

Dr Deborah Verran Submission to Australian Law Reform Commission (ALRC)  
Discussion Paper -Review of Human Tissue Laws

The following encompasses the points that I am making having taken the time to consider most of the proposals along with the questions that have been raised in the ALRC Discussion Paper. Some general points will be made initially followed by more specific points around a number of the proposed reforms. Of note I have no conflicts of interest to declare in that I currently do not hold a formal position with any of the organizations mentioned in the DP. I have previously provided the background information pertaining to the roles that I held within Australia particularly round the development of jurisdictional guidelines pertaining to donation after circulatory death.

I also previously held advisory roles with one of the medicolegal insurers here in Australia (AVANT previously United Medical Protection), from 2005-2019.

A) Comments of a general nature

It is essential that all the State and Territory Health departments/agencies provide further feedback on the proposed reforms that are contained within this Discussion paper (DP), noting the nature and scope of these proposals as well as the implications for the relevant legislative processes.

There are complexities which will potentially arise from any of the proposals being enacted into new legislation at whatever level that this occurs, whether it be Federally or at the level of the jurisdictions. Plus, it is evident that for the non-solid organ tissue sector there are additional layers of complexity due to the nature and range of the types of legislation that already apply to this sector along with how various tissue products are both being sourced and then utilised here within Australia. For the tissue sector I believe that this will also require a lot more in the way of further consultation from all the relevant stakeholders, particularly noting what is contained in the DP pertaining to proposals 42-44. This will also apply to how best to proceed with potentially harmonising and/or streamlining the relevant legislation along with any new governance arrangements which may need to be put in place as per the discussion around a new regulatory framework.

The afore mentioned considerations are also a factor in the following more specific points I am making. In doing so I have opted to place in descending order what I consider to be the importance/urgency of these proposed reforms by also taking into consideration the information contained in Section 14 along with Question 46. This is because I believe that the potential time frames for both undertaking the requisite legislative processes as well as the subsequent implementation of same could extend into multiple years. This also includes taking into consideration the potential new

governance arrangements outlined in Proposals 2 and 3. Hence in my opinion it is extremely important to decide where the most pressing priorities might currently actually lie and factor this into the decision making around how best to proceed with the reforms.

B) Specific comments around the Proposed Reforms as well as the questions that are being asked.

- 1) I agree with what is stated in points a and b of Proposal 1, in that there is a clear need to harmonise and update the relevant legislation pertaining to organ and tissue donation here in Australia.
- 2) From my perspective the **first priority** of any of the proposed reforms needs to be around what is outlined in both Proposal 10 and Proposal 11. This is because in my opinion the wording of the current legislation around the **determination of death** is acting as a significant barrier to a) increasing the numbers of organs retrieved from donation after circulatory death (DCD) organ donors and b) improving the longevity of the organs being transplanted from DCD donors. The removal of this barrier as also mentioned by other respondents during the previous round of consultations held by the ALRC would benefit kidney and liver recipients by far the most numerically (1). Amending the statutory provisions for determining death such that they reflect a modern understanding of when death occurs will then facilitate the implementation of normothermic regional perfusion in DCD donors. The various DCD guidelines that are already in place would then need to be updated to reflect all of this, as outlined in subsections 5.66-5.67 of the DP. The content of the updated guidelines will need to reflect the current knowledge pertaining to all aspects of NRP internationally, including as to what type of safeguards need to be put into place (Attachment 1- AST and ASTS statement 2025).
- 3) It is important that the statutory provisions for determining death are amended such that they contain what is listed in Section X and Section Y of Proposal 10. The location for these provisions can then be as per what is stated in Proposal 11, which can be achieved via an intergovernmental agreement. This would not necessitate any alterations in the current governance arrangements noting that the majority of circumstances where individuals are declared dead are in situations where organ donation is not even a remote consideration. Hence, I agree with what is proposed in Question 8, that the determination of death

provisions apply for all purposes. This would then be best served by the approach described in Question 9 under option a. – That there be A ‘Uniform Death Act’. Option c would be another possibility should option a not be decided upon. This aligns with the points also made in sub sections 5.6-5.9 of the DP.

- 4) It is also important to have one definition of when death occurs because having two different definitions in place has been confusing for some in the wider community and divisive for others. The legal definition for brain death has functioned as a beacon for individuals who are not confident/certain that this is consistent with death having occurred. Even now there are ongoing discussions about this both in the literature as well as via social media. One only has to look at the relevant literature pertaining to the attempts to revise the Uniform Determination of Death Act in the United States in recent years to appreciate these various sentiments. The proposed definition of when death occurs will go a long way to remedying this uncertainty/criticism as outlined in sub sections 5.51-5.59 of the DP. Plus, this in itself should assist with both securing and maintaining ongoing public trust in the wider community.
- 5) Are there any risks with this as per Question 8? Possibly, in that there is always the potential for confusion to occur in the minds of some once new determination of death provisions are in place. Hence it is important that consideration be given to what is outlined in the final sentence of subsection 5.60 of the DP. This risk can also be mitigated if it is made abundantly clear via all future communications that death is to be determined according to accepted medical practice. This also takes into consideration what is stated in subsections 5.73-5.79 of the DP. There will also be the requirement for all the relevant stakeholder guidelines (not just those pertaining to the organ and tissue donation sectors), to be updated once the new statutory provisions for determining death are established into law. This should be able to be achieved under the current governance arrangements that are in place for the healthcare system across each of the states and territories.
- 6) It would not be wise to alter the established governance arrangements whilst new legislation of this nature is being implemented-i.e. undertake structural type of reforms. The proposed functions pertaining to a new National Regulator as outlined in Proposal 3 would mean that some of the current work being undertaken by the Organ and Tissue Authority (OTA), would then no longer fall within its remit. Hence there potentially would be changes being made to workflows along with staffing levels within OTA, which could be disruptive. This would also potentially add extra complexity and/or delay the periods for the

proposed legislative reforms noting that additional legislation and time would also be required to establish a new National Regulator.

- 7) Proposal 13 This seems to fall within the realm of the proposed new human tissue legislation and is best considered along with the other Reforms relating to deceased donation.
- 8) The **second priority in the reform agenda** is to address the other proposed reforms for the new human tissue legislation, including those which pertain to deceased donor organ donation.
- 9) Considering the number of other proposed reforms in the DP relating to organ and tissue donation which will require that new human tissue legislation be developed and then enacted, I agree with what is stated in Proposal 4. That is that an intergovernmental agreement be arrived at to agree upon as to how best to move towards national uniform legislation. Perhaps either of the options c. or d. may be required however this will also require that further intergovernmental agreement be sought. The other reforms that pertain to deceased donor organ donation are can either be tackled together or dealt with according to what the then agreed upon priorities are. Should the statutory provisions for the determination of death be amended first, then this may also lead to the requirement for new human tissue legislation to subsequently be enacted.
- 10) As to Proposals 5-7. I agree with what is outlined in Proposal 5. However, when it comes to Proposal 6 I am not sure that there is much to be gained by establishing a new Regulatory agency noting the numbers of organ donors that are currently being identified per annum along with the numbers of organs that are then transplanted across Australia. See also my previous point 6.
- 11) When it comes to the regulatory functions pertaining to the Tissue sector it may be more appropriate for the Therapeutic Goods Administration to have a greater role, along with the National Blood Authority and the Organ and Tissue Authority.
- 12) It would seem timely to have an updated definition of human tissue form part of any new human tissue legislation as per Proposal 7. In my opinion the definition under Question 5, point b. seems the best option for this.

- 13) As Proposals 23-27 also relate to deceased donation (including of solid organs), I have some additional comments to make about the wording of these along with some of the questions that have been raised in Chapter 7 of the DP. Particularly as these proposals may form part of any new human tissue legislation.
- 14) Regarding Proposal 23 , I agree with the statements made under points 1-4 inclusive. However, when it comes to point 5, further clarification is needed as to the context as to where tissue removal may be occurring once death has been declared. If solid organ retrieval forms part of the potential tissue removal should the person die within the hospital setting, then the removal of the role of the Designated officer is potentially problematic as per Question 16
- 15) There is also a suggestion in sub section 7.76 of Chapter 7 of the DP that an independent medical practitioner be involved in the oversight of gaining consent for antemortem procedures (Proposals 26 and 27). This raises two important points. The first is that involvement of an independent medical practitioner is being viewed as being important for one subgroup of deceased organ donors, whilst the established role for designated officers is no longer felt to be essential for the other deceased donors. This lack of consistency is concerning. Second, despite DonateLife employees being spread across the healthcare system nationwide, they are not based in every hospital and/or they may be replaced by other healthcare professionals whilst on leave. Also, the industrial awards for healthcare professionals differ between the various states and territories along with how serious adverse events are managed and investigated within the hospitals. Hence there are complexities within the hospital setting which require further consideration as to what are the appropriate checks and balances that need to be in place.
- 16) There is always the possibility that in a hospital setting particularly where deceased donor organ donation is a rarity, along with where the relevant healthcare professionals are not fully abreast of the applicable clinical guidelines, that there is an increased risk of error and/or of incidents occurring. It is this type of scenario that has contributed to concerning headlines in the United States in recent years including around the lack of process/governance around deceased donors within the hospital setting. Allowing for all the proposed legislative changes outlined in the DP, I believe that there will still be a role for an independent healthcare professional to be involved in the authorization of the relevant processes at the clinical coal face pertaining to deceased donors. This may also be applicable in the setting of organ and tissue donation following Voluntary Assisted Dying (VAD) where this also occurs in a

hospital setting, noting that reference is made to VAD in some of the subsections of Chapter 7 including Proposal 24. From my perspective this is all about **mitigating any risks that potentially may arise considering the proposed changes to the current human tissue legislation**. This is also a consideration in my following response to Question 17.

- 17) Although valid consent might be considered as sufficient legal authority to remove specified tissue(s) for specified uses as per point 5 in Proposal 23, in clinical practice within the hospitals, authorization is also sought from the next of kin as per the point made in sub sections 7.6 and 7.10 of the DP. Hence although it is important to have consistency in the consent and authorization frameworks as per the point made in sub section 7.16, again further thought needs to be given to the additional safeguards that need to be in place within the hospital setting.
- 18) From my perspective registering to be an organ donor on the Donor Register does not meet the threshold for valid consent but instead is more of an expression of intent. Hence, I agree with what is contained in sub section 7.22 around what might now need to be considered as representing valid consent, noting what is also outlined in sub section 7.75. This also takes into additional consideration as to what is contained in Proposals 36 and 37 particularly around what might constitute valid consent in other circumstances. The current donor registries would need to be restructured as well as have significant additional resources allocated to them in order to raise the registrations from being of intent to being of consent to being an organ and tissue donor.
- 19) As to Proposal 24 I believe that the relevant guidelines can either be developed or updated as required by the current stakeholders who are active in the development of guidelines around deceased donor organ donation. Allowing for the fact that organ donation is already occurring in the setting of voluntary assisted dying (albeit in a limited number of cases), there will already be some regional guidelines/protocols in place. Plus, there have already been cases over the years where other individuals with decision making capacity have requested the withdrawal of life sustaining therapy and have then gone on to become organ donors via the DCD pathway.
- 20) I agree that it is important to align the tissue donation and voluntary assisted dying laws if this is felt to be achievable as per sub section 7.39. As to Proposal 25. This may require further consultation with the relevant professional

organisations/stakeholders noting that unmet needs pertaining to organ and tissue donation have been identified for this subgroup of the healthcare workforce (2).

21) When it comes to pre-mortem interventions as outlined in Proposal 26 I do believe that it is important that this now be harmonised within new human tissue legislation. However as per Question 21 I do believe that the provided definition could be subject to interpretation. Safeguards/explanatory notes will also need to be added making it clear that additional consent/authorization is required should any of these interventions be considered experimental/are not part of standard practice/involve research. This is in addition as to what is contained in Proposal 27 and is my response to Question 23. Plus, there needs to be an exception as to what might be considered a minor procedure as per Question 22. I would suggest that this be something like accepted/standard routine screening laboratory tests. I noted with interest the inconsistency in the current New South Wales legislation as per point 7.6

22) I agree with what is outlined in Proposals 28 and 29 as well as Proposals 32-37. As to Question 24, further feedback needs to be obtained from the various State and Territory coronial services. Back in time the opinion of the New South Wales State Coroner was formally sought as to what type of process needed to be put in place for the DCD organ donors within the jurisdiction, where the potential donor was of interest to the coroner. This occurred prior to the finalisation of the initial NSW DCD guidelines in 2007. There may well now be a requirement for guidelines to be developed pertaining to coronial consent to organ donation, noting that there is jurisdictional legislation pertaining to the functions of the coroners (3). I am not the first person to suggest that this now needs to occur (4).

23) I agree with what is outlined in Proposal 40. It is important that there is now consistency between the jurisdictions for this as mentioned in subsection 11.2 as well as subsections 11.5-11.18 in Chapter 11. This is particularly relevant to the paired kidney exchange program. Also, as to what is stated in Question 35, and outlined in sub sections 11.34- 11.50 this requires further consideration, noting the issues associated with either organ or tissue trafficking. As to whether individuals who engage in transplant tourism should all be subject to criminal prosecution, I think requires further thought noting subsection 11.47. The majority of the solid organ transplant recipients are chronically unwell and often it is desperation that leads to them going down this path. It may well be that the type of penalty needs to be commensurate with the degree of seriousness of the type of activity being undertaken along with how this would then be dealt with by

any new Criminal Code legislation. In my mind, there needs to be a far more serious penalty for the brokers/middlemen, some kind of penalty for the living donors (as per 11.9), and a lesser penalty for the recipients.

24) I noted with interest the information contained in the subsection of the DP pertaining to paid plasma donation. There is already an Australian Government program which is in place which provides financial support to living kidney donors via the remuneration of expenses (5). It is possible that something similar could be established for other tissue donors.

25) In response to Question 45 I believe that the future compliance with any newly developed legislation should not be an issue for employees of state/territory governments due the nature of their employment contracts and hence obligations. The same obligations need to apply to all employees within tissue banks as well as any other non-governmental facilities if this is not already the case.

C) In summary-

The National Legislative Framework pertaining to human tissue needs to be updated.

There are potential risks associated with some of the proposed alterations to the current governance structure and processes around solid organ donation, which require further consideration

The proposed reforms need to be prioritised and proceeded with in a step wise manner, with the determination of death being addressed first.

The implementation of any new legislation pertaining to deceased donor organ donation, should be achievable via the current established mechanisms. This will require that all other relevant stakeholders are also identified in advance, particularly when it comes to the determination of death. The relevant established clinical guidelines will need to be updated along with new guidelines for NRP being developed. The ensuing implications for the other relevant protocols and education programmes across the healthcare system will also need to be addressed.

As to whether any additional and or new governance arrangements are required for the short to medium term seems to be most applicable to the non-solid organ donation Tissue sector. The Therapeutic Goods Authority may need to have an

increased role along with the National Blood Authority and the Organ and Tissue Authority.

As to whether a new National Regulatory Agency is established, this is something that seems to be more of a medium to long term objective noting the anticipated time periods and processes that will also be required.

## References

- 1) Statistics in Australia, DonateLife Australia (Accessed January 2026)  
<https://www.donatelife.gov.au/all-about-donation/statistics-in-australia>
- 2) Dutch MJ, Amsden JL, Stitt ND, Jury SC. Perspectives on organ donation: a survey of Australian voluntary assisted dying practitioners. Internal Medicine Journal 2025  
<https://doi.org/10.1111/imj.70299>
- 3) NSW Legislation, Coroners Act 2009, NSW Government (Accessed January 2026)  
[Coroners Act 2009 No 41 - NSW Legislation](#)
- 4) Ward, A. Organ donation in the forensic setting. Pathology 2020, 52 (Supplement 1), S21 <https://doi.org/10.1016/j.pathol.2020.01.097>
- 5) Supporting Living Organ Donors Program, Australian Government, Department of Health Disability and Ageing (Accessed January 2026) <https://www.health.gov.au/our-work/supporting-living-organ-donors-program/about>

Attachment 1. ASTS-AST Statement on DCD

[View in browser](#)

The **American Society of Transplant Surgeons (ASTS)** and the **American Society of Transplantation (AST)** reaffirm their commitment to expanding access to organ transplantation while preserving the safety, dignity, and trust of donors, families, and the public. Amid growing public concern, particularly following Congressional hearing and media coverage, ASTS and AST emphasize the importance of medical accuracy, ethical clarity, and public education in Donation after Circulatory Death (DCD) and the use of Normothermic Regional Perfusion (NRP). In addition, ASTS and AST applaud the **recent unified actions of the U.S. government and federal agencies** with transplantation oversight within the U.S. Department of Health and Human Services (HHS), including the Health Resources and Services Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA), in their dedicated efforts to support and advance the U.S. organ transplant system.

The September 2025 decision by HRSA to decertify a poorly performing organ procurement organization (OPO) is a powerful act that will strengthen the organ transplant system going forward. ASTS and AST are committed to partnering with federal agencies to support the organ transplant network and foster public trust to increase life-saving transplants.

Due to the recent discourse surrounding the determination of death and the performance of several OPOs, ASTS and AST have co-authored this statement which aims to clarify standards, address misconceptions, and reinforce the integrity of the transplant system.

### **I. Addressing Misunderstandings of the Declaration of Death Process**

Recent media reports and congressional hearings have contributed to public confusion by implying that organs are retrieved from donors before death is legally confirmed. These portrayals often fail to distinguish between **withdrawal of life-sustaining treatment (WLST)**, the **declaration of death**, and **organ procurement**. In DCD, WLST is a clinical decision made independently of donation considerations and managed by patient care teams that are completely separate from organ procurement teams. Only after the **permanent cessation of circulation**—confirmed by a standardized, mandatory **5-minute no-touch observation period**—can organ recovery proceed.

In the rare occurrence of a misapplication or deviation from protocol, it is imperative that the isolated cases do not obscure the rigorously structured, ethically-sound process practiced

nationally and globally. Misconceptions of the declaration of death process can only be combatted through education, which is why ASTS and AST have outlined below the pathways that lead to declaration of death.

Death by neurologic criteria (DNC), commonly referred to as brain death, is determined through a rigorous, standardized clinical process that includes:

- Confirmation of irreversible, catastrophic brain injury of known cause.
- Exclusion of reversible confounding factors (e.g., drug effects, hypothermia).
- Neurological assessment confirming coma and absence of brainstem reflexes.
- An apnea test to confirm absence of spontaneous breathing.
- Ancillary testing when parts of the exam cannot be completed.
- Repeat evaluation as required, especially in pediatric cases.

This process ensures ethical, accurate, and irreversible determination of death prior to donation.

DCD applies to patients who do not meet brain death criteria but for whom the family and clinical team have agreed to the withdrawal of life-sustaining treatment (WLST). This pathway follows strict ethical and clinical protocols:

- WLST is a clinical decision made independently of donation.
- After circulatory arrest, a **mandatory 5-minute no-touch observation period** confirms the permanence of death and ensures autoresuscitation does not occur.
- Only after this observation period can death be officially declared, and organ recovery permitted.

The transplant team is **NOT** involved in **ANY** step of end-of-life care or the declaration of death. This separation safeguards the autonomy and dignity of the patient and their family.

ASTS and AST oppose calls to redefine death to include irreversible coma, a move that would blur critical ethical boundaries and erode public trust. Instead, ASTS and AST advocate for reinforcing the existing safeguards that currently uphold the integrity of the process.

## II. Ethical Safeguards: The 5-Minute Observation Period

A cornerstone of the DCD process is the mandatory observation period following cessation of circulation, designed to ensure that **autoresuscitation does not occur**. Based on a multicenter prospective study published in the *New England Journal of Medicine*,<sup>1</sup> the **longest recorded instance of autoresuscitation was 4 minutes and 20 seconds**.

To uphold both ethical and scientific standards, ASTS and AST recommend a **standardized 5-minute waiting period** after the cessation of circulation and before the declaration of death. This no-touch period is critical to confirm death beyond doubt and to protect the donor, their family, and the public's confidence in organ donation.

### III. Normothermic Regional Perfusion (NRP) and Cerebral Isolation

Normothermic Regional Perfusion (NRP), particularly Thoracoabdominal NRP (TA-NRP), is used to restore circulation selectively to the organs after death to preserve organ viability and improve transplant outcomes. It is **not** used to restore life or resuscitate the deceased in any fashion.

ASTS and AST emphasize that **cerebral reperfusion must be actively prevented** to uphold the dead donor rule. Robust clinical studies have shown **no evidence of brain perfusion** when proper measures are taken—such as **occlusion and venting of the aortic arch vessels** during TA-NRP and occlusion and **venting of the aorta** for **abdominal-NRP**. These safeguards are essential to maintain the ethical boundary between organ recovery and the confirmation of death.

Accordingly, ASTS and AST **recommend continued use of both occlusion and venting of the aortic arch vessels during TA-NRP** and **occlusion and venting of the aorta for abdominal-NRP** until further definitive evidence becomes available.

To read the consensus statements on NRP, see, and

1. *Transplantation* 108(2):p 312-318, February 2024 | [Read more](#)
2. *Transplantation* 108(8):p 1655-1659, August 2024 | [Read more](#)
3. *Transplantation* 108(8):p 1660-1668, August 2024. | [Read more](#)

### Conclusion

Donation after Circulatory Death (DCD) and Death by Neurologic Criteria (DNC) are critical, ethically robust practices of modern transplantation that saves lives. However, recent media narratives and misinformation have risked undermining public trust by misrepresenting how death is determined, and organs are recovered.

ASTS and AST caution against the call to redefine death and instead advocate for continued adherence to proven safeguards, including the 5-minute observation period and cerebral isolation during NRP. The Societies also urge increased investment in clinician education and public communication, drawing on successful international models like that of Spain<sup>2</sup>.

Only by maintaining clear boundaries, reinforcing transparency, and honoring donor dignity can we preserve the trust of the public and continue to save lives through organ donation.

### References

1. Dhanani S, et al. Resumption of Cardiac Activity after Withdrawal of Life-Sustaining Measures. *N Engl J Med*. 2021;384(4):345-352.
2. Streit S, et al. Ten Lessons from the Spanish Model of Organ Donation and Transplantation. *Transpl Int*. 2023 May 25;36:11009.doi: 10.3389/ti.2023.11009. eCollection 2023.



**American Society of Transplant Surgeons**  
1401 S. Clark St., Ste. 1120, Arlington, VA 22202  
703-414-7870

[Manage your email preferences](#)

To unsubscribe from all ASTS emails, please [click here](#).

