Submission to ALRC addressing Review of Human Tissue Laws, Discussion Paper 90

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Thank you for the opportunity to respond to the ALRC's Review of Human Tissue Laws. Please see my responses in relation to selected Proposals and Questions. I am happy to be contacted to discuss any aspect of my submission.

National legislative framework

Proposal 3: The approach that should be adopted is that most likely to gain political acceptance and funding approval. If this means expanding the role of an already existing body (such as OTA) then I would favour that approach. The creation and establishing of an entirely new regulator may be less desirable given the funding costs associated with establishing such a body.

As the ALRC reforms hinge on the role of a new regulator, it seems essential to the success of the reforms that any new proposed regulator is politically palatable and funded by the Cth Government.

Reforms relating to the definition of tissue

Question 5: If the reforms and consent processes are to be applied to all human material including the body as a whole (as proposed in Proposal 38-39), then it seems to make sense to have a definition of 'tissue' (or its selected alternative) that incorporates the human body as a whole, unless there is a rationale for its exclusion.

Question 7: For each of the specific tissue listed in Q7, the implications of those tissues being within the scope of the provisions of the Act need to be tracked through. It seems unlikely that we would want the same consent requirements to be applied every time someone wanted to donate human milk as compared with a kidney.

Gametes also seem to be given a special status given their potential role in reproduction. In relation to reproduction there are already regulatory frameworks in existence – i.e. State based assisted reproductive legislation[1] and the NHMRC Assisted Reproductive Technology Ethical Guidelines. In that context, and given the specialised nature of those existing frameworks, I would suggest that the ALRC recommend exclusion of gametes from the definition of tissue (or equivalent term) in the proposed legislation. Consideration should be given to whether this should be for all gametes – which would then place reliance for consent requirements for donating sperm and eggs within the ambit of other specialised frameworks – or whether this should be limited to gametes from deceased donors. Generally, the living donation consent requirements in the HTAs (with limited exceptions) have in mind donation of blood, bone marrow, HSCT and associated blood derivatives rather than the donation of sperm or eggs.

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[1] E.g. *Assisted Reproductive Treatment Act 1988* (SA); *Human Reproductive Technology Act 1991* (WA); *Assisted Reproductive Treatment Act 2008* (Vic); *Assisted Reproductive Technology Act 2007* (NSW); *Assisted Reproductive Technology Act 2024* (Qld).

Reforms relating to the determination of death

I make no comment on the suitability of the proposed definition of death but note that any definition adopted must be understandable to the clinicians who will implement it and to the public at large. Trust in the system is intimately tied to determination of death so any misunderstandings introduced by a new definition need to be minimised.

Proposal 10: While I express no view on the overall suitability of the definition, I do note that it would be preferable to provide a definition of ‘valid end of life decision’ or else require the regulator to clarify what this includes as this is not a known term. From the DP this is intended to cover decisions made in a VAD context as well as prior decisions in advance directives and decisions by substitute decision-makers (as clarified at 5.54). This is not apparent from the term ‘valid end of life decision’ so clarification in the legislation or via the regulator would be desirable.

Proposal 12: This proposal is designed to ensure that post-mortem interventions – and particularly NRP - are carried out in accordance with accepted medical practice.

There might by a potential cross over between NRP clinically and NRP as part of research as it might be expected that at least some NRP use would be considered in the context of a research project. As such, the interaction or application of this section and that for research under Proposal 38-39 ought to be considered to clarify what is required of a researcher in that context.

Given that Proposal 12 applies to removal for transplantation and other ‘medical, educational or scientific purposes’ this would presumably extend to removal for inclusion in cadaver labs for teaching purposes. In that context query whether ‘accepted medical practice’ – which to my mind has a direct clinical connotation – is the appropriate term. Instead, direct reference to professional or ethical guidelines may be more appropriate.

Reforms relating to the donation of tissue by living persons

While I support the removal of the distinctions between regenerative and non-regenerative tissue for the reasons provided by the ALRC, a consequence of putting all types of donation (from blood, bone marrow through to kidney and partial liver) together is that some of the safeguards put in place in relation to children in particular, have been eroded. I discuss this fully below.

An additional point that is not, I believe, raised in the DP is that due to the way ‘blood’ is currently defined in WA to include bone marrow, the procedural safeguards for children donating that tissue differ between WA and other jurisdictions.[2] It would be good if this inconsistency was also addressed in the ALRC’s recommendations.

Children

The current legislation in the majority of Australia prohibits non-regenerative tissue donation by children either through an express prohibition or impliedly through operation of the offence provisions which operate to make removal of tissue not in accordance with the Act an offence.[3]

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[2] SN Then, *Children as Tissue Donor: Regulatory Protection, Medical Ethics and Practice* (2018), Springer, at page 130-1.

[3] See M Toews, ‘Organ and Tissue Donation and Transplantation’ in B White, F McDonal, L Willmott, SN Then (eds), Health Law in Australia (4th ed), at page 846 (regarding the express prohibition) and SN Then,

This has created legal protection against children being considered whole organ donors and in most of Australia would only be overcome through a court order. Given the higher risks involved in most whole/partial organ donation this prohibition seems justified. It would be undesirable for children – who are inherently a vulnerable group – to be viewed as a potential source of matched organs. We see that this has happened in the USA to some extent[4] where there has been a 'historical medical, legal and social acceptance of children acting as donors of tissue *and organs* (emphasis added)' .[5] This is not a practice that should in any way be endorsed in Australia.

I would recommend that the current prohibition on high risk/whole or partial organ donation by children be maintained, unless authorised by a court. Given the seriousness of the matter, should it be sought, authorisation by a court rather than Committee, where reasons will be made public, seems appropriate.

I would also recommend that the court's jurisdiction (whether Supreme Court *parens patriae* or Family Court under the *Family Law Act* (in relation to children)) be explicitly maintained in any new legislative scheme in relation to matters involving children or adults with impaired capacity.[6] As previously articulated, I believe:

> *Recourse to the courts* should *remain available as an alternative legal avenue for deciding if a child ought to act as a tissue donor. Although courts will rarely be called upon to decide whether or not a child should donate, undoubtedly when they do, they provide an additional safeguard—an independent judicial inquiry into the appropriateness of the proposed non-therapeutic procedure. Court oversight, while viewed as troublesome, expensive and unnecessary by some, does provide a forum where a decision-maker is required by law to focus on the best interests of the donor child.*[7]

Recourse to the court over any Committee should remain an option with case law in these cases offering valuable guidance for clinicians and hospitals.

Question 11: Additional factors for inclusion:

- The level of risk involved in the proposed tissue removal should be an explicit relevant factor for a Committee deciding for children. This should be a key consideration and aligns with the approach taken by courts who have considered cases of children donating tissue.[8]

Children as Tissue Donor: Regulatory Protection, Medical Ethics and Practice (2018), Springer, at page 129 (in relation to the implication of offence provisions).

[4] See SN Then, *Children as Tissue Donor: Regulatory Protection, Medical Ethics and Practice* (2018), Springer, at page 164: [I]n the United States, children have historically been used as both organ donors and HSC donors. The numbers of children serving as kidney donors since records started in 1988 is unclear, with various publications citing the numbers between 48 and 96 for a two decade period, but needless to say, the numbers are significant. In addition, five children are reported as having served as partial liver donors.'

[5] Ibid at 187.

[6] This is consistent with the view I have articulated in SN Then, *Children as Tissue Donor: Regulatory Protection, Medical Ethics and Practice* (2018), Springer, at page 232.

[7] Ibid.

[8] See SN Then, I Kerridge, M Marks, *Children as Allogeneic Haematopoietic Progenitor (Stem) Cell Donors: ethically challenging and legally complex*, (2018) 208(8) Medical Journal of Australia 334; *In the marriage of GWW and CMW* (1997) 21 Fam LR 612; *Re Inaya* (2007) 38 Fam LR 546.

- Steps taken to ensure the proposed donor understands and has participated in the decision-making process to the maximum extent possible.

Question 12: Under Proposal 18, an application to the Committee seems necessary for non-therapeutic blood collection for paternity testing. Others (including families with lived experience and genetic counsellors) may have a view on whether parental consent is sufficient in this circumstance or whether a child has a right to know about the testing.

Regarding whether a competent child should be able to provide consent independent of a Committee, please see my response to proposal 18 below.

Proposal 18:

There appears to be an incorrect assumption that all children will lack decision-making capacity for some medical decisions. This appears in the DP at 6.32 where it is stated 'In the context of medical treatment, a child's decision-making capacity is assessed by reference to whether the child fully understands the particular treatment proposed. This means that a child might have the capacity to consent on their own behalf to simple procedures that carry little risk *but do not have the capacity to consent to more complex treatments'* (emphasis added). Case law has demonstrated that findings of decision-making capacity by children for bone marrow donation[9] and other complex interventions such as abortions do occur at ages below 16.[10] In that context, allowing a Gillick-competent child to consent to blood donation, or bone marrow or haematopoietic blood stem cell donation seems appropriate. Where it may be appropriate to provide some safeguards are in relation to ensuring that children are not subject to undue pressure from family to act as living donors – but where this is not in issue, their consent to blood donation or bone marrow or haematopoietic blood stem cell donation is appropriate and consistent with common law legal principles and case law.

In contrast, under Proposal 18, there is authority for the Committee to determine if the child has decision-making capacity but only in relation to whether a valid application has been made by a child. This seems to accept that a child can have decision-making capacity for some things – i.e. bringing forward an application to the Committee – but not others.

The current approach suggested in the DP also seems inconsistent with the approach proposed in relation to research (Proposal 35) which seeks to adopt s 22B of the *Human Tissue Act 1985* (Tas). That provision notes the 'consent' can be given in accordance with National Statement (at 8.25). The National Statement 2025 recognises that children under 18 years of age will sometimes have the capacity to consent to research directly.[11] Recognising and relying on the capacity of a child to consent in relation to research but not in relation to donation seems inconsistent unless the rationale for this discrepancy is discussed and justified.

Despite the foregoing, I suggest that where it would be appropriate to restrict the ability of any child (regardless of capacity) to independently consent and where court oversight should be mandated would be in the case of higher risk donations such as whole/partial organs. This

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[9] E v E [1999] Fam CA 2403 (1 September 1999) discussed in SN Then, *Children as Tissue Donor: Regulatory Protection, Medical Ethics and Practice* (2018), Springer, at page 147-8.

[10] See for example, *In The Matter Of An Application By A Hospital* (2025) QSC 175 (12 year old girl found Gillick competent to consent to termination of pregnancy)

[11] NHMRC National Statement on Ethical Conduct in Human Research (2025), chapter 4.3 and particularly [4.3.4] and Fig 2.

would be the case if the prohibition against a child donating a whole/partial organ suggested above (on pages 2-3 of this proposal) were implemented.

Adults who lack decision-making capacity

Question 13: Removal of tissue for donation and other non-therapeutic purposes from adults who lack decision-making capacity has not, to date, been included within the ambit of the human tissue acts. As a consequence, there is ad hoc State/Territory provisions included in other legislative schemes (mostly guardianship legislation) that require Tribunal authorisation prior to an adult who lacks decision-making capacity having tissue removed for the purposes of donation[12] and isolated case law that has attempted to fill this space[13]. If it adopts the approach suggested in the DP, the ALRC should make specific recommendations to relevant States (e.g. ACT, NT, Qld, Tasmania and Victoria) to address and avoid the duplication that may results across HTA and guardianship legislative schemes.

There are also number of differences between adults and children that justify a different approach between the two groups even if levels of safeguards ought to be consistent.

One difference relates to the guiding decision-making principle governing authorisation of any donation. The terminology used in Proposal 22 is 'best interests', which is generally accepted as the appropriate guiding principle for children. Even though that term is inclusively defined as including the donor's views, the term 'best interests' is associated with paternalistic approaches that are not consistent with current human rights approaches in relation to adults.

While the *parens patriae* jurisdiction retains 'best interests' as the legal standard at common law, nearly all modern legislation encompassing decision-making frameworks for and on behalf of adults with impaired capacity are moving away from the use of this term (the recently enacted NT Health Care Decision-making legislation is an exception rather than the norm). Almost every law reform body in Australia (including the ALRC[14]) has suggested a movement away from this terminology as a guiding principle.[15] It is noted that elsewhere in the proposals - where consideration is being given to whether to donate tissue following death - that authorised decision-makers: 'must have regard to the adult's known beliefs, values, and preferences regarding the use of their tissue' (for example, see Proposal 36). The guiding principle expressed in those principles is more consistent with the human rights approach being recommended by the majority of reform bodies in Australia in relation to when substitute decision-making is used as a last resort.

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[12] See jurisdictions identified in SN Then, B White and L Willmott, 'Adults Who Lack Capacity: Substitute Decision-making' in B White, F McDonal, L Willmott, SN Then (eds), Health Law in Australia (4th ed), at page 250 and fn 147.

[13] See, for example, *Northern Sydney and Central Coast Area Health Service v CT* (2000) 50 NSWLR 549.

[14] Australian Law Reform Commission, *Equality, Capacity and Disability in Commonwealth Laws: A Final Report* (Australian Law Reform Commission, 2014), chapter 2.

[15] For example, see ACT Law Reform Advisory Council, Guardianship Report (2016) Recommendation 1; New South Wales Law Reform Commission, Review of the Guardianship Act 1987 (Report 145, 2018) Recommendations 5.2, 5.4; Queensland Law Reform Commission, A Review of Queensland's Guardianship Laws, Report No 67 (2010) Recommendation 4.4; South Australian Law Reform Institute, The Need for New Solutions? Establishing Legal Frameworks for Supported Decision-Making in South Australia (June 2025) Recommendation 3; Tasmanian Law Reform Institute, Review of the Guardianship and Administration Act 1995 (Tas) Final Report (2018) Recommendations 3.1, 3.3; Victorian Law Reform Commission, Guardianship Final Report (2012), Recommendations 21, 284, 285, 286.

The current NHMRC guidelines also note this contemporary move away from the terminology of best interests for adults lacking decision-making capacity.[16]

In light of this, I would suggest that the ALRC reconsider the use of the term 'best interests' for adults who lack decision-making capacity in relation to living tissue donation.

Additional factors for inclusion:

- Similar to the above list in relation to children, the level of risk involved in the proposed tissue removal should be an explicit relevant factor for any decision-maker/Committee on behalf of an adult. This should be a key consideration and aligns with the approach required to be taken by Tribunals[17] and taken by a court that considered cases of an adult donating tissue.[18]
- Consistent with human rights approaches in contemporary decision-making frameworks, supported decision-making approaches should be embedded into the legislation. This can be through requiring consideration of any steps taken to ensure the proposed donor understands and has participated in the decision-making process to the maximum extent possible.

Question 15: Any independent committee ought to be multidisciplinary with clinical expertise in the proposed procedures (including risk profiles etc), paediatric expertise (where relevant), an understanding of a legal frameworks and of the ethical issues. Consideration could be given to whether a 'donor advocate' ought to also be part of the committee or required to come before the committee.[19]

Valid consent

The ALRC DP relies on the concept of 'valid consent' which is defined throughout a number of the proposals. While the threshold of valid consent as outlined in Proposals 14, 23 and 32 may be appropriate for some of the provisions, its use in all the contexts suggested in the DP as it is currently defined warrants consideration. Below I raise some issues in relation to the use of the term.

- **Proposal 23: consent and authorisation for removal of tissue after death** –
  I question if the need to explain the 'nature and effect of the removal of tissue' is necessary for substitute decision-makers. Most people understand implicitly that donation involves the removal of organs and tissue – beyond this, it may be harmful to substitute decision-makers to be informed of further details. It is not clear what is intended to be covered by the 'nature and effect of the removal of the tissue' component of the definition of valid consent. To include this in the definition may place an undue burden on clinicians who feel that to comply with the law that more details must be provided to grieving families before their consent is valid. This outcome should be avoided.

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[16] See NHMRC Ethical guidelines for cell, tissue and organ donation and transplantation in Australia (2025) at [5.3.2].

[17] See e.g *Guardianship and Administration Act 2000* (Qld), s 69.

[18] See *Northern Sydney and Central Coast Area Health Service v CT* (2000) 50 NSWLR 549.

[19] See NHMRC Ethical guidelines for cell, tissue and organ donation and transplantation in Australia (2025) at [3.4.5].

- **Proposal 27: pre mortem interventions –** The other definitions of ‘valid consent’ do not logically apply here as those definitions relate to removal of tissue and PMIs usually extend to a range of interventions - not simply removal. Therefore, clarification is needed around how the standard of ‘valid consent’ will be met.

- **Proposal 30: non-coronial post-mortem examination** - The other definition of ‘valid consent’ does not logically apply here. Therefore, clarification is needed around how the standard of ‘valid consent’ will be met.

- **Proposal 36 and 37: Consent and authorisation to remove tissue for research**
    - This provision currently covers consent for removal but does not appear to cover (unless I’m mistaken) subsequent consent for use of *already removed* tissue (for a different purpose). This situation may arise where, for example, ‘valid’ consent is obtained for donation and transplantation and a particular research project that is discussed. However, after harvesting, the organs and tissue are unsuitable for transplant and there is excess tissue that can be used in *other* research projects. To address this, Proposal 36 could be extended to include not only ‘removal of tissue’ in 36(5)(f) but also ‘use’ of tissue previously removed.
    - Proposal 36(5) defines valid consent. However, similar to the issue I raise above in relation to Proposal 23, I question whether the explanation of the ‘nature and effect of the removal’ of tissue is necessary for substitute decision-makers. Most people understand implicitly that donation for research means that tissue will be removed and used in research projects – beyond this, it may be harmful to substitute decision-makers to be informed of further details regarding the *removal*. (Of course other salient details of how the tissue will be used are more relevant.) It’s possible that including this in the definition may place an undue burden on researchers who feel that to comply with the law that more details must be provided to grieving families before their consent is valid. This outcome should be avoided

Reforms relating to pre-mortem interventions

Proposal 26 and 27: I agree with the approach of the ALRC.

Question 22: The ALRC recognises that minor interventions may be undertaken to determine a person’s suitability to donate tissue after death and there may be justifiable reasons for making certain interventions exempt from the need for consent.

Similar to the justification for proposal 49, minor interventions may lead to there being ‘clear medical reasons why a person will not be able to donate organs or tissues, identifying these issues before donation is raised as a possibility with families will avoid unnecessarily adding to the family’s distress’ (at 12.32). This rationale – which is based on the wish to prevent further harm to distressed families – appears strong enough to justify exceptions for the need for consent for low risk and routine interventions that may fall within the definition of PMIs but which are identified in contemporary professional ethical guidance as being appropriate without the need for explicit consent.[20]

These could be provided for by being excluded from the definition of pre-mortem interventions through regulations. This would allow, similar to other proposals in the DP, definitions to be reviewed and maintained in line with contemporary societal views and medical advancements.

I would recommend that the ALRC allow for such exceptions. If the legislation does not provide for such exceptions clinicians and donation staff may feel either compelled to seek consent in circumstances that they feel are ethically inappropriate or act contrary to the law if they abide by current practice.

Reforms relating to deceased donation

Proposal 24: Protocols or guidelines for deceased donation after VAD are advisable. It is suggested that instead of the new Regulator, appropriate professional body(ies) may be better placed to develop these in a timely manner. Such guidelines are already needed, and professional bodies may be better placed to address the issue now.

Proposal 25: The ALRC has recognised that current senior available next of kin definitions are outdated and can lead to conflict where different people are legally authorised treatment decision-makers at the end of life. Aligning the donation decision-maker with the treatment decision-maker at the end of life is desirable. While a recommendation could be made for each State and Territory to adopt a donation decision-maker list consistent with their own guardianship/medical treatment decision-making list, given the aim for national consistently on this issue I can see why that option would not be attractive.

Question 19: Below are some considerations that the ALRC should take into account if recommending adoption of the listed persons in section 13 of the *Health Care Decision Making Act 2023* (NT):

- *A person with health care authority appointed by the person to whom the authority relates under an advance care directive*: The NT legislation limits this to a person with health care authority *appointed under an advance care directive*. However, in most States and Territories in Australia, a person with health care authority can be appointed under other enduring documents (e.g. enduring power of attorney, enduring guardianship) either instead of, or alongside, an appointment under an advance care directive.[21] Accordingly, the wording should be altered to encompass equivalent appointments under other enduring documents.
- *Guardian appointed under guardianship legislation*:
    - Appointed guardians will sometimes be last resort statutory appointments - especially in the not uncommon situation of there being conflict between family members of an adult before a Civil and Administrative Tribunal or where there is no one willing to take on the role of a guardian. In these cases, the Public Guardian (or equivalent e.g. Public Advocate (Vic), OPTG (ACT) etc) will be

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[20] One example of such guidelines is the Australian Organ and Tissue Authority, Best Practice Guideline for Donation after Circulatory Determination of Death in Australia | DonateLife, ed 1.0 (October 2021) at pp 9-10.

[21] See for example discussion at in SN Then, B White and L Willmott, 'Adults Who Lack Capacity: Substitute Decision-making' in B White, F McDonal, L Willmott, SN Then (eds), Health Law in Australia (4th ed), at page 262-271.

    appointed as a Guardian of last resort. Within those organisations, individual case workers are likely to be allocated to adults to make decisions when required. While statutory guardians are charged with medical treatment decision-making in some cases, they will often have the advice of the treating medical team regarding what is medically recommended for that individual and have input from others about the person's views and past medical history. The case of a donation decision after death seems normatively different from a medical decision during life. The underlying principles guiding donation decision-making is altruism, autonomy and dignity. A statutory appointee who may know very little about that person's history or values in relation to this issue is unlikely to be the appropriate donation decision-maker and I would argue that statutory guardians be excluded from the definition of 'Guardian appointed under guardianship legislation'.
  - There is also the possibility that a guardian will be appointed for personal matters outside of health care. As appointments of guardians must follow the least restrictive principle, Tribunals will generally limit the scope of appointment to what is needed at that time for that person. As such, consideration needs to be given if all appointed guardians (including those who may have a limited appointment for the purposes of, for example, organising accommodation) is always the most suitable individual for donation decisions. One possibility is to limit it to guardians with responsibility for health care – as it would be hoped that such an appointment at least anticipates some knowledge about what the person would have wanted to happen to their body during their lifetime and this may inform a decision regarding donation after death.
- *A carer of the person who is not providing that care as a service on a commercial basis*: It is unclear why the words 'close or continuing relationship' are excluded from this category of person.
- *Child, parent, sibling, friend*: The NT list is unusual in that it divides and particularises the familial relationships that ought to be prioritised over others. In other States and Territories guardianship/medical treatment decision-making legislation this category is usually a single one described as a close relative or friend who has a close relationship with the individual. This may be a simpler approach and one more consistent with how it is described in a significant proportion of States and Territories equivalent legislation.[22]

Question 20: Priority should be given to the decision-maker who has the most recent and/or accurate knowledge of what the person would want. Where this is not apparent then, unless there is evidence that the approach in Victoria has led to problems in practice, I would adopt the approach under the current 26(6) of the *Human Tissue Act 1982* (Vic) that allows a consent to have effect despite any indication to the contrary by another donation decision-maker.

Reforms relating to tissue donation for research

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[22] *Guardianship and Management of Property Act 1991* (ACT), s 32B; *Guardianship Acct 1987* (NSW), s 33A and definition in s 3E; *Powers of Attorney Act 1988* (Qld), s 63; *Guardianship and Administration Act 1995* (Tas), s 4 (noting that the definition of 'close family member' is satisfied where 'the person maintains both a close personal relationship with the other person through frequent personal contact and a personal interest in the other person's welfare').

The proposals relate to the use of tissue in research but do not extend to the regulation of the data obtained from the use of tissue. While perhaps understandable, it would be good for the ALRC to perhaps clarify how they think subsequent data is currently regulated and whether that is an area (outside of the scope of the ALRC's current review) that ought to be looked at in the future. I note that the National Statement does have some guidance on this issue, particularly where it involves specimens that could lead to genomic data being collected.[23]

Living Donors

Proposal 33: This proposal currently seems to make a person's ability to withdraw consent to the use of removed tissue to 'circumstances where all the specific research uses for the tissue are not yet known'. Consistent with ethical guidelines,[24] no such limitation should be placed on a person's ability to withdraw consent to use of their tissue. However, as we are talking about the use of physical specimens, the limitations on the right to withdraw consent specified in Proposal 33(1)(a) and (b) seem practical and appropriate.

A further issue that would be good to address is that of children reaching adulthood who donated a tissue sample during childhood who now wishes to withdraw from research. Most donations of paediatric tissue will have been authorised by parents. However, upon reaching 18 years old, these participants should equally have a right to withdraw their samples from research (subject to the limitation in Proposal 33(1)).

While many guidelines suggest that best practice is to reconsent those participants upon adulthood,[25] this is in many cases impractical or may be logistically impossible and, in my opinion, should not be legally mandated. However, one thing that could be clarified here it that Proposal 33 should extend to not just when consent is provided under Proposal 32 (i.e. by an adult themselves) but also when parents have provided prior consent on behalf of a participant who is now 18 yrs or older.

Proposal 34: I agree with the approach of the ALRC.

Proposal 35: I am in favour of including a provision modelled on section 22B of the *Human Tissue Act 1985* (Tas). I note that s 22B allows 'consent' to be given in accordance with the National Statement. The National Statement 2025 recognises that children under 18 years of age will sometimes have the capacity to consent to research directly (see chapter 4 of the National Statement).

Question 28: The position of adults without decision-making capacity donating tissue for research purposes is more complicated than for children due to pre-existing and potentially overlapping legal frameworks. Some of the current regulatory complexities for research (and this would extend to taking tissue sample for research) involving adults with impaired decision-making capacities is highlighted in a publication co-authored with the Qld Public Advocate, Dr John Chesterman.[26] Any proposed legislative system needs to anticipate and resolve rather than further complicate the already crowded regulatory landscape for research involving adults

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[23] NHMRC National Statement on Ethical Conduct in Human Research (2025) at chapter 3.3.

[24] See NHMRC National Statement on Ethical Conduct in Human Research (2025) at [2.2.20].

[25] S Prince, SN Then, and K O'Grady, 'Determining the state of guidance on pediatric biobanking for researchers HRECs, and families: Regulatory mapping of international guidance' (2024) 183 European Journal of Pediatrics 2477 https://doi.org/10.1007/s00431-024-05469-8

[26] SN Then, J Chesterman, Y Matsuyama 'Supporting the involvement of adults with cognitive disabilities in research: the need for reform' (2023) 30 Journal of Law and Medicine 459

without decision-making capacity. Unnecessary duplication of processes and safeguards will negatively impact medical research that is ultimately aimed at benefitting these cohorts of people.

Provisions that rely on existing mechanisms of ethical approval and compliance with the National Statement (as occurs in s 22B of the *Human Tissue Act 1985* (Tas)), seem sensible.

In relation to donation of tissues for research for adults without decision-making capacity, it would be useful for the ALRC to clarify their position regarding whether any proposed scheme would be in addition to or is recommended to replace other conditions imposed by different legal frameworks (e.g. guardianship legislation), should both apply.

For example, under Qld's *Guardianship and Administration Act 2000*, for an adult who lacks decision-making capacity to donate tissue for research, depending on the way the research is categorised, it may fall into the category of 'special medical research or experimental health care' or 'clinical research'. One of these categories requires the Tribunal (QCAT) to consent on behalf of the adult only when certain conditions are satisfied, namely,:

(a) the special medical research or experimental health care is approved by an ethics committee;

(b) the risk and inconvenience to the adult and the adult's quality of life is small;

(c) the special medical research or experimental health care may result in significant benefit to the adult or other persons with the condition;

(d) the special medical research or experimental health care can not reasonably be carried out without a person who has or has had the condition taking part;

(e) the special medical research or experimental health care will not unduly interfere with the adult's privacy.

Similar requirements for Tribunal approval for certain categories of research are also present in the legislation in NSW, NT and WA.[27] In other jurisdictions a dedicated substitute decision-maker has the ability to consent on behalf of an adult lacking decision-making capacity for certain categories of research.[28] In Victoria, advance research directives also allow research decisions to be made in advance.[29]

In light of provisions such as these, any proposed legislation will need to clarify how it intersects with other legal frameworks such as this. Crucial will be clarifying the related questions of:

- If there is overlap between the new HTA legislation and an existing legislative framework, will the conditions imposed by the new HTA legislation be in addition to the existing framework or will the ALRC recommend that the new provisions (to the extent that they apply) will replace the requirements under the other framework?

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[27] SN Then, B White and L Willmott, 'Adults Who Lack Capacity: Substitute Decision-making' in B White, F McDonal, L Willmott, SN Then (eds), Health Law in Australia (4th ed), at page 250.

[28] See, for example, the a medical research power of attorney (in the ACT), a research decision maker (in WA) or a medical treatment decision maker (for a medical research procedure In Victoria).

[29] See *Medical Treatment Planning and Decisions Act 2016* (Vic) ss 3, 75; SN Then, J Chesterman, Y Matsuyama 'Supporting the involvement of adults with cognitive disabilities in research: the need for reform' (2023) 30 Journal of Law and Medicine 459 at 462.

- Where the conditions for tissue removal cannot be satisfied under an existing framework (e.g. in the Qld provision quoted above – some proposed research may not be limited to benefiting populations with the same condition as the adult), will it be possible to get authorisation under the new HTA and will that override the need for consent under the other legislative framework?

Proposal 36: I would recommend that Proposal 36 be expanded to also provide for consent to be provided for tissue that has *already been removed* from a person. Proposal 36 as currently worded seems limited to consent for 'removal of tissue from the adult's body for the purpose of research'. However, it could be anticipated that circumstances might arise where tissue has already been removed and consent for additional use in research would be desirable. For example, a situation could arise where 'valid' consent is obtained for donation and transplantation and a particular research project that is discussed with a substitute decision-maker. However, after removal, the organs and tissue are considered unsuitable for transplant and there is extra tissue that can be used in other research projects.

Proposal 37: Similar to the wording of Proposal 33, there seems to be a limitation on a withdrawal of consent for use of removed tissue to 'circumstances where all the specific research uses for the tissue are not yet known'. Consistent with ethical guidelines,[30] no such limitation should be placed on a person's ability to withdraw consent to use of their tissue. However, as we are talking about the use of physical specimens, the limitations on the right to withdraw consent specified in Proposal 37(1)(b) seem practical and appropriate.

Reforms relating to donation and use of deceased bodies

Proposal 38 and 39: The proposals as currently written seem to limit consent to the donation of a person's body for research (and other purposes) to the adult themselves. Is that the intention or is the reference to Proposal 23 meant to include the option for the 'authorised decision-maker' for adult and children? There does not seem to be any rationale to exclude an authorised donation decision-maker from consenting to the donation of a loved one's body for these purposes if it reflects what that person would have likely wanted.

While these proposals deal with the donation and use of the body following death, the current wording of the proposals 'donate/use of their body after death' does not seem to anticipate the situation of research during the end of life and dying period. Although this is specifically mentioned as a situation that needs addressing (see the DP at 9.4), the proposal as currently worded does not seem to cover this situation. I note that the proposals in relation to tissue donation for research by living participants (proposals 32-34) also does not address this situation (it being limited to 'removal of tissue from their body' rather than research involving the whole body).

This is a growing area of interest and researchers would benefit from having clarity on who and how consent can be obtained. I would recommend that the ALRC include a proposal that specifically addresses this current lacuna in regulation.

Reforms relating to the prohibition of trade

Proposal 40: I support proposal 40.

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[30] See NHMRC National Statement on Ethical Conduct in Human Research (2025) at [2.2.20].

Question 35: I would support the prohibition on trade to be given extra-territorial effect. This seems a sensible next legal step in deterring illegal transplant tourism.

Reforms relating to how information can be disclosed and shared

Proposal 48: This proposal includes the different ways in which disclosure of a tissue donor or recipient's personal information can be authorised. I disagree that in the circumstances that accord with section 48(c) that the authorised decision-maker should always be the person to make a decision about disclosure.

In relation to a child who has donated or is a recipient, there is no provision for that child being Gillick-competent and having views about whether they want contact with a recipient or donor family. Given that any disclosure will have a direct impact on that child – and in some cases 'forcing' them into a relationship with the donor's family – in circumstances where they are competent, they should be the one to make the decision, regardless of what an authorised decision-maker thinks.

Compliance

Question 45: The current method of enforcement used in most HTAs is through offence provisions. I am not aware of these provisions being utilised in relation to removal of tissue from living or deceased donors but it no doubt has had a deterrent effect. Whether offence provisions remain the most appropriate method of ensuring compliance is debateable. Given that they seem to rarely (if ever) be used, other mechanisms, such as reliance on professional regulation of clinicians or researchers, may also be appropriate.

Please feel free to contact me if you wish to discuss any of the issues I have raised.

Kind regards

[redacted]

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