again, this question points to a black and white answer. If this situation was in place when we consented to tissue donation I would not have consented. Accredited, qualified surgical staff is, for me, essential in respecting and honouring the donor and their family.

Question 9 received fewer responses and given it was focused entirely on Tissue Donors, unsurprising. All responses were aligned. *If you were a Tissue Donor Family, was it explained to you that the surgery could be performed by a person not required to have any medical qualification? As a member of the community do you have a concern that Tissue Donation retrieval surgery can be performed by someone not required to have any medical qualification- only on the job training?*

> I would not give permission under these circumstances.
>
> I don't agree with this proposal!!! Was it ever raised with the general public who are being asked to become Donor upon their death?

> I had no explanation given at all and it did not occur to ask. See above for my thoughts on non-accredited surgical staff performing the removal of relevant tissue. I would like more information on the training required to be a retrieval technician.
>
> Yes I have concerns as they should have qualifications.
>
> There was no reference made as to the qualifications of the person doing the operation. You would think governments would be wanting more tissues. This blatant disrespect and unethical behaviour can only place at risk people's lives. Why would you say yes?
>
> I was not informed that his tissue donation could be performed by someone without medical qualification. I feel that this lack of training cold impact on the way my son was treated- that it is disrespectful.
>
> I was not informed as to who was performing the operation. I would not have assumed anyone one other than a surgeon would be carrying out this operation. I strongly feel, as part of informed consent, I should be told who would be doing the operation, especially if it was to be carried out by someone other than a medical specialist.

Question 10 was included to gain a sense of what information is required for Donor Families when making donation decisions, considering especially the ethical assumptions that underpin informed consent processes in Australian hospitals: *Do you think Donor Families should, during the informed decision-making process, be given as much information as to what they are deemed capable of handling, or should every family be given the same information regardless of their situation at the time? Bearing in mind that the informed decision-making process is dependent on the family being able to understand and comprehend the information so they can give an informed consent.*

Responses ranged from:

> All donor families should be given the same information. Whether it is absorbed or under-stood is another concern.

This position was supported by this respondent:

> One of the biggest issues for me, and still is, at the time I was so frustrated with not being given all the information. I constantly felt information was being withheld as they deemed the majority of people in my position would not be capable to make decisions. I didn't appreciate being put in a basket by the councillor, or the donate life team. I wanted all the information and just be upfront and not hide, or downplay, what was happening.

Another view:

> There is no question; to give proper informed consent you must be provided all the information. If a family is not able to process or comprehend the information at the time, then consent should not be

> sought. The family should be treated with the utmost care at the time that they are coping with the loss of their loved one.

This is the first to comment on the Registration process and its value:

> This information needs to be part of the Donor Registration process. It is very hard to comprehend this type of material when in the ICU at the side of your loved one.

The final DFA **question (10b)** was: *Should this information be provided to all Australians as part of a national education and awareness program?*

This question also received a good response rate with most agreeing, in the words of one:

> "Yes, 100%"

The challenges of the lived experience of donation and its aftermath were expressed here as:

> SHARE THIS INFORMATION WITH EVERYONE IF YOU WANT TO SCARE THE HELL OUT OF THEM WITH ALL THE RULES AND REGULATIONS ...... OR INTRODUCE THE IDEA OF ORGAN AND TISSUE DONATION INTO THE EDUCATION SYSTEM AT A VERY EARLY AGE SO THAT A CHILD BECOMING AN ADULT WILL ACCEPT THE IDEA OF DONATION WITHOUT QUESTION AND NOT FEAR THE PROCESS.

> Respect for the dignity of donors - including potential donors - means that a donor should never be treated solely as a means to achieve the goal of transplantation for another individual. Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes unethical exploitation.

Responses to NHMRC specific Questions

Consultation with the Donor Family Australia community regarding the specific questions that related to contemporary ethical issues that impacted the group drew considerably more response than the over arching questions presented in the NHMRC consultation document.

In response to **Question 1,** *In your opinion, do the guidelines adequately address current ethical considerations in cell, tissue and organ donation and transplantation?* DFA received 8 responses.

Yes	No	Unsure
3	3	2

Question 2, which was, *If you answered no or unsure to question 1, which ethical considerations have not been included and/or which issues have not been adequately addressed?* Generated the following responses which summarised concerns frequently mentioned to DFA from community members which all relate to transparent and effective communication, respectful relationships, informed discussions and strategies to support trust. The ethical principles and values that underpin altruistic donation are clearly challenged in the experiences of the people who have responded.

HAVE PUT UNSURE AS I DO NOT HAVE EITHER THE PATIENCE OR ENERGY TO WADE THROUGH 242 PAGES OF GUIDELINES LET ALONE RETAIN THE INFORMATION... AS I WOULD SUSPECT 90%OF THE POPULATION ARE THE SAME .... BUREAUCRACY WEARS YOU DOWN EVENTUALLY!!!!

- The current Guidelines provide strict rules regarding parties meeting and yet no action has ever been taken against parties the defy these guidelines concerning the meeting of parties. It then raises the question as to why have these restrictions in the first place if they are not going to be upheld.
- The benefits that can be gained by allowing consenting parties to communicate with each other.
- One example is the assumption regarding privacy. Every individual has varying requitements regarding privacy and for me the guidelines are far too prescriptive.
- The proper consultation of donor families and recipients.
- Agreed meeting between donor families and recipients.

Question 3 asked: *If there is any content or aspect of the guidelines that you would consider redundant or dispensable, please provide details below.*

- There is no content that I consider to be redundant or dispensable:

One person supported this statement.

_ *There is content that I consider to be redundant or dispensable. The content that I consider to be redundant or dispensable is:*

Four people responded:

- *SIMPLIFY THE CONTENT ...... MORE CONCISE.*
- *Not allowing consenting parties to communicate with each other.*
- *Many of the issues regarding privacy.*
- *All decisions need to be made based on what donor families and recipients want and need to heal. Trust is required for individuals to make their own decisions.*

Question 4 asked, *For donors, recipients, family members or members of the community*

Are these guidelines helpful to you in increasing your understanding of the ethical aspects of donation and transplantation? Seven responses were received.

Yes	No
5	2

Question 5 related to Q4. *If you answered yes to question 4, which component/s of the guidelines is/are most useful for you (e.g. the values and principles, the background in Chapter 2, a specific chapter, the case studies, etc.)?*

- The issues considering donor family/ recipient contact
- I find it creates issues that in the real world do not exist or are unlikely to exist in most cases.
- The values and principles of the organ donation and transplantation was informative.
- Too many to list. It is an incredibly long document.
- I was unaware of the impending change of implement non-qualified surgeon to perform on donor's bodies.

Question 6 related to Q4. *If you answered no to question 4, in what ways were these guidelines not helpful to you (e.g. topics covered, specific content, complexity of language, document structure, etc.)?*

- SIMPLIFY THE CONTENT ...... MORE CONCISE
- The document is far too long and overly complex.

Question 7 asked: *What type/s of additional resources (such as short fact sheets) might be helpful to you in understanding the ethical aspects of donation and transplantation issues?*

- SIMPLIFY THE CONTENT ...... MORE CONCISE
- If the authors are unable to write a short, simple set of guidelines available to the "man in the street", the entire exercise will be a waste of time and effort.
- Just a fact sheet with maybe a Top 10 list of important info, and perhaps a list of 5 "Fun facts" (fun is not the correct term, but maybe a form of 'Did you know?'
- Simplification and transparency. Additional resource ideally would be time for the donor's family to understand the facts of what is involved through the transplant process as well as a short fact sheet.

Question 8: *If you have any additional comments on the guidelines, please provide them here.*

- SIMPLIFY THE CONTENT ...... MORE CONCISE
- There should separate Ethical Guidelines for the medical fraternity and another for those from the Public considering donation, Families having donated and recipients and their family members. A document of 120 pages plus is just too much to absorb.
- Allow consenting parties to communicate.
- The guidelines should have canvassed and focused on the views of the “man in the street”.
- I am sorry but I could not answer the consultation questions. (This respondent answered the DFA questions).
- LISTEN TO THE NEEDS AND WANTS OF THE PEOPLE WHO LIVE EVERYDAY WITHOUT LOVED ONES WHO HAVE DONATED AND TO THE RECIPIENTS.
- No.

DFA SPECIFIC COMMENTS ON THE DRAFT ETHICAL GUIDELINES

REFERENCE PAGE	*GUIDELINE*	*DFA COMMENTS*
8	Ensuring ethical policy and practice in donation and transplantation activities within Australia is essential to maintain public trust and willingness to participate in donation, thus enabling more Australians to benefit from transplantation.	Public Trust and willingness to participate in donation is being challenged right now, consent rates of 54% 2022 and 55% 2023. We need the ethics of how our donation services are delivered by our government services examined, the public is sending the message of mistrust.
8	They are consistent with established ethical and legal norms governing healthcare practice in Australia, and with respect for human rights and the rights of all individuals as patients receiving healthcare.	The focus needs to be squarely around human rights and the right of autonomy of **all** concerned.
9	These ethical guidelines provide a framework to support ethical practice and **inform decision-making** by all those involved in Australia's donation and transplantation system, including: potential donors and recipients of transplanted cells, tissues and organs, and their families, carers, and communities.	With the emphasis on informed decision-making.
16	DonateLife staff work closely with intensive care staff, emergency department staff, hospital executive and other key personnel to ensure all of the steps for supporting donation are optimised. This includes ensuring all potential donation opportunities are recognised, that families of potential donors receive excellent care and communication, and that the process of donation is undertaken to a high medical and ethical standard.	Agree, very important. That care to families and recipients needs to continue way past retrieval.
18	2.3.6 *Eye and tissue banks* It mentions the "**surgical retrieval** of eye and other tissues".	Do you need a medical qualification to do surgical retrieval? The community would assume surgical retrieval would involve a medical doctor. In the interest of transparency and trust it needs to be clearer who is doing the retrieving of tissues. Currently retrieving is being done by non-medically qualified staff. The term *surgical* needs to be more transparent.
20	2.3.9 *Community, special interest and advocacy groups* **Transplant Australia** is a key community group supporting donors and recipients and their families: https://transplant.org.au . Kidney Health Australia, the peak body for kidney health provides education and support for those impacted by kidney disease. (Kidney.org.au)	Donor Families Australia is disappointed that there was a need to mention (and hyperlinked web page) two recipient organisations and not include the only Donor Family organisation in Australia that represents Donor Families. To actually make it seem as though only recipient organisations make up the 'Key community groups' in this space is undermining Donors and their Families contribution to organ and tissue donation. This comes down to respect or lack of for Donor Families. In the interest of correctness for this document Transplant Australia does not support deceased Donor Families. For the documents purpose Donor

		Families Australia's web page address is - https://www.donorfamiliesaustralia.org/
23	People are encouraged to register their wishes on the AODR and to tell their family about their decision about being an organ and tissue donor. The AODR is checked by authorised clinical personnel, usually donation specialist staff, and the patient's registration status is shared with the family as part of the donation discussion seeking informed consent.	Good to see acknowledgement around registration not being the informed consent. Informed consent is given by the family after they have been given all the necessary information they need to make that informed consent.
25	If the family (or rarely the conscious, competent patient) agrees to donation, the assessment for donation suitability and organisation of the **surgical** donation procedure occurs prior to death.	Again reference to the term **surgical** donation. Surgical donation term is used for organ donation under the heading DCDD. Earlier point that tissue donation uses the term surgical retrieval. Very similar terms and the community can be forgiven to assume that medically qualified personnel will be used on both occasions when in fact this is not the case as tissues will be retrieved by personnel with no tertiary qualification and in a morgue. Again emphasis is on transparency and trust.
29	Post transplant care	There is no mention of post-transplant care for Donor Families. Families need ongoing care after what they have experienced both in the death of their loved one and the transplant process.
31	The family are advised about the donor's appearance and steps may be taken to preserve the donor's appearance.	Advising the family of the donor's appearance should be mandatory. DFA can say this is not current practice. We know families that had no information around their loved one's appearance. Nor were they invited to have a viewing either pre or post the retrieval. That was all left to the funeral directors. When the information was finally given about appearance it made it very difficult to dress their loved one appropriately. That treatment again does not help trust and sticks with the family.
32	*Living kidney donation.* Short term risks of living kidney donation mostly relate to the surgical procedure, which is usually performed as keyhole surgery but occasionally requires to be open surgery. Pain, reduced mobility, and time required off work are usual. More serious complications are infrequent and include bleeding, infection, thrombo-embolism (blood clots), and rarely death. Longer term risks include a small increase in the likelihood of chronic kidney disease and requirement for dialysis. Assessment of donors seeks to exclude individuals at greater life-time risk of renal failure, although donors with co-morbidities are not excluded.	Some very serious risks for the living donor, including death. Risk assessment must conclude still worth doing. And yet the risks with consenting adults meeting is very minimal, one being the family could face disappointment if the other family does not want to meet. These risks are considered so bad that consenting adults are not enabled to meet. And yet the risk of death is not considered bad enough to stop living donation. There needs to be very careful consideration given as to whether living donation is going ahead purely for the donation. Is this action ethical?
39	*Ethical Foundations of donation and transplantation in Australia*	The principle of individuals to govern their own lives (respect for autonomy) and respect for human rights are so important in organ and tissue

	The ethical foundations of healthcare policy and practice in Australia include respect for human beings (respect for human dignity), for the rights of individuals to govern their own lives (respect for autonomy), and for justice, as well as obligations to help and avoid causing harm to others (respect for beneficence and nonmaleficence). These principles are all applicable in the context of donation and transplantation policies and practices. This requires decision-making that • respects the human rights, dignity, and autonomy of all members of the Australian community, • promotes the wellbeing and broader interests of donors and recipients and their families and communities.	donation. At present laws and the public sector make this realisation very difficult.
40	Principle 1 Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination. (see Chapter 3.3.1) -	This is done by providing families with all the information they need to make an informed consent. This includes any laws that will affect them once they have left the hospital after having said yes.
40	Principle 5 Donation and transplantation activities and associated decision-making should be transparent and open to scrutiny. (See Chapter 3.3.5)	All government departments that are involved in the process should be open to and responsive to being transparent and to scrutiny.
41	Respect for the dignity of donors - including potential donors - means that a donor should never be treated solely as a means to achieve the goal of transplantation for another individual. Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes unethical exploitation. . Acknowledging the invaluable contribution of living and deceased donors is ethically important and respectful of their dignity. Providing formal expressions of gratitude to donors in recognition of their gift and paying respect to the families of deceased donors may also help to encourage donation and foster long-term donor and donor family wellbeing.	Respect in how tissue is retrieved. Recently in WA new legislation has been introduced where the donor can now have tissue removed by a non-qualified person. It has gone from a medical doctor to someone with no qualification at all. (Appendix 3). That sounds like a donor being treated solely as a source of tissues for tissue transplantation. In WA a butcher who performs procedures on deceased animals is more qualified than the person retrieving tissues from deceased humans. The butcher needs to do a two and a half year TAFE course to acquire a licence. The WA Health Dept openly say the new laws are in place solely because the surgeon who would otherwise do the surgery can be unavailable at the time and they lose the opportunity to retrieve tissue. No thought is given to the donor it is totally treating the donor as a tissue source. The lack of respect for the donor makes the WA Health Dept are doing unethical. There is a lack of respect in how Donor Families have been excluded by the NHMRC and the OTA in the review of the ethics guidelines process. As mentioned in the text, this disrespect is not helpful

		with the long-term Donor Family wellbeing or the encouragement of donation.
43	Some burdens or risks may sometimes be necessary in order to produce benefits. It is important to ensure that the expected benefits of an action are proportionate to the expected risks or burdens of the action, all things considered.	Given individuals should have their right to autonomy and human rights the decision should be theirs where the benefits and the risks relate to them and the benefits outweigh the risks.
44	All custodians of human cells, tissues and organs should also act in accordance with relevant laws, regulatory frameworks and clinical standards governing their practice.	It is important that our government services operate within the state/territory laws. This has not been happening.
47	Principle 5. Donation and transplantation activities and decision-making should be transparent and open to scrutiny.	Two very important aspects ie transparency and open to scrutiny. Not the strength of our current system. Transparency and scrutiny should not just be for the chosen few. All donor families and recipients should have equal access.
51	3.4.1 Framework for ethical decision making The following steps are commonly considered as part of structured approaches to ethical decision-making in clinical practice. They are described sequentially but in practice these often occur in parallel. - Information gathering and **disseminating**	Should families in WA, SA and NT be told that their respective legislations prohibit them from mentioning their loved one's donation story freely to family, friends and community? Do they need to be told that by saying yes they effectively lose ownership of their loved ones donation story? Should families be told that the retrieval of tissues is done by staff with no formal qualification? Surgeons and medical practitioners are not used for this operation. Should information passed onto the family be determined by the condition of the family at that time i.e. should information only be given as to what is considered the family may be able to cope with at the time and thus make it more likely they will say yes? The WA Health Department have told DFA that they change the information given to families depending as to what they consider the family can cope with. That is every family is given different information to come to a so called informed consent.
55	As rules that govern many aspects of our society, knowledge of relevant laws is important for appropriate ethical decision-making in donation and transplantation. Failure to follow the law can result in offences being committed or penalties being imposed. This is the case, even if a person does not know about the specific law.	In WA the Health Minister has said that she will not prosecute Donor Families where they pass on their loved one's information. She has said it is not in the publics best interest. Is it unethical to knowingly contravene legislation when you know you can get away with it? One must keep in mind that Minister's can change. It is important for the decision making process that families are made aware of what the law is around them making their loved ones information publicly known. As mentioned it doesn't matter if a person

		does not know about the specific law penalties can still be given.
58	Procedural justice and inclusivity in decision-making Decision-making relating to policy, practice and governance of donation and transplantation activities should be procedurally fair. This requires equitable inclusion of relevant stakeholders or their representatives in decision-making, and transparency in decision-making. Representatives of stakeholders including donors, donor family members and transplant recipients should routinely be involved in decision-making about donation and transplantation policies and governance of donation and transplantation programs and activities.	DFA applauds the idea of Donor Families being included in the discussions around policies and governance of the system. DFA looks forward to the introduction of such a system and being invited to contribute. Again, this should not be open to only the chosen few.
66	General considerations in consent The decision-maker must also meet the following criteria: Has decision making capacity, Is making a voluntary decision without undue influence, manipulation, or deceit, Has received and understood **sufficient** information that is relevant to the decision, including the risks and benefits of relevant interventions, and available alternatives if relevant.	What does **sufficient** information mean? Should it be **all** information that may influence the decision making? Sufficient information implies the family does not need all the information. Also then implies those giving the information will be selective as to what they tell the family. .
69	In general, information should be provided about • the intervention that is proposed, such as the surgical or medical procedures that may be necessary for donation and transplantation, • the purpose of the intervention(s) and who will be involved in the process, • the expected outcomes of the intervention and its likely risks and benefits, • alternatives to the intervention including the option of doing nothing, • any limitations on the information provided such as uncertainty regarding potential outcomes, • potential conflicts of interest or other factors that may lead to bias (see Chapter 3.8), • any limitations of privacy that may be relevant such as the requirement to disclose some clinical information about donors to transplant recipients	Families need to have the intervention explained to them ie where it will be performed and who will be doing the procedure and what qualifications have they. Families should have it explained to them how their loved one will look after the procedure. We have been told by families that it is clear their loved one has been operated on.
104	6.1.4.1 Limits of risk acceptance and concerns about paternalism • While an individual has a right to make informed choices about the risks they may assume in their own life, this does not mean that a health	• Very important principles when deciding what is best for the Donor and the Donor Family. The Donor Family is constantly being told by the system what is good for them.

	professional has an unrestricted obligation to perform clinical interventions at an individual's request irrespective of the risks and benefits involved. - Health professionals must strive to avoid paternalistic decision-making, in which their own personal beliefs regarding the proportionality of risks and potential benefits in a particular case are valued over those of the individual patient who is best placed to evaluate this in the light of their personal values and preferences.	
110	Evaluating risks and benefits of deceased donation for donor families	Donor Families stand the risk of prosecution if they pass on any donation information about their loved one.
121	Privacy and confidentiality - Principle 5 Donation and transplantation activities and decision-making should be transparent and open to scrutiny. - Principle 6 Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families and the confidentiality of information related to donation and transplantation activities.	The system has a history of shutting down conversations that they do not agree with. Also history of shunning those that question. There is a total lack of transparency, and scrutiny is punished. DFA Totally agrees with this principle. This principle stands for the public sector as well. How hospital data of Donors and Recipients moves from the hospital environment to all other sectors within government without consent needs to be followed up.
121	General considerations in privacy and confidentiality Privacy and confidentiality are inter-related concepts that fall within the scope of an individual's general right to autonomy or self-governance over their own person; including their right to control access to and use of their body and personal information.	This concept is so important. And there are two aspects about this i.e. their right to control access to and use of their body and personal information. The two aspects seem to go hand in hand, you should not be able to have one without the other. This becomes very confusing when we refer to the deceased Donor. It would seem the nation agrees that the family has control of their deceased loved one's body, by seeking the family's consent for retrieval, but does not have the same control over their deceased loved one's information. Technically the deceased Donors information is locked inside the hospital as no one has the right to pass that information on.
123	7.1.1.1 Legal considerations in disclosure of identity of donors and recipients In the human tissue legislation offences exist in some States and Territories applicable to health professionals involved in donation or transplantation who disclose 'to the public' the identity, or identifying information about, donors or transplant recipients. Exceptions do exist where consent to disclosure has been provided by the donor or recipient. However, **uncertainty exists regarding who, if anyone, can lawfully provide such consent in relation to children and deceased donors.**	This uncertainty needs to be passed onto the families at the point of informed decision making. The family has a right to know before they consent that they can be prosecuted, and that knowingly contravening law is unethical.

128	Box 7.1 Prospective donors, donor families and transplant recipients should be informed of potential limits on or risks to privacy or confidentiality at the time of decision-making about donation or transplantation. They should also be advised of strategies to reduce the risk of privacy breaches	At the time of decision- making families need to be made aware of their respective state/territory's legislation. They need to know that they cannot discuss their loved one's donation as it contravenes legislation. DFA has been told by the OTA that this will not be done as it will increase the likely hood of a decline to retrieval.
129	Both the ABMDR and the transplant centres take responsible for reviewing correspondence and removing any identifying information that may lead to a breach of privacy or loss of anonymity. Similar processes are in place, for example at DonateLife and eye and other tissue banks to facilitate anonymous correspondence between deceased donor families and recipients of deceased donor transplants.	How is this a breach of privacy or loss of anonymity when the Recipient has given consent for that information to be in their correspondence? Perhaps it is more a breach of the individual's autonomy and human rights?
130	Donors, deceased donor families, and transplant recipients all have rights to privacy, and when consenting to non-directed donation or transplantation both parties should be informed of the requirement for anonymity in the donation relationship and the **relevant limits of information disclosure.** They should also be informed about relevant opportunities for contact and the default restriction to anonymous communication as well as strategies to reduce the risk of privacy breaches.	What are these **relevant limits of information disclosure**? And what are the relevant opportunities for contact and default restrictions to anonymous communications? The point is strongly made that families should be informed of the requirements around information disclosure. This needs to be part of the decision-making process. Families need to be made aware of the law in their respective state/ territory so as to protect them from penalties and fines and also so they are aware of the policies of the OTA/Donate Life around consenting adults meeting. The basics of information being shared is that with the consent of the person to whom it relates information can be shared. We know no one can share deceased Donors information, however we know Recipients have a basic right to share their information if they so wish whether via correspondence or any other medium.
130	Assuming that in some cases, both donors (or donor families) and their recipients may be willing to disclose their identity to one another, such disclosure may no longer be a breach of privacy. However, there are concerns that disclosure and non-anonymous contact between donors and recipients who are otherwise unrelated could in some cases lead to harm.	If the guidelines are going to mention 'lead to harm', which on the risk scale is very low, it also needs to mention that it can lead to benefits. DFA knows of many hundreds of consenting adults meeting. We have not heard of one instance of either party coming to harm. When the OTA identifies harm it needs to provide substance to this claim. Earlier in the guidelines we read that a living donors ultimate risk can be death but still OTA let that procedure go ahead. We do not consider the harm to either the consenting Recipient or the consenting Donor Family can experience as being as risky as the potential of death. OTA does not want to be seen as going ahead with procedures for their own benefit and forgoing others because of their paternalism.

131	Waiving anonymity may also be associated with significant risks. These include:	The risks listed as **disappointment** (page 133), **psychological impact, pressure and exploitation** are things that DFA has not come across. DFA acknowledges and knows that not all consenting meetings are the same. The relationships developed are different but none that adults don't face everyday in their life. Donor Families have potentially experienced the worst moments in their lives with the death of a loved one, the risks identified are minimal by comparison to what they have been through and again is less than the risk of death. When weighing up the number of positive meetings over negative meetings the positive ones far outweigh the negative ones. Those risks as identified are more likely to occur when people seek each other out and make contact via social media or their own investigations. If contact was to be made via Donate Life proper introductions can be made and adults can decide whether they wish to proceed. And given only 1% take up this offer in the United States we would not be looking at a large increase to Donate Life's workload. When DFA put to the ABMDR, how many assisted meetings they organised between donors and recipients ended not well because of the risks as listed, the answer was none. In fact, the ABMDR said they use all of them for promotional aides.
134	The ABMDR has established further conditions aimed at supporting donors and transplant recipients to make an informed and voluntary choice about waiving anonymity and establishing direct contact and reducing the risks that may be associated with loss of anonymity. These include:	*The ABMDR assist consenting adults to meet.* Risks in meeting are seen to be the same for ABMDR and deceased donor families. DFA asked the ABMDR if they know of any occurrences of any of the risks as listed occurring in Australia. They answered none. How can one group be assisted to meet and the other not?
135	Disclosure of information that may encourage or facilitate identification of potential donation relationships should be made with care and only with the consent of individuals who may be affected to reduce the risk of undesired identity disclosure or unsolicited contact.	In WA, SA and NT the disclosure of information relating to the deceased donor is unlawful unless DL passes the story on after seeking consent from the family. Hence the Police Commissioner in SA has been placed in the awkward position as his son's story in the media contravenes SA legislation.
136	Box 7.2 Summary of ethical recommendations regarding anonymity in donation • Prospective non-directed living donors, transplant recipients and deceased donor families should be informed of the requirement for anonymity in the donation relationship, as well as ○ legal barriers to disclosure of private or identifiable information about donor or transplant recipients by health	• Families should be informed that they cannot pass on their loved one's donation information as part of the decision-making process to protect them against penalties and fines.

	professionals and others involved in donation and transplantation activities. • The following conditions for facilitating contact between donors and recipients where this is legally possible are recommended: ○ Contact should only be facilitated if both the recipient and the donor independently request direct contact. ○ A minimum waiting period should elapse following donation and transplantation before identifying information is shared between the donor and recipient, to allow time for reflection on experiences and decisions to waive anonymity. Both donors and recipients should be counselled before providing consent to disclose their identity. Counselling should address: ○ Obligations to respect the privacy of the other party; ○ Risks related to loss of anonymity including, for the recipient, the risk of negatively influencing future decision-making by the donor if a second or subsequent donation is required; ○ Expectations regarding the potential experience and outcomes of identity disclosure, include the possibility that the other party will not choose to disclose their identity, and that direct contact, if established may not result in a positive or ongoing relationship. ○ Contact should not be facilitated if the recipient is currently seeking another HSC transplant.	• This is how all requests made by consenting adults should be conducted and assisted by Donate Life.
179	To ensure the integrity of donation and transplantation activities, and so that individuals and organisations involved in these activities may be held accountable to the public, the economic activities of the sector should be transparent. Transparency should also assist in review of the various sectors to ensure that the broader Australian economy and healthcare funding systems are not jeopardising the sustainability of individual organisations such as tissue banks or donation or transplant programs. Requirements for transparency and accountability include	Tissue Banks need to operate on a cost recovery basis. The guidelines show that the banks must be transparent and accountable. They do this by being audited. Auditors do not audit on the 'basis of cost recovery". From what DFA has found out from Tissue Banks there is no accountability on cost recovery. The WA Tissue Act recently introduced the concept of cost recovery into its legislation. There is no way of monitoring this piece of legislation, it seems to be on an honour basis. The concept of cost recovery is as suggested merely a concept, authorities have no intention of insuring it actually is regulated.

	• the maintenance of records for auditing purposes, • communication of fees and charges, justification of costs and prices in accordance with the principles outlined in Chapter 10.5.2) definition of profits arising from donation and transplantation activities and explanation and justification of how these are managed	

Submission by Professor Wendy Rogers on behalf of the International Coalition to End Transplant Abuse in China EndTransplantAbuse.org

Preamble

The *Ethical guidelines for cell, tissue and organ donation and transplantation* have been developed by NHMRC in collaboration with the Organ and Tissue Authority (OTA). The document draws on five existing NHMRC guidelines[1], combined with additional material, to create a single, comprehensive set of ethical guidelines that can be applied broadly across all aspects of cell, tissue and organ donation and transplantation.

These guidelines provide donors, transplant recipients, their families, clinicians and donation and transplant professionals with clear and current guidance.

The guidelines include both high-level ethical principles and specific guidelines for ethical practice related to cell, organ and tissue donation and transplantation from living and deceased donors. The document aims to provide guidance on a broad range of complex intersecting issues.

The document is a set of *ethical* guidelines and does not seek to provide advice on technical matters relating to clinical practice. However, it is noted that there is substantial background information on donation and transplantation and discussion of some clinical and procedural issues in the document.

For any questions related to the public consultation process, please direct your query to the NHMRC Ethics and Integrity section at ethics@nhmrc.gov.au.

Consultation questions

[Note: questions seeking identifying information, contact information, acknowledgment of privacy policy and permission to publish from those taking part in the consultation are standard and will be included in the survey.]

1. In your opinion, do the guidelines adequately address current ethical considerations in cell, tissue and organ donation and transplantation?

   _ Yes **X No** _ Unsure

2. If you answered no or unsure to question 1, which ethical considerations have not been included and/or which issues have not been adequately addressed?

Issues of organ trafficking and risk of complicity in transplant-related crimes are not adequately addressed.

9.4 (p 164)

This sentence is misleading and possibly incorrect: “Only a small number of Australians are known to travel internationally for organ transplantation.(143)” Smith et al (ref 143) make the point that as no data is collected, the number of Australians travelling internationally for transplants is unknown. However, these authors report that there is evidence that reporting of transnational transplants to ANZDATA has declined in recent years. Therefore it would be more accurate to say that the number of Australian who travel internationally for organ transplantation is unknown.

9.4.1.1 (p 165)

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[1] In 2017, NHMRC initiated a review of five related guidelines (available on the NHMRC website):

- *Organ and tissue donation after death, for transplantation – Guidelines for ethical practice for health professionals*, 2007
- *Making a decision about organ and tissue donation after death*, 2007
- *Organ and tissue donation by living donors – Guidelines for ethical practice for health professionals*, 2007
- *Making a decision about living organ and tissue donation*, 2007
- *Ethical guidelines for organ transplantation from deceased donors*, 2016.

First paragraph – as well as raising 'ethical concerns", the Guidelines should not that Iran is the only country that has a legal organ market, therefore any purchase or sale of organs in other countries is in breach of the Council of Europe Convention against Trafficking in Human Organs (CETS No. 216), as well as raising "specific ethical concerns".

Third paragraph, this sentence requires correction: "In addition, in China, a former transplant tourism "hot spot", organs used in transplantation for foreign (and domestic patients) have historically been obtained from executed prisoners. (150)" There is no evidence that procuring organs from executed prisoners in China has ceased. Reference 150 is eleven years out of date. As recently as 2021, multiple United Nations Special Rapporteurs reported on credible information about forced organ procurement from prisoners of conscience (see https://www.ohchr.org/en/press-releases/2021/06/china-un-human-rights-experts-alarmed-organ-harvesting-allegations). Additionally, Smith et al. note that China is the most frequent destination for Australians travelling internationally for transplants, making this a matter of urgent concern for the Australian transplant community.

9.4.2 (p. 166)

The incorrect claim that few Australian residents travel overseas for transplants is repeated – see first comment above on this. The cited reference does not provide support for this statement given the numbers are unknown.

Second paragraph: In addition to the duties cited, it is important to note that health care practitioners have business and human rights obligations regarding organ trafficking crimes. See "*Do No Harm: Mitigating Human Rights Risks when Interacting with International Medical Institutions & Professionals in Transplantation Medicine", published* by the international law firm Global Rights Compliance (GRC) (Legal Advisory Report and Policy Guidance). These documents contain information on relevant Australian laws and regulation about avoiding complicity in organ trafficking crimes.

9.4.2 (p. 167)

To further support the points made in this section, the Guidelines could cite the House of Representatives Joint Standing Committee on Foreign Affairs, Defence and Trade Human Rights Sub-Committee report "Compassion, Not Commerce: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism", which calls for a register among other actions to combat organ trafficking. This call for a register was supported by the 2024 Federal Inquiry into the Migration Amendment (Overseas Organ Transplant Disclosure and Other Measures) Bill 2023.

10.6 (p. 178)

The final statement in the second paragraph ignores the comprehensive data collected on organ trafficking in China. See for example, the China Tribunal which, based on forensic examination of multiple sources of evidence, found evidence of large scale forced organ harvesting in China.

10.6.1.2 (p. 181)

Under the reasons listed to consider reporting organ trafficking, include the business and human rights obligations of healthcare practitioners and their institutions, as outlined in the Global Rights Compliance Legal Advisory Report and Policy Guidance.

3. If there is any content or aspect of the guidelines that you would consider redundant or dispensable, please provide details below.

_ There is no content that I consider to be redundant or dispensable

_ There is content that I consider to be redundant or dispensable. The content that I consider to be redundant or dispensable is:

For donors, recipients, family members or members of the community

4. Are these guidelines helpful to you in increasing your understanding of the ethical aspects of donation and transplantation?

_ Yes _ No

5. If you answered yes to question 4, which component/s of the guidelines is/are most useful for you (e.g. the values and principles, the background in Chapter 2, a specific chapter, the case studies, etc.)?

6. If you answered no to question 4, in what ways were these guidelines not helpful to you (e.g. topics covered, specific content, complexity of language, document structure, etc.)?

7. What type/s of **additional resources** (such as short fact sheets) might be helpful to you in understanding the ethical aspects of donation and transplantation issues?

8. If you have any additional comments on the guidelines, please provide them here.

Appendix (1) Letter to request inclusion in consultation sent to Assistant Minister for Health and Aged care

Donor Families Australia
admin@donorfamiliesaustralia.org

URGENT

The Hon Ged Kearney MP
Assistant Minister for Health and Aged Care
Via email

30/5/24

Dear Minister Kearney,

Re: Urgent response required: re due to unrealistic Donor Families Australia (DFA) deadline imposed by the NHMRC for Ethics Guideline on Organ and Tissue Donation Review.

Once again DFA finds itself in an impossible position where it needs to respond to a consultation process that directly affects it and its Donor Family members within such a short time that proper consideration is impossible. Once again Donor Families have been disrespected by the OTA and the NHMRC under your leadership.

You will remember in August of 2023, when we spoke in regarding the Amendment to the Federal Tissue Act. You gave me assurances that Donor Families, and more specifically, DFA, will be consulted as a key stakeholder in the future where its membership is directly affected.

Two days ago, 28th May 2024, I received an email from the Acting Director, Ethics and Integrity NHMRC responding to my email, 22nd May 2024, requesting an update as to the Ethics Guidelines for Organ and Tissue Donation Review. In my email I included a quote from the then Director of Ethics and Integrity email, 20th January 2023, saying "We will certainly ensure that Donor Families Australia receives the documents and look forward to your feedback on them".

My email, 22nd May 2024, was a follow up to my initial email, 12th December 2021, to the NHMRC where I requested information regarding the ethics review and that DFA wishes to be able to contribute to it. I received a reply on the 15th December 2021, stating that "we will add you to our list of stakeholders to be informed about the consultation". DFA stayed in touch with the NHMRC over this three and half years to ensure that we would be given the courtesy of being part of this very important process that affects how Donor Families are treated.

Again, I made contact with the NHMRC via email, 22st May 2024, requesting the current update on the ethics guidelines. The replying email of the 28th May 2024 stated that the guidelines "recently underwent public consultation and the feedback from the consultation is being reviewed by the Australian Health Ethics Committee (AHEC) on 6th June 2024. Regrettably, it seems that the DFA was not included on the stakeholder list".

Donor Families AUSTRALIA

Ironically the guidelines refer to respecting Donor Families. The way Donor Families are treated by the various government departments under your leadership has been nothing but appalling. In this current environment with declining Consent Rates, it is even more important to listen to Donor Families to help understand the impact the current process has on decision making by the donor (through Registration) and the Donor Family.

We demand and quite frankly have earned a right to have a say in the ethics guidelines. One week's notice is a ludicrous amount of time to think that a serious review of the guidelines material by our membership can be achieved. We need an extension of the AHEC's Review to allow proper consideration of what's within. Given the length of time this has taken to put together we do not consider this to be unreasonable.

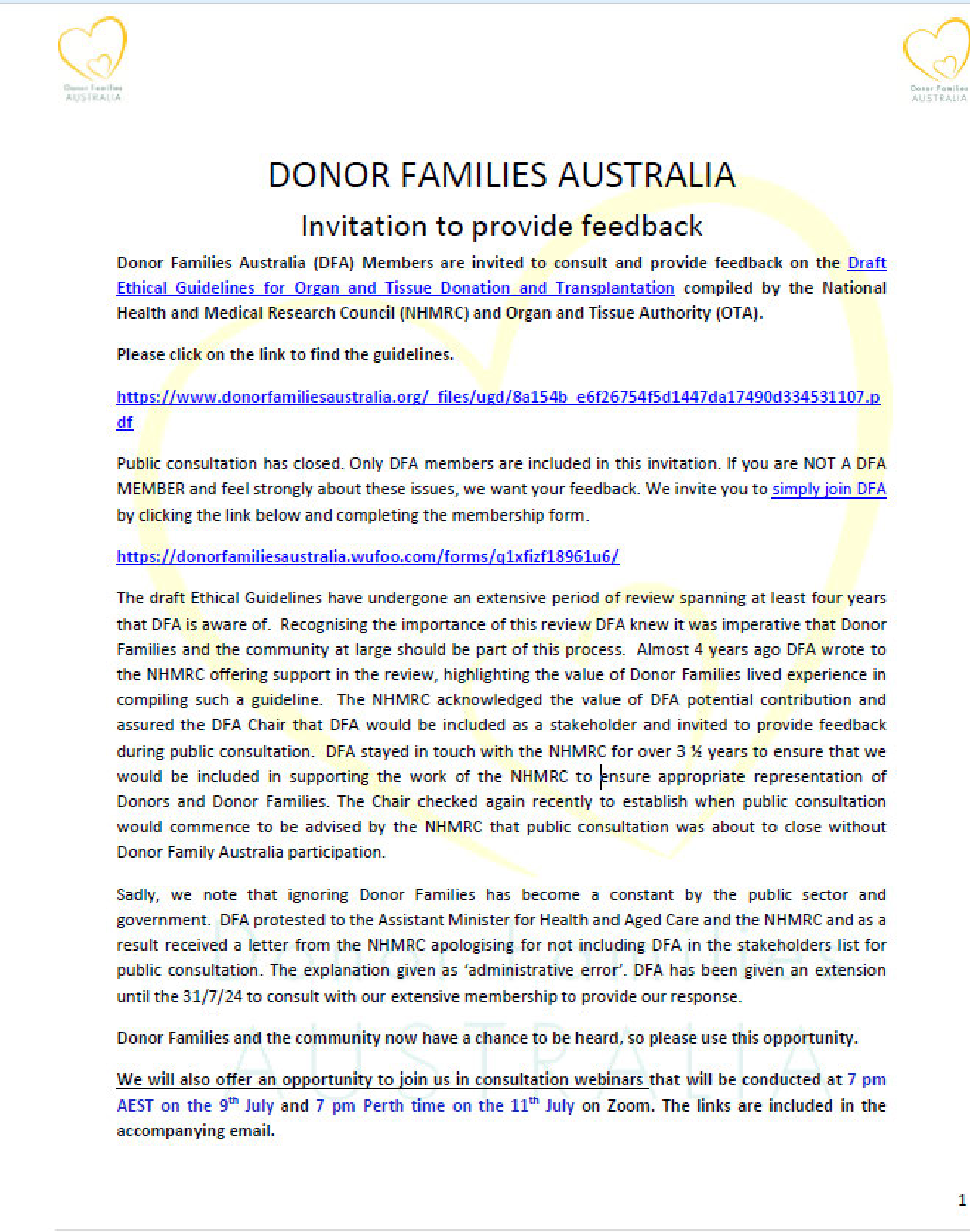
We look forward to your early response.

Kind regards

[redacted]

Bruce McDowell
Chairman

Appendix (2) DFA Feedback Form sent to all DFA membership.



DONOR FAMILIES AUSTRALIA

Invitation to provide feedback

Donor Families Australia (DFA) Members are invited to consult and provide feedback on the Draft Ethical Guidelines for Organ and Tissue Donation and Transplantation compiled by the National Health and Medical Research Council (NHMRC) and Organ and Tissue Authority (OTA).

Please click on the link to find the guidelines.

https://www.donorfamiliesaustralia.org/_files/ugd/8a154b_e6f26754f5d1447da17490d334531107.pdf

Public consultation has closed. Only DFA members are included in this invitation. If you are NOT A DFA MEMBER and feel strongly about these issues, we want your feedback. We invite you to simply join DFA by clicking the link below and completing the membership form.

https://donorfamiliesaustralia.wufoo.com/forms/q1xfizf18961u6/

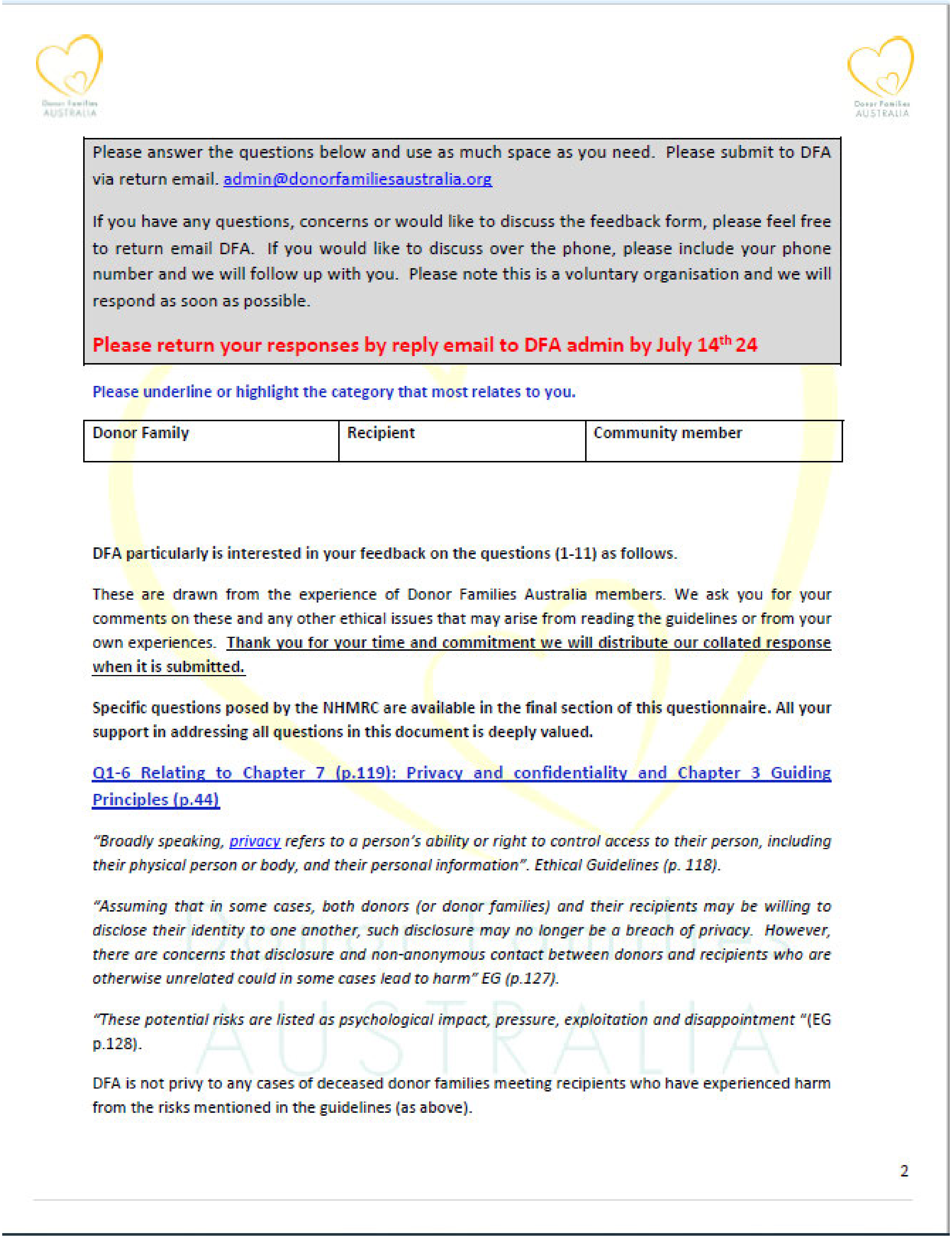
The draft Ethical Guidelines have undergone an extensive period of review spanning at least four years that DFA is aware of. Recognising the importance of this review DFA knew it was imperative that Donor Families and the community at large should be part of this process. Almost 4 years ago DFA wrote to the NHMRC offering support in the review, highlighting the value of Donor Families lived experience in compiling such a guideline. The NHMRC acknowledged the value of DFA potential contribution and assured the DFA Chair that DFA would be included as a stakeholder and invited to provide feedback during public consultation. DFA stayed in touch with the NHMRC for over 3 ½ years to ensure that we would be included in supporting the work of the NHMRC to ensure appropriate representation of Donors and Donor Families. The Chair checked again recently to establish when public consultation would commence to be advised by the NHMRC that public consultation was about to close without Donor Family Australia participation.

Sadly, we note that ignoring Donor Families has become a constant by the public sector and government. DFA protested to the Assistant Minister for Health and Aged Care and the NHMRC and as a result received a letter from the NHMRC apologising for not including DFA in the stakeholders list for public consultation. The explanation given as 'administrative error'. DFA has been given an extension until the 31/7/24 to consult with our extensive membership to provide our response.

Donor Families and the community now have a chance to be heard, so please use this opportunity.

We will also offer an opportunity to join us in consultation webinars that will be conducted at 7 pm AEST on the 9th July and 7 pm Perth time on the 11th July on Zoom. The links are included in the accompanying email.

1



Please answer the questions below and use as much space as you need. Please submit to DFA via return email. admin@donorfamiliesaustralia.org

If you have any questions, concerns or would like to discuss the feedback form, please feel free to return email DFA. If you would like to discuss over the phone, please include your phone number and we will follow up with you. Please note this is a voluntary organisation and we will respond as soon as possible.

Please return your responses by reply email to DFA admin by July 14th 24

Please underline or highlight the category that most relates to you.

Donor Family	**Recipient**	**Community member**

DFA particularly is interested in your feedback on the questions (1-11) as follows.

These are drawn from the experience of Donor Families Australia members. We ask you for your comments on these and any other ethical issues that may arise from reading the guidelines or from your own experiences. Thank you for your time and commitment we will distribute our collated response when it is submitted.

Specific questions posed by the NHMRC are available in the final section of this questionnaire. All your support in addressing all questions in this document is deeply valued.

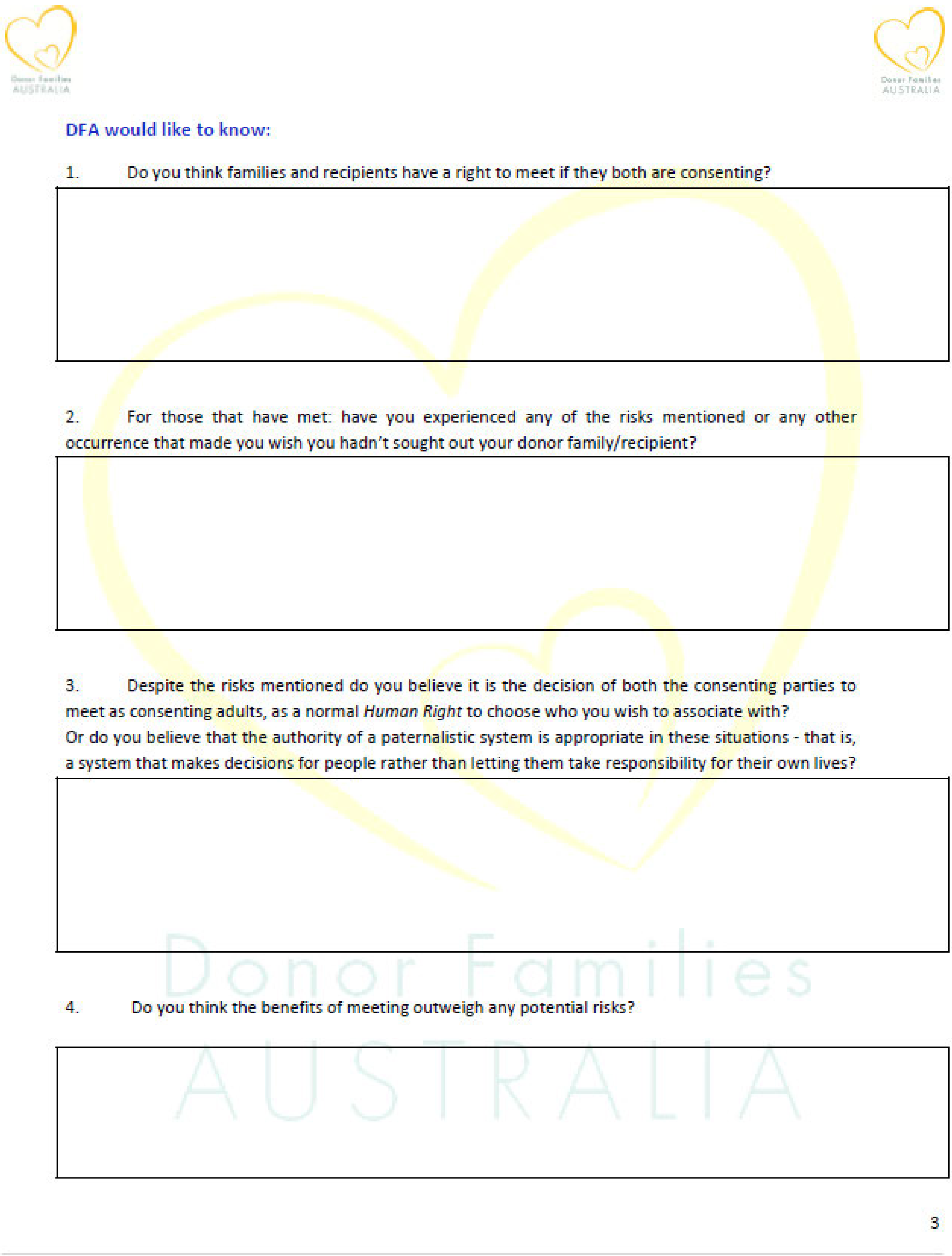
Q1-6 Relating to Chapter 7 (p.119): Privacy and confidentiality and Chapter 3 Guiding Principles (p.44)

"Broadly speaking, privacy refers to a person's ability or right to control access to their person, including their physical person or body, and their personal information". Ethical Guidelines (p. 118).

"Assuming that in some cases, both donors (or donor families) and their recipients may be willing to disclose their identity to one another, such disclosure may no longer be a breach of privacy. However, there are concerns that disclosure and non-anonymous contact between donors and recipients who are otherwise unrelated could in some cases lead to harm" EG (p.127).

"These potential risks are listed as psychological impact, pressure, exploitation and disappointment "(EG p.128).

DFA is not privy to any cases of deceased donor families meeting recipients who have experienced harm from the risks mentioned in the guidelines (as above).



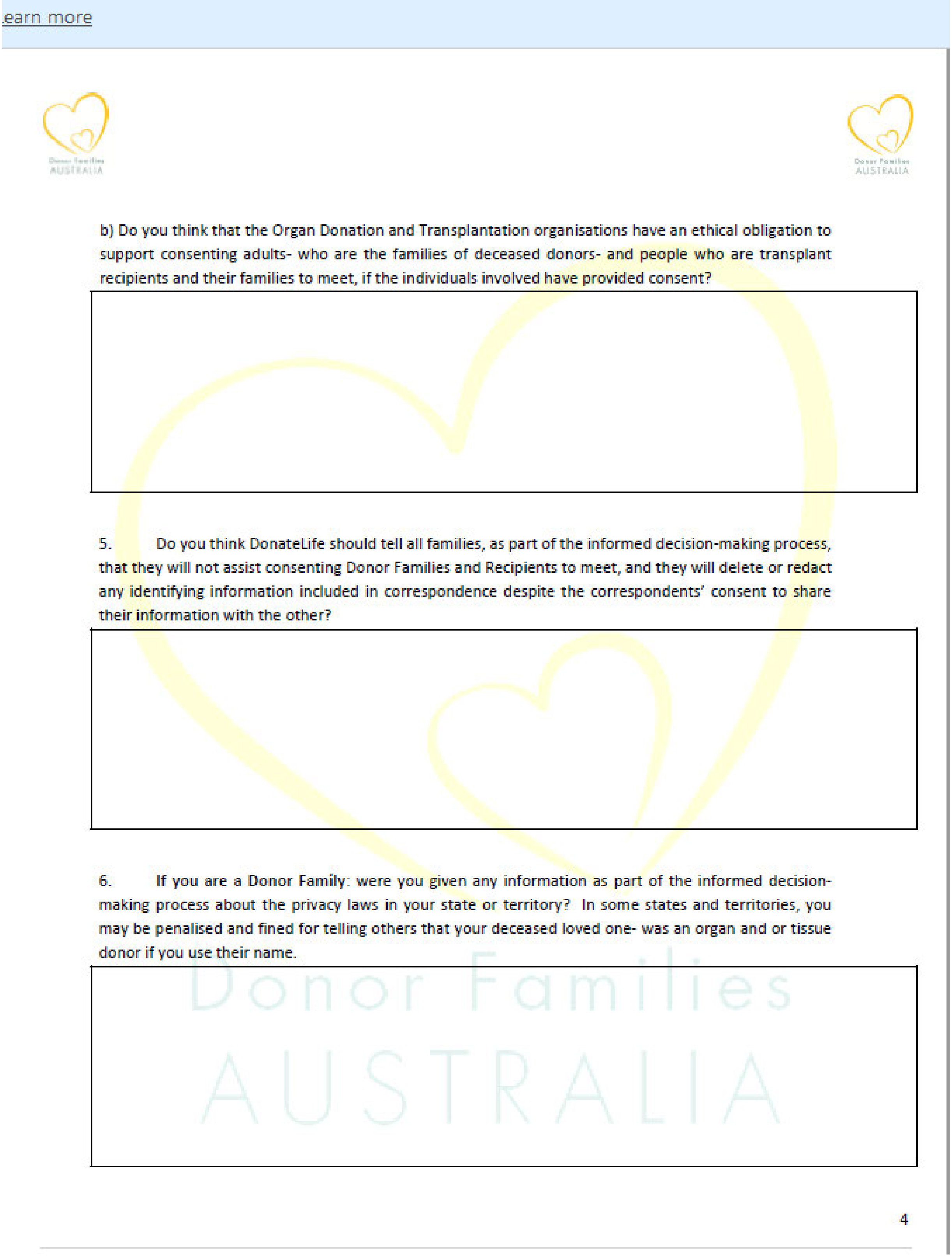
DFA would like to know:

1. Do you think families and recipients have a right to meet if they both are consenting?

2. For those that have met: have you experienced any of the risks mentioned or any other occurrence that made you wish you hadn't sought out your donor family/recipient?

3. Despite the risks mentioned do you believe it is the decision of both the consenting parties to meet as consenting adults, as a normal *Human Right* to choose who you wish to associate with?
Or do you believe that the authority of a paternalistic system is appropriate in these situations - that is, a system that makes decisions for people rather than letting them take responsibility for their own lives?

4. Do you think the benefits of meeting outweigh any potential risks?



earn more

b) Do you think that the Organ Donation and Transplantation organisations have an ethical obligation to support consenting adults- who are the families of deceased donors- and people who are transplant recipients and their families to meet, if the individuals involved have provided consent?

5. Do you think DonateLife should tell all families, as part of the informed decision-making process, that they will not assist consenting Donor Families and Recipients to meet, and they will delete or redact any identifying information included in correspondence despite the correspondents' consent to share their information with the other?

6. **If you are a Donor Family**: were you given any information as part of the informed decision-making process about the privacy laws in your state or territory? In some states and territories, you may be penalised and fined for telling others that your deceased loved one- was an organ and or tissue donor if you use their name.

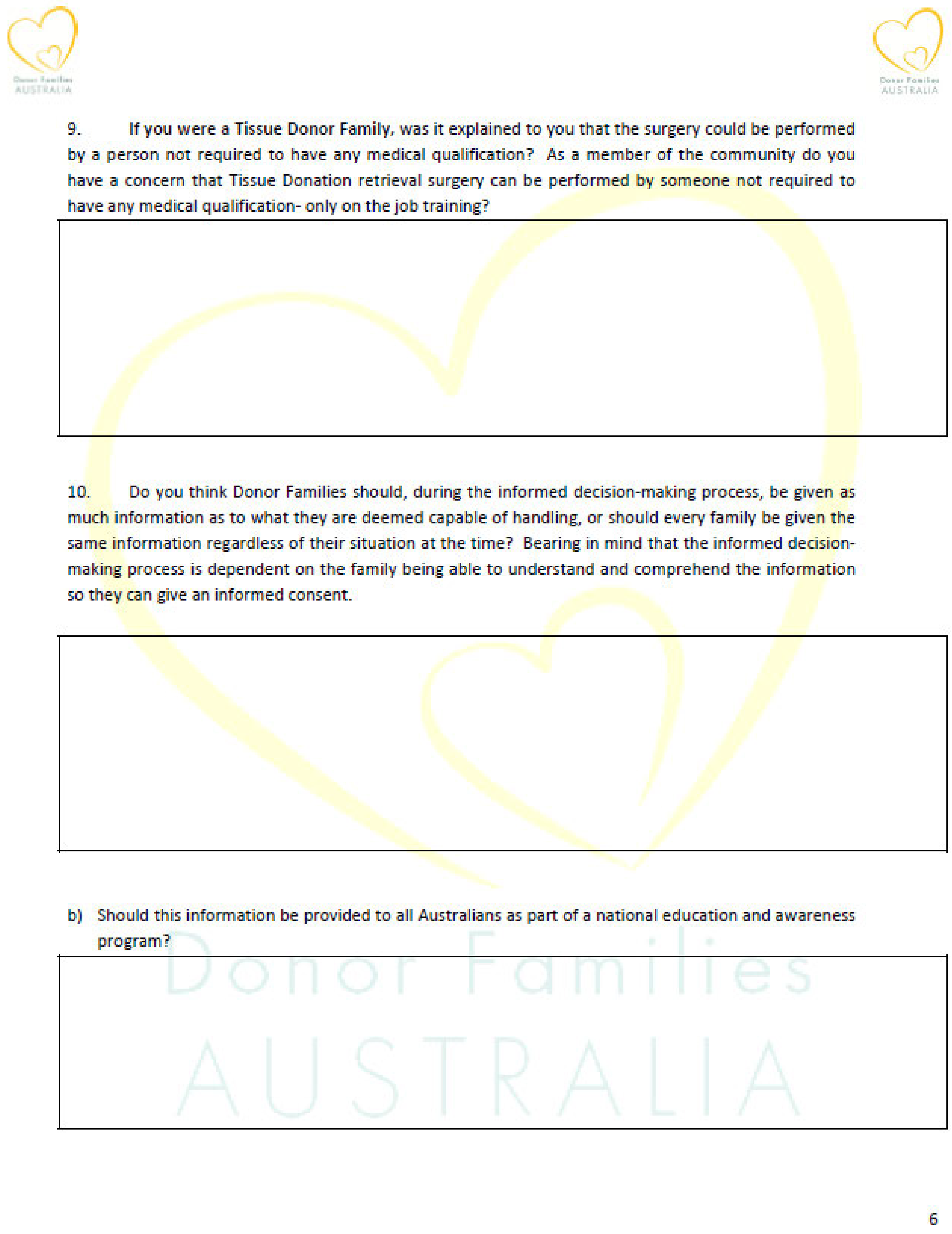
Q7-10. Relating to Chapter 4 (p.64). Decision making and consent.

7. If you are a Donor Family, were you given any detail about who would perform the organ or tissue removal operation- what are their professional qualifications? Where the operation would be performed? What operation would take place for your loved one and what are the risks? In the same way as we are informed when we have our own operations.

The West Australian (WA) parliament recently passed legislation to allow a retrieval technician to perform the retrieval of musculoskeletal tissue from our deceased loved ones. This is something that may already occur in most/ every state and territory. The Job Description for a retrieval technician does not include, as essential criteria, the requirement for a tertiary qualification within any medical/ nursing/ allied field. This suggests that If your loved one is to have tissue retrieved that the procedure may be done by someone without any medical qualification. The retrieval technician will be replacing a medical doctor, a Allograft Fellow, who is an advanced orthopaedic surgical trainee who spends 12 month undergoing specialist training in musculoskeletal tumour surgery and prosthetic reconstruction, as well as donor tissue retrieval processes. The WA parliament's rationale for passing this legislation is argued that the Allograft Fellow has competing demands on their time and may not always be available with the consequence that in the past that opportunities for donation have been lost.

The Ethical Guidelines (p.40) state – *"Respect for the dignity of donors - including potential donors - means that a donor should never be treated solely as a means to achieve the goal of transplantation for another individual. Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes unethical exploitation"*.

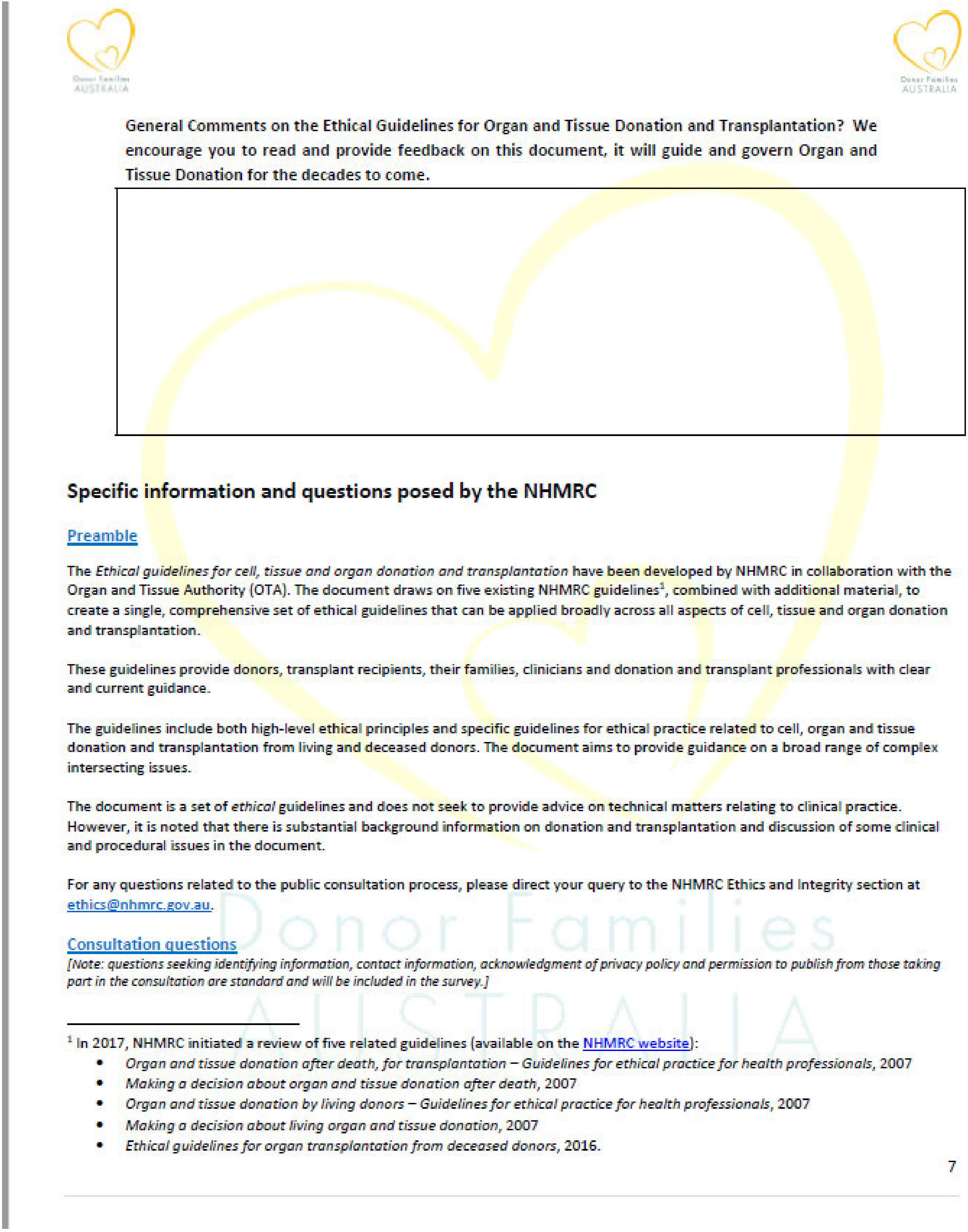
8. Is the downgrading of the expertise of the person performing surgery on a deceased donor showing disrespect for the dignity of that donor? Has the goal now become about the transplantation for another individual and the donor now being treated solely to achieve the goal of transplantation for another individual? Do you think the WA government has upheld the ethical principles with this new legislation?



9. If you were a Tissue Donor Family, was it explained to you that the surgery could be performed by a person not required to have any medical qualification? As a member of the community do you have a concern that Tissue Donation retrieval surgery can be performed by someone not required to have any medical qualification- only on the job training?

10. Do you think Donor Families should, during the informed decision-making process, be given as much information as to what they are deemed capable of handling, or should every family be given the same information regardless of their situation at the time? Bearing in mind that the informed decision-making process is dependent on the family being able to understand and comprehend the information so they can give an informed consent.

b) Should this information be provided to all Australians as part of a national education and awareness program?



General Comments on the Ethical Guidelines for Organ and Tissue Donation and Transplantation? We encourage you to read and provide feedback on this document, it will guide and govern Organ and Tissue Donation for the decades to come.

Specific information and questions posed by the NHMRC

Preamble

The *Ethical guidelines for cell, tissue and organ donation and transplantation* have been developed by NHMRC in collaboration with the Organ and Tissue Authority (OTA). The document draws on five existing NHMRC guidelines[1], combined with additional material, to create a single, comprehensive set of ethical guidelines that can be applied broadly across all aspects of cell, tissue and organ donation and transplantation.

These guidelines provide donors, transplant recipients, their families, clinicians and donation and transplant professionals with clear and current guidance.

The guidelines include both high-level ethical principles and specific guidelines for ethical practice related to cell, organ and tissue donation and transplantation from living and deceased donors. The document aims to provide guidance on a broad range of complex intersecting issues.

The document is a set of *ethical* guidelines and does not seek to provide advice on technical matters relating to clinical practice. However, it is noted that there is substantial background information on donation and transplantation and discussion of some clinical and procedural issues in the document.

For any questions related to the public consultation process, please direct your query to the NHMRC Ethics and Integrity section at ethics@nhmrc.gov.au.

Consultation questions

[Note: questions seeking identifying information, contact information, acknowledgment of privacy policy and permission to publish from those taking part in the consultation are standard and will be included in the survey.]

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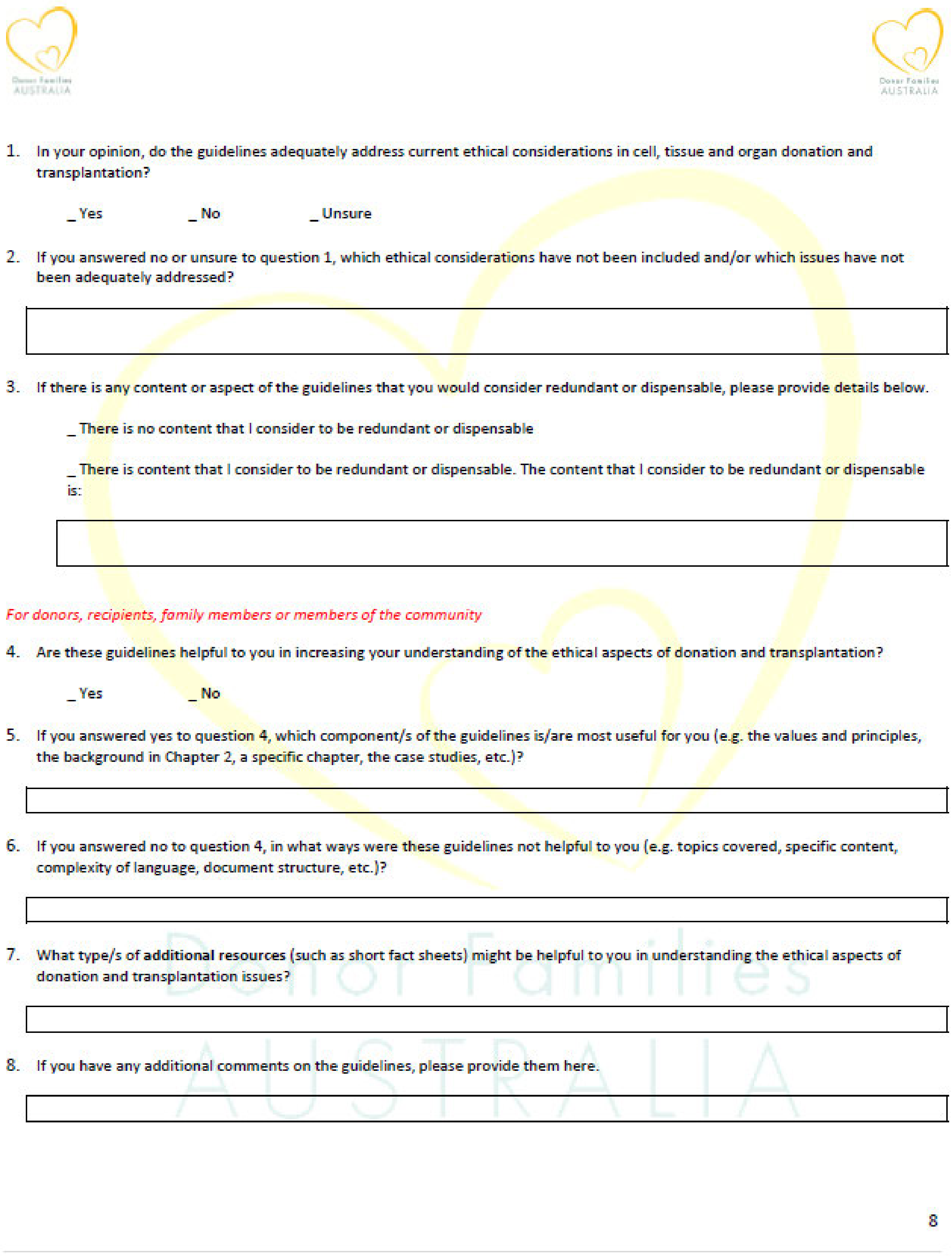
[1] In 2017, NHMRC initiated a review of five related guidelines (available on the NHMRC website):
- *Organ and tissue donation after death, for transplantation – Guidelines for ethical practice for health professionals*, 2007
- *Making a decision about organ and tissue donation after death*, 2007
- *Organ and tissue donation by living donors – Guidelines for ethical practice for health professionals*, 2007
- *Making a decision about living organ and tissue donation*, 2007
- *Ethical guidelines for organ transplantation from deceased donors*, 2016.



1. In your opinion, do the guidelines adequately address current ethical considerations in cell, tissue and organ donation and transplantation?

   _ Yes _ No _ Unsure

2. If you answered no or unsure to question 1, which ethical considerations have not been included and/or which issues have not been adequately addressed?

3. If there is any content or aspect of the guidelines that you would consider redundant or dispensable, please provide details below.

   _ There is no content that I consider to be redundant or dispensable

   _ There is content that I consider to be redundant or dispensable. The content that I consider to be redundant or dispensable is:

For donors, recipients, family members or members of the community

4. Are these guidelines helpful to you in increasing your understanding of the ethical aspects of donation and transplantation?

   _ Yes _ No

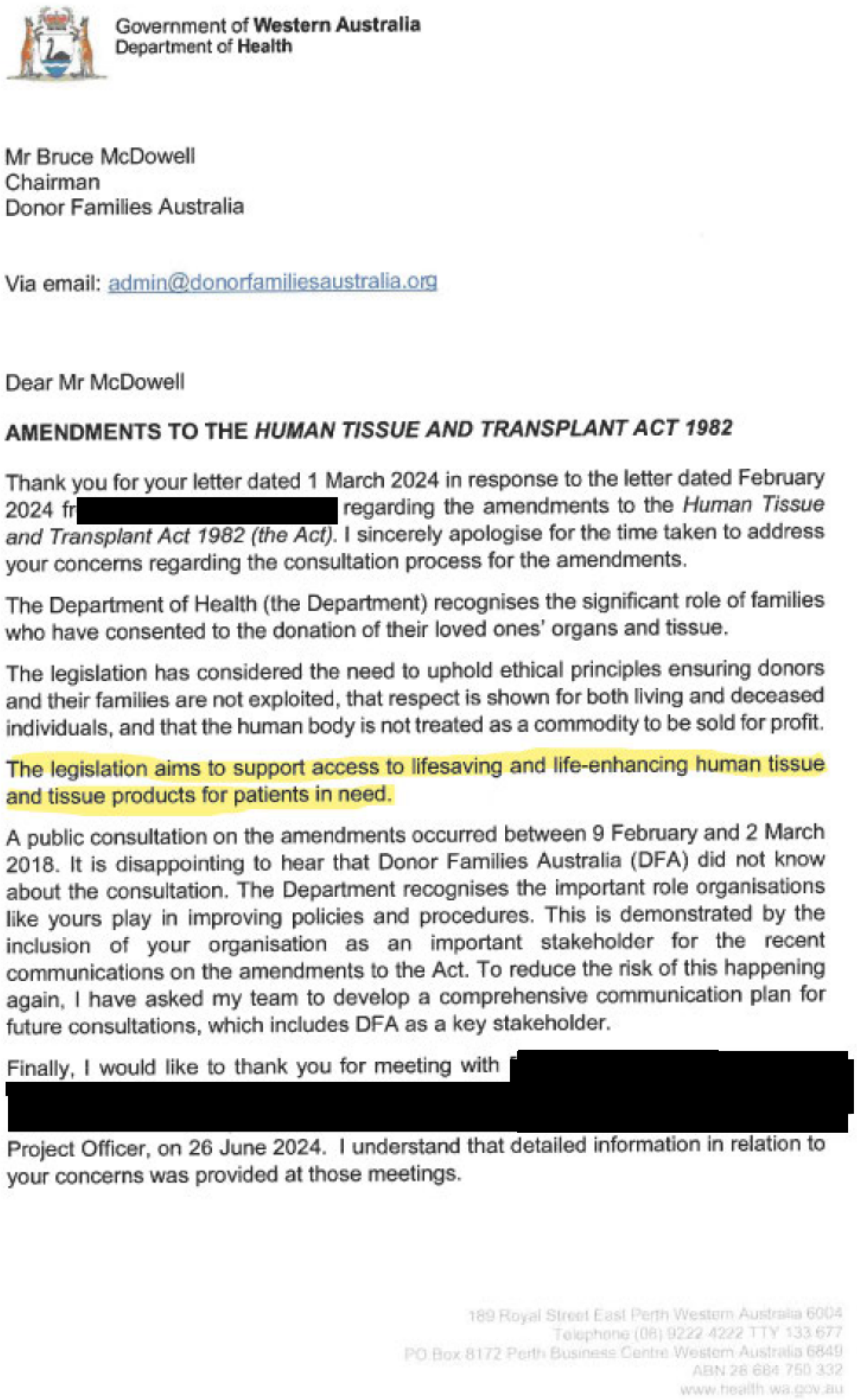
5. If you answered yes to question 4, which component/s of the guidelines is/are most useful for you (e.g. the values and principles, the background in Chapter 2, a specific chapter, the case studies, etc.)?

6. If you answered no to question 4, in what ways were these guidelines not helpful to you (e.g. topics covered, specific content, complexity of language, document structure, etc.)?

7. What type/s of additional resources (such as short fact sheets) might be helpful to you in understanding the ethical aspects of donation and transplantation issues?

8. If you have any additional comments on the guidelines, please provide them here.

Appendix (3) Example: Letter of Concern from WA Chief Health Officer sent to DFA regarding WA Amendment to legislation regarding donation



Government of **Western Australia**
Department of **Health**

Mr Bruce McDowell
Chairman
Donor Families Australia

Via email: admin@donorfamiliesaustralia.org

Dear Mr McDowell

AMENDMENTS TO THE *HUMAN TISSUE AND TRANSPLANT ACT 1982*

Thank you for your letter dated 1 March 2024 in response to the letter dated February 2024 fr[redacted] regarding the amendments to the *Human Tissue and Transplant Act 1982 (the Act)*. I sincerely apologise for the time taken to address your concerns regarding the consultation process for the amendments.

The Department of Health (the Department) recognises the significant role of families who have consented to the donation of their loved ones' organs and tissue.

The legislation has considered the need to uphold ethical principles ensuring donors and their families are not exploited, that respect is shown for both living and deceased individuals, and that the human body is not treated as a commodity to be sold for profit.

The legislation aims to support access to lifesaving and life-enhancing human tissue and tissue products for patients in need.

A public consultation on the amendments occurred between 9 February and 2 March 2018. It is disappointing to hear that Donor Families Australia (DFA) did not know about the consultation. The Department recognises the important role organisations like yours play in improving policies and procedures. This is demonstrated by the inclusion of your organisation as an important stakeholder for the recent communications on the amendments to the Act. To reduce the risk of this happening again, I have asked my team to develop a comprehensive communication plan for future consultations, which includes DFA as a key stakeholder.

Finally, I would like to thank you for meeting with [redacted] Project Officer, on 26 June 2024. I understand that detailed information in relation to your concerns was provided at those meetings.

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In addition, my team has updated the Department's website at [Human Tissue and Transplant Act 1982 legislation amendment (health.wa.gov.au)]() to reflect the feedback provided in your letter. Please share this link with your members.

Yours sincerely

[redacted]

23 July 2024

GOVERNMENT OF WESTERN AUSTRALIA

Appendix (4) Individual responses beyond the questions.

Email1: Donor Family

I believe all legislation should be uniform throughout Australia.

Further to this I have some points to highlight from the guidelines.

2. Overview of cell, tissue, and organ donation and transplantation in Australia

Cell, tissue and organ donation and transplantation are made possible in Australia through State and Territory legislation and clinical guidelines which provide a governance framework and guidance for many important practices and procedures.
Q. Is the legislation solely State and Territory? it doesn't seem consistent in the guidelines.

As in 2.2 it says Commonwealth and State or Territory legislation???
Knowledge and application of relevant laws is critical for appropriate clinical decision-making in donation and transplantation. In many aspects of clinical practice it is important to be aware of and understand Commonwealth and State or Territory legislation.

3.5.1 Human tissue legislation

Legislation in each State and Territory governs donation and transplantation for clinical purposes (see Table 3.2). Although referred to as "human tissue legislation" in accordance with the terminology used in much of this legislation, the legislation is also inclusive of cells and organs.

In 7.1.1.1 below, this paragraph is talks about who can provide consent re disclosure of identity. In the last sentence re deceased donor.
As donor family we gave consent for organ donation after the death of our loved one. Therefore we should be able to give consent to disclose the identity.

7.1.1.1 Legal considerations in disclosure of identity of donors and recipients In the human tissue legislation (see Chapter 3.5.1), offences exist in some States and Territories applicable to health professionals involved in donation or transplantation who disclose 'to the public' the identity, or identifying information about, donors or transplant recipients. Exceptions do exist where consent to disclosure has been provided by the donor or recipient. However, uncertainty exists regarding who, if anyone, can lawfully provide such consent in relation to children and deceased donors.

This is also mentioned on Page 127
As noted in Chapter 7.1.1.1, legislation in some Australian jurisdictions permits disclosure of identifying information with the consent of the person to whom the information relates, however it may be uncertain who can consent to disclosure where the information relates to a deceased donor. This means that in some circumstances it may be lawful for individuals to identify themselves and establish direct contact with donors, donor families or recipient

Appendix (4) Individual responses beyond the questions.

Email 2: Donor Family
<u>Ethical Guidelines Review</u>

Pg 8 The ethics about not adequately educating the community about the donation process PRIOR to donation. Is it acceptable to ambush families at the time of death?

Pg 9 What is "informed consent"?
* Are they providing the information they feel the family can cope with?
* Are they only providing the information that will encourage the family to say yes?
* Transparency in regard to the rights families are giving up

Pg 16 Why is this not all medical staff; not just intensive care, ER and hospital Exec? If we are to maximise all potential donation opportunities especially in regard to bone and tissue donation.

Pg 32 Post Care
*Within this section there is no mention of the care for the Living Donor nor is there anything in the Living Donor Section (2.8.1)

Pg 40 Principle 5
*Why is there not an independent body to handle complaints?

Pg 41 Q2.
*This recognition must take place within the wider community not just the "closed" Remembrance Forums.

*This states "<u>formal</u>" expressions of gratitude to donors in recognition and "<u>respect</u>" to the families of deceased donors. As the majority of donors are deceased I'm not sure how this works! Should the formal expression not go to the deceased family?

Pg 55 Is it ethical that DF's are treated differently across Aust given the differing State Legislations?

Pg 66 Has been given <u>sufficient</u> time to digest this information and discuss with the family? It states typically 24 hours (2.5.3). How is this determined and by whom? In our experience we had very little time and our "decision making capacity" was greatly affected by sleep deprivation (not unlike .05). Where is the protection for families?

Pg77 States registration on the AODR is "lawful" but families are consulted. My concern is should the govt change their current standing on this (as many would like) how then does informed consent imply. (referring back to other ambiguities)

*"People who are considering joining the AODR are encouraged to
read information in order to make an informed decision"

AND

"Although registering as a donor is an important indication of a persons willingness to become a donor the **self directed** nature of joining the registry means that it is not possible to ensure that all those who register have made a fully informed, voluntary and competent decision to donate"

Given these two statements why is it not being adhered to and considered?

Pg120 7.1.1.1

This refers to "health professionals" but what about Donor Families given the changes to Federal Legislation

Pg 129

As the recipient is alive and can give their consent; why can't I as a DF give my consent to sharing MY information?

Pg 130 How does this differ to contact between

- Adopted persons
- Sperm donors

Both of which are allowed but may also have negative outcomes.
In a supportive process this "harm" could be minimized (like in adoption contact; having to attend a pre-disclosure meeting)

Pg131 Many studies have now been done around the ethics of this topic but why do we focus on the risks rather than the benefit
Pg 149 In regard to the Donor having to be placed on the "waiting list" to be considered for a transplant is this potentially not maximizing all donations?
In Brett's case they could not find a suitable donor for his liver and pancreas so these organs were wasted.
What if the match was just outside the list?

Appendix (5): Donor Families Australia Submission to Senate Inquiry July 2023

admin@donorfamiliesaustralia.org

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam,

On behalf of the DFA committee and our Donor Family Membership thank you for the opportunity to provide a submission for the Inquiry into the Australian Organ and Tissue Donation and Transplantation Authority Amendment (Disclosure of Information) Bill 2023 (Cth).

DFA is the only organisation that represents Donor Families nationally, and as such, we are able to speak from lived experience how these changes to the proposed amendment as mentioned will directly affect our membership and in fact donation and consent rates in the future.

As can be demonstrated by our submission we, and our membership, strongly feel that the wording of the proposed amendment is excluding families, in their grief, to their human right of free speech.

Please find attached our submission.

We look forward to having the opportunity to speak formally at the inquiry to assist Senate members with achieving the best outcome for families and ultimately donation and consent rates.

Kind regards

[redacted]

Bruce McDowell
Chairman DFA

3/7/2023