Response to the Australian Law Reform Commission

REVIEW OF HUMAN TISSUE LAWS

Discussion Paper 90 November 2025

From The Board of the Australian Bone Marrow Donor Registry (ABMDR)

National legislative framework

Proposal 1

The retrieval, storage, and use of human tissue in Australia for medical, educational or scientific purposes should be regulated either:

a. with substantial consistency across states and territories through a coordinated and harmonised set of state, territory, and Commonwealth legislation; or

b. uniformly by Commonwealth legislation.

A single National Regulator should be established (**Proposal 3**) and responsible for setting codes of practice, guidelines and standards, and for enforcing compliance.

ABMDR supports the need for substantial consistency across Australia either by coordinated and harmonised state, territory and Commonwealth legislation or by uniform Commonwealth legislation.

The cost-benefit of a proposal to establish a new National Regulatory Authority would need to be considered carefully, since it is not immediately clear what benefits would be derived to offset the considerable cost that would be incurred to establish and maintain such a new National Regulatory Authority.

Proposal 2

The regulatory framework established by **Proposal 1** should be structured so that:

a. the substance of any obligation, right, entitlement, or prohibition conferred or imposed, is dealt with in legislation; and

b. any necessary corresponding detail is dealt with by delegated legislation, or codes of practice, guidelines or standards set by the National Regulator (**Proposal 3**) or other responsible agencies or organisations.

It would be important to avoid 'freezing' in legislation any issue which can be predicted to change in the reasonably short term – such as Infectious Disease Markers used to reduce the chance of donor disease transmission.

National Regulator

Proposal 3

The Australian Government should establish a National Regulator by:

a. expanding the powers and functions of the Organ and Tissue Authority by amending the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth); or

b. establishing a new statutory regulatory body, which would incorporate the Organ and Tissue Authority as a branch within the new statutory regulatory body; or

c. establishing a new statutory regulatory body, which would supplement and support the existing powers and functions of the Organ and Tissue Authority in a way that is consistent with the goal for national governance set out in the National Strategy for Organ Donation, Retrieval and Transplantation.

The National Regulator could have the following powers and functions:

- set national policies in relation to human tissue;
- create binding codes of practice and standards;
- provide guidelines for medical practitioners, researchers, and organisations that retrieve, store or use human tissue;
- provide educational material for the general public about tissue donation;
- accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors;
- monitor, collect data, investigate, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.

The ABMDR's main concern, as noted above, with the proposal for a new national regulator, is the cost of resourcing the proposal. The end user payer mechanism used in other regulatory areas, such as for the TGA, is not directly applicable to the vast majority of the donation and transplant field which does not have commercial industry participants and instead operates almost exclusively through state public hospitals.

The roles that are proposed to be delegated to the Regulator are many and substantial and as such there will need to be a substantial increase in the costs of the donation and transplant system. It is very hard to see how that investment would significantly increase access to transplantation in Australia or indeed change the ethical practices, since there is no existing concern that the system is operating outside of legal and ethical boundaries, especially given the actual direct operational control of almost

all donation and transplantation by the Commonwealth, States and Territories through the OTA, ABMDR and the State Hospital systems.

To avoid duplication of responsibility for areas that are already regulated, in establishing the National Regulator, regard should be had to the scope of other regulatory entities in Australia, such as the:

- Therapeutic Goods Administration;
- National Blood Authority; and
- the Organ and Tissue Authority.

The Human Tissue Regulator should be adequately funded to carry out its powers and functions.

Please note the potential for duplication with respect to the Gene Technology Regulator which needs also to be acknowledged.
https://www.ogtr.gov.au/

Implementing a national legislative framework

Proposal 4

To implement **Proposals 1–3**, the Commonwealth, states, and territories should come to an intergovernmental agreement to implement national uniform legislation. The structures of national uniform legislation that could be implemented include:

a. referred legislation;

b. applied legislation;

c. mirror legislation; or

d. hybrid legislation — referred/applied legislation or mirror/applied legislation.

The ABMDR Board takes no position on this proposal which is outside our area of expertise. We support the proposition that there should be national uniform legislation.

The objects of human tissue laws

Proposal 5

New human tissue legislation should include an opening section explaining that the objects of the legislation are to:

a. modernise and ensure adaptability and consistency in the laws and regulatory frameworks governing the donation of human tissue, and use of human tissue for medical, educational and scientific purposes;

b. increase access to human tissue, and to the benefits of human tissue donation, transplantation and use;

c. ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia's international human rights obligations;

d. promote equity and reduce inequities in access to human tissue and the benefits of human tissue use;

e. ensure respect for individual dignity and autonomy, and for the human body;

f. prevent the exploitation of individuals in relation to how their tissue is removed, and used for medical, educational and scientific purposes; and

g. promote public trust in the laws and regulatory frameworks that govern human tissue donation and use for medical, educational or scientific purposes.

Question 1

Do you agree with the objects listed in **Proposal 5** for human tissue legislation?

Question 2

Aside from the objects set out in **Proposal 5**, should new human tissue legislation include other objects?

Question 1

We agree that these are necessary objects, though they are not sufficient, as below.

Question 2

There are additional important additional objects which we strongly recommend for inclusion:

h. **facilitating ethically appropriate international exchange to permit two way access for Australian donors for international patients and for international donors for Australian patients.**

This is needed to permit the following existing activities:

- Deceased donor organ transfer/exchange between Australia and New Zealand

- Living donors (related and emotionally related) who are domiciled and potentially also citizens overseas but wish to donate in Australia to an Australian relative.
- Living donors donating to Australian non-citizens in Australia – examples from Nauru and PNG in the past and potentially the future from these and other Pacific Islands involve both donor and recipient from an overseas country without the capacity to undertake the transplant. This also might apply to a NZ citizen resident in Australia but receiving an organ in Australia from a living or deceased donor, depending on the NZ citizenship position in Australia.
- Importantly, and critically for the ABMDR: The vast majority of Haematopoetic Stem Cell (HSC) donor and recipient pairs cross international boundaries either donating from Australia to an international patient, or from an overseas donor via an overseas registry to an Australian, with more than 80% of current HSC donations for Australians sourced from overseas. This makes the additional object critical for continued HSC transplantation.

The second additional object is:

i) **distinguish and define the scope of the laws with respect to the regenerative potential of donated materials. The self-contained limitations of an organ which will not replicate after donation must be compared and contrasted to tissues with a proliferative capacity which may be used to derive cell lines/banks or organoid models in research.**

A cohesive definition and clarity of scope will ensure the use of tissues not considered under an 'organ orientated donation model', such as tissues with proliferative capacity used to derive cell lines/banks or organoid models in research and haematopoietic stem cells, often collected from living donors for autologous or allogeneic use, cannot be considered in the same context as functional self-contained donated organs which are not expected to regenerate through normal physiological function following donation. This distinction is important in ensuring the scope of the new legislation protects donors and recipients whilst not unintentionally restricting routine healthcare or medical research.

National Regulator to have regard to the objects

Proposal 6

In carrying out its functions, including in relation to the creation of guidelines and codes of practice, the National Regulator (or alternative) (**Proposal 3**) must have regard to the objects of the new human tissue legislation.

We agree. However, there is also a need to bind the proposed Committee to the objects.

Promoting equity

Question 3

Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?

Removing barriers

Question 4

If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (**Question 3**), what are the specific barriers that new human tissue legislation needs to address?

In considering this question, please ignore:

- *definitions of senior next of kin that may be outdated and unsuitable (we address these in* **Proposal 25***); and*
- *disclosure of information provisions that in some jurisdictions prevent the families of deceased donors talking about their family member's experience (we address these in* **Proposals 46** *and* **48***).*

Question 3

The objects already include provisions designed to promote equity, recognizing that to legislate specific provisions for equity would almost certainly lead to unintended consequences, for example by 'requiring' equity with respect to race or sex. With the exception of the issues raised in question 4, we do not believe that specific provisions would be helpful.

'Equity' is not as straightforward as it might seem and cannot be seen as the only criterion for a decision. Equity for whom, becomes a crucial issue since the needs and rights of donors and recipients are often not aligned. Equity between recipients needs to be balanced with patients' clinical and other criteria in most circumstances. Does equity for a donor mean that

their donation must be used for the maximal benefit that can be achieved by the donation?

In the ABMDR context, for example, there would be an unintended consequence of a solely 'equity-led' donor recruitment strategy. Focus on simply balancing the ABMDR donor register to represent the ethnic origins of the Australian community would lead to the majority of patients having an even greater reliance on overseas donors but would also not result in a significant improvement in match rates for ethnic minority groups. Thus, decisions on recruitment need to be balanced between equity and effectiveness as well as additional medical criteria. The goal of HSC registry collections is to deliver optimal transplant patient outcomes and therefore establishing and maintaining a seemingly appropriately equitable donor pool is not the right decision for patients, since there is a substantial preference for male HSC donors to maximise transplant outcomes for both male and female recipients. (This is a biological/medical issue since female donors may become sensitised by pregnancy to recipient Tissue Types leading to worse Graft versus Host Disease).

With respect to organ transplantation the critical question would be: what is the criterion with which equity would be judged in the setting of feasible clinical consensus? There is no point putting a small heart into a large person since it will fail – even if the large recipient is 'next in line for a transplant' using an 'equity' criterion. Similarly medical and immunological criteria are often more important, to achieve a functioning kidney transplant, than a community led notion of 'next in line'.

Question 4

The ALRC consultation appears to be silent on the specific issue of donation by and receipt of transplants by incarcerated prisoners. The existing HTAs may forbid donation by prisoners, which has become an issue either when a person dies in prison and wished to become a deceased donor, or wishes to provide a living donation to a relative. The same issue in reverse may prevent a prisoner from receiving a transplant needed for life saving measures such as HSCT, Kidney, Liver, Heart or Lung transplant.

If silence is specifically intended by the ALRC and the proposal is to allow prisoner access to all forms of donation and transplant, then a separate issue arises, since this is a critical issue in the international environment where a prisoner is deemed to be a person unable to provide consent without coercion. Some recognition of this issue would be needed – while we do not execute prisoners and the issue of donation after execution, that has caused so much ethical concern globally, is not relevant here – there remains the possibility that prisoners might be coerced into donation in 'perceived exchange' for favourable consideration in appeals or in applications for release on probation. A donation while in prison could thus be specifically excluded from being taken into consideration for such appeals to avoid this circumstance.

There have been Deceased organ donation requests in which the donor family wishes to direct a deceased donation to a next of kin and to refuse donation consent if that is not permitted. These donation requests have not been permitted unless the donor had already provided written consent to donate in life to a specified individual (the same provision has limited Sperm donation, though there are additional issues in that instance). There have also been prospective living donors in the process of work up for donation to an individual, who then die in circumstances where they could be a deceased donor, but prior to formally signing consent, which to be valid must take place in a limited time period prior to the actual surgery. The intent to donate was clear even if the actual consent had not been signed. The revision of the Act is an opportunity to resolve this.

Legislative and administrative barriers exist in the lack of prioritisation for haematopoietic stem cell collection infrastructure and financial support at designated 'collection centres'. Enshrining the prioritisation of this healthcare service should be considered to ensure equity for living donors to access geographically convenient centres and ensure potential recipients have access to their best available donor.

Definition of human 'tissue'

Proposal 7

New human tissue legislation should include a definition of human 'tissue' (or an alternative label for human tissue) that is broad and provides for a flexible mechanism to adjust the definition.

Question 5

How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?

In your response, you might consider the following options:

a. tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the *Human Tissue Act 2004* (UK)); or

b. tissue means the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from human cells (a definition based on section 7 of the *Human Tissue Act 2008* (NZ)).

Question 6

In new human tissue legislation, should the word 'tissue' be replaced with another label?

In your response, you might consider alternative options such as:

a. 'substance of human origin';

b. 'human material'; or

c. 'cell, organ, and tissue'.

The word tissue, in common use, is a word that is usually applied to combinations of cells and extracellular matrix material, in this context – of human origin. In accepted usage in the transplantation environment, 'tissue' is largely reserved for material derived from human donation that consists of structural extracellular matrix within which any cells have died naturally during processing or have been deliberately killed to sterilise the tissue, reduce the chance of disease transmission and to prevent a host rejection reaction. If the term 'tissue' is used to encompass everything that is of human origin, then the current group of 'tissues' will need a new general name. Organs and the cornea, in distinction, are structurally intact combinations of living cells, which together comprise an organ, that must be transplanted alive to replace the function of a diseased organ. Cells donated for haemopoietic reconstitution are separate living cells donated through donation of blood, bone marrow or placental/foetal blood. The distinction between these different therapeutic donations using the extended term 'cells, organs and tissues' when seeking to combine them for regulatory or legislative purposes, has served many jurisdictions well for

the past 40 to 50 years. Not included are fluids derived from human donation such as plasma or milk. Blood remains a special case and in Australia, as elsewhere, has specific legislation and regulation, but is never routinely included in the term 'tissue'. We agree that the issue of nomenclature is of considerable importance as new legislation is considered.

We raise the following points for consideration by the ALRC in determining appropriate definitions:

- Taking a stance in legislation, that 'it is all in unless it is specifically out' has some merits as long as the mechanism for exclusion is made clear in law and known exclusions are included in the law to demonstrate intent.
- Using the term 'tissue' but including such fluids as human milk and faeces will be confusing since they are not in any sense of common usage defined as tissue.
- The word 'Tissue' is used in other legislative and regulatory instruments (such as by the TGA) and there will need to be a review of how different legislation may define the word differently.
- The word 'Tissue' does not adequately describe cell donations and cell products such as Haemopoietic Stem cells from peripheral blood cytapheresis or Umbilical Cord Blood, in terms of the common understanding of the word 'tissue'. There is a need to consider the regenerative potential of materials, derived from either living or deceased donors, where there is the capacity for the living tissue or material to replicate ex-vivo, as well as the replicative capacity to be replaced in-vivo through normal physiological function, following donation. These types of donations are in marked contrast to donated organs or tissue grafts such as bone and vascular conduits which do not regenerate either in-vivo or in-vitro.
- The term "Substance of Human Origin" leaves little room for doubt about the scope of the legislation, but will then be too general and will need careful scope definition, in addition to the overall term used. Hair used from the floor of barbers' shops for wig manufacture would, for example, be included. 'Human Material' is likewise far too

broad a definition. Qualifying the term might help eg; Therapeutic Human Material, or “Human Material for Therapeutic Intent.

- The New Zealand definition (b) is probably the easiest to understand.

Adjusting the scope of the definition

Proposal 8

The human tissue regime should have a mechanism to adjust the scope of the definition of ‘tissue’ (or an alternative label) by authorising the National Regulator (or alternative) to make delegated legislation for this purpose.

Both authorising the new National Regulator (or alternate regulator) and the option to amend by delegated legislation, should be included. The question that will then arise is the basis for deferring to an alternate regulator – definitions that would lie in the relevant acts authorising those regulators (TGA, NBA, Food regulator, Gene technology Regulator). This would also provide the option of creation of a new regulator in future to which some part of the work of the HTA National Regulator could then be delegated seamlessly.

Guidelines to support the definition

Proposal 9

The National Regulator (or alternative) should, as part of its function, create guidelines to provide interpretive guidance and clarity about the definition and scope of 'tissue' (or an alternative label).

Exclusions from the definition

Question 7

Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?

- Human milk.
- Foetal tissue.
- Faecal tissue.
- Gametes (from deceased donors).
- Cell lines.

If you think some of the above materials should be excluded from human tissue laws (either completely or for particular purposes, circumstances, or provisions), why?

Are there other types of tissue that you think should or should not be regulated by human tissue laws?

In your response, you may want to consider **Proposal 5** (the objects of human tissue laws) **Proposals 40–44** (reforms relating to the prohibition of domestic trade) and **Proposals 32–39** (reforms relating to tissue donation for research).

Question 7

Exclusion from the HTA for a therapeutic substance used in clinical practice must imply that whatever is excluded is regulated under a different provision when used for therapeutic purposes. The better solution might be to define what is excluded as: that which is regulated under a different national regulator. The problem has arisen when that regulator has limited remit to consider ethical principles, such as perhaps the TGA's role in commercially processed bone imported from overseas with too little regard for whether the source of the material would meet Australian laws, which might then originate from paid or executed prisoners, or be stolen from graves.

A prime example of the need for therapeutic regulation but not HTA legislation is faecal material. It is regulated (by the TGA) but only when the microbiota are used as a treatment to reconstitute human bowel flora. The

only therapeutic live components are microbial not human, though live human cells may also be excreted in the faeces, this is incidental and unintended. Thus, including faecal material in the HTA might lead to the absurd proposition that the HTA will regulate toilets, bed pans and childrens' nappies. 'Consent provisions' and 'Respectful disposal' of unused faeces..... Exclusion of faecal material from the HTA thus seems essential, but regulation as a therapeutic good must remain as the safety and efficacy protection for the community.

Human Milk must fall into the same category. Human milk may be used by the donor's child, a surrogate child for the mother (a wet nurse in many Arab nations' laws is included on the same terms as a blood relative with respect to donation as a related donor), or an alternative child whose mother is unable for any reason to produce sufficient milk. Subjecting these uses to the provisions of the HTA will be unreasonably burdensome. Regulation as a food seems much more applicable.

Gametes from a deceased donor of either sex should be considered in the Reproductive Technologies legislation and regulation rather, than in the HTA, since the additional provisions that could be needed to resolve all issues around deceased gamete donation into the HTA may not be appropriate to, or conflict with, the broader objects of the HTA.

Foetal Tissue takes the exclusion provisions into a different therapeutic territory. The current and future therapeutic uses of foetal tissue are potentially extensive and subject to both substantial processing and to commercialisation as well as banking provisions. Depending on how one defines ownership of cord blood as belonging to the mother or the child, this leads to inclusion of cord blood in the HTA – unless of course it is defined as 'blood' and regulated by the provisions of the National Blood Authority. Cord Blood used for therapeutic HSCT is however regulated by the TGA. In the future, other foetal tissues may be utilised after death of the foetus or from the placenta and it is not realistic to consider the range of future uses to which such material might be used therapeutically.

Cell lines also cross boundaries into predominant research utilisation, but with increasing commercialisation issues. Cell lines derived from

deceased and from living donors present different problems with respect to consent, but their therapeutic use lies firmly with the TGA Biologics provisions with respect to regulations. It is hard to see what the HTA might add to safety, efficacy and ethical control exerted by the TGA.

In summary we support the view that:

If it is derived from a human, it is 'in scope' unless excluded

Excluded human material should include:

- Material regulated by one of the following Australian regulators (TGA, Food regulator, Gene Technology Regulator, NHMRC, National Blood Authority). Subject to detailed consideration of the implications of this exclusion, eg the wording of exemption of organs by the TGA.
- Human Embryos and gametes
- Milk, hair, nails, urine, faeces, sputum

New statutory provisions for determining death

Proposal 10

Statutory provisions for determining death should contain the following:

Section X *When death occurs*

1. For the purposes of the law, a person dies when there has been a permanent cessation of the person's critical brain functions, determined in accordance with **section Y**, where 'permanent' means:
    a. that the critical functions of the person's brain cannot resume on their own; and
    a. that the critical functions of the person's brain will not be restored through intervention because:
        i. it is not possible to restore those functions through intervention; or
        ii. intervention would violate a valid end-of-life decision made by or on behalf of the person; or
        iii. intervention or the continuation of intervention would be contrary to accepted medical practice in end-of-life care.

2. In this section-

a cessation of the critical functions of a person's brain requires the complete absence of any form of consciousness (wakefulness and awareness) and brainstem functions, including the ability to breathe independently.

Section Y *Determination of death*

1. A determination that a person has died under **section X** must be made according to accepted medical practice.

2. Regulations may identify professional standards or guidelines for the purpose of determining accepted medical practices under **(1).**

3. To determine the death of a person where the person's respiration is being maintained by artificial means, two registered medical practitioners, one of whom is a specialist and both of whom have been registered medical practitioners for a period of at least five years, must each confirm in writing that they have carried out a clinical examination of the person and, in their opinion, the person has suffered a permanent cessation of the critical functions of the person's brain, within the meaning of **section X**.

New statutory location for the determination of death provisions

Proposal 11

Commonwealth, state and territory legislation should contain a consistent legal standard for determining death, as set out in **Proposal 10**. By an intergovernmental agreement, measures should be put in place to maintain consistency of this definition over time.

Consequences of a determination of death provision that applies for all purposes

Question 8

If the proposed determination of death provisions apply for all purposes rather than only for the purpose of human tissue laws, will there be any adverse and unintended consequences in areas of law other than human tissue laws?

We note that with the exception of Queensland, current state and territory legislative provisions relating to the determination of death apply for all purposes rather than only for the purpose of human tissue laws.

Maintaining national consistency

Question 9

To maintain national consistency, which of the following statutory locations or approaches would be most appropriate for provisions relating to the determination of death, assuming that these provisions apply for all purposes?

a. A 'Uniform Death Act', adopted as national uniform legislation in each state and territory; or

b. New human tissue legislation (**Proposal 1**); or

c. Each state and territory decide where to locate the determination of death provisions but make an intergovernmental agreement that there be a consistent approach to future amendments to these provisions.

Post-mortem interventions

Proposal 12

The following provision should be included in new human tissue legislation:

When tissue will be removed for the purpose of transplantation into the body of another person or for other medical, educational or scientific purposes, any post-mortem interventions must be conducted in accordance with accepted medical practice.

For the purpose of determining accepted medical practice, regulations can specify professional standards or guidelines to be complied with.

The Dead Donor Rule

Proposal 13

New human tissue legislation should include provisions that provide safeguards to ensure deceased donation only proceeds after it has been determined that a person has died. These provisions should provide that:

1. Where deceased donation of tissue is occurring for transplantation or other medical, educational or scientific purposes, tissue cannot be removed from the body until there has been a confirmation of death in accordance with this section.
2. Where a deceased person's respiration is being maintained by artificial means:
    a. the confirmation of death requirements under **section Y(3)** must be met; and
    b. neither medical practitioner confirming death can be involved in or responsible for:
        i. the removal of tissue or medical care of a recipient of the removed tissue, or
        ii. any medical, educational or scientific use of the removed tissue.
3. Where the deceased person's respiration is not being maintained by artificial means:
    a. a registered medical practitioner must confirm in writing that they have carried out a clinical examination of the person and, in their opinion, there has been a permanent cessation of the critical functions of the person's brain, within the meaning of **section X**; and
    b. the medical practitioner confirming death cannot be involved in or responsible for:
        i. the removal of tissue or medical care of a recipient of the removed tissue, or
        ii. any medical, educational or scientific use of the removed tissue.

This is outside the expertise, involvement and relevance of the ABMDR

Consent and authorisation for removal of tissue from living persons

Proposal 14

New human tissue legislation should provide:

1. That an adult may give valid consent to the removal of tissue from their body for the purpose of transplantation into the body of another person, or for other medical, educational or scientific purposes;
2. Valid consent is:
    a. given voluntarily;
    b. given at a time when the adult who is consenting has decision-making capacity;
    c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal;
    d. given after the adult who is consenting has been informed about the intended use of the tissue after it has been removed; and
    e. able to be withdrawn at any time before the removal of the tissue.
3. Valid consent is sufficient legal authority for the removal and use of the specified tissue for the specified purpose(s).
4. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in **Proposal 32** must be met.

Additional safeguards

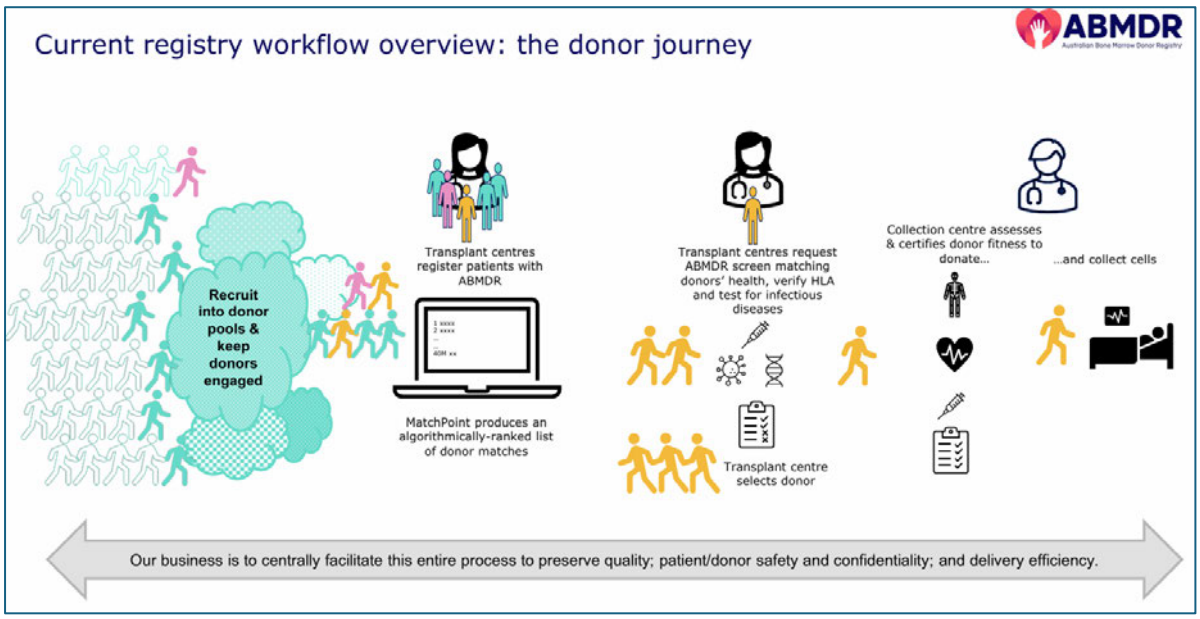
Question 10

Are there additional safeguards aside from those set out in **Proposal 14** that should be set out in new human tissue legislation?

Question 10

The issue in this section, for the Unrelated Stem Cell Donor sector, is to understand that while an HSC donor may not be legally compelled to donate if they change their mind after consenting to donate, this will have lethal consequences for any recipient that has been ‘conditioned’ (ie. has received chemotherapy and/or radiation intended to ablate all bone marrow function) as a result of the previously provided consent. The ABMDR would thus ensure within our span of control (as we do today), that the donor must be informed about the consequences of withdrawal of consent, at the time of providing consent and also prior to a proposed withdrawal of that consent. Please see the following figure describing the donor journey for uunrelated HSC donation.

Figure – The Unrelated HSC Donor



The issue of a 'cooling off period' needs careful consideration, since what is applicable to the need for consent to living kidney or partial liver donation may not be applicable to HSC donation or for consent to donation of cells for research use. Requiring a cooling off period between consent and donation for blood or haemopoietic stem cells for clinical or research purposes would be burdensome, potentially lethal for the intended recipient and likely substantially reduce access.

Definition of 'adult' and 'child'

Proposal 15

New human tissue legislation should define an adult as a person who is 18 years of age or older, and a 'child' as a person who is under 18 years old.

Donation of blood

Proposal 16

New human tissue legislation should provide that for the purpose of blood donation, a child aged 16 years or older is deemed to be an adult.

Wording in proposal 16 requires clarification, as donation of blood product derivates such as haemopoietic stem cells to related recipients is currently permitted in people younger than 16 years. Any proposed changes should

not affect current practice in haemopoietic stem cell donation encompassed within the existing HTAs.

Donation of tissue by children

Proposal 17

New human tissue legislation should:

a. allow a parent or guardian of a child, or a child with decision-making capacity, to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the child's body for the purpose of transplantation, or for other medical, educational or scientific purposes; and

b. provide that an application to the Committee is not required for the removal of tissue for use in research that satisfies the requirements of **Proposal 35**.

Proposal 18

The Committee (**Proposal 17**) should have the power to authorise removal of tissue if it is in the child's best interests. For the purpose of determining whether a valid application has been made by a child, the Committee should be empowered to determine if the child has decision-making capacity.

Proposal 19

New human tissue legislation should provide that in determining if removal of tissue for transplantation or for other medical, educational or scientific purposes is in a child's best interests, the Committee (**Proposal 17**) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the child's views, if any, given, where appropriate, directly by the child;
- the child's age and level of understanding;
- the child's physical and psychological wellbeing;
- the child's relationship with the intended tissue recipient;
- the views of the child's parent(s) or guardian(s) or other persons who have a significant relationship with the child;
- the support available for the child after removal of their tissue; and
- the availability of an alternative donor.

Additionally:

- Where a child does not have decision-making capacity, donation should only be approved with the consent of a parent or a guardian.
- If a child has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

Question 11

Are the considerations listed, and the guidance provided, in **Proposal 19** appropriate? Are there additional considerations that the Committee (**Proposal 17**) should take into account?

Question 12

Aside from the removal of tissue from a child for use in research (**Proposal 35**), are there situations where the removal of tissue from a child should not require approval by a Committee, and where new human tissue legislation should require only parental consent, or individual consent where a child has decision-making capacity?

Abolition of the distinction between regenerative and non-regenerative tissue would be retrogressive in our view with respect to allowing organ donation by children.

Organs.

It is incorrect to suggest that the liver is regenerated after partial liver donation. If the left lobe of the liver is removed it does not regenerate, instead the right lobe enlarges. Similarly, removal of the left kidney does not regenerate the left kidney, though the right kidney will enlarge measurably.

There is very poor medical knowledge about the risks associated with the loss of a non-regenerative organ on the long-term health of the child as they grow into old age. The best interests of the child cannot include removal of an organ with long term uncertainty about the health of that person as they age.

Leaving a 'Committee' to arbitrate all cases, leaves the healthcare system in limbo if removal of a kidney or part of a liver from a child to donate to a family member remains a theoretical option for anyone with a child. There is no justification for bringing that uncertainty into the Act and into daily clinical practice for the first time.

Paired kidney exchange needs to be identified in the legislation as permitted without the need for ministerial exemption as currently required. This can most easily be achieved by legalising paired kidney exchange only within the Organ and Tissue Authority's exchange system.

HSC.

The consequences of placing a 'Committee' routinely into the decision path for transplantation of HSC between sibling children, will be to ensure delay in what may be a highly time critical decision. Current provisions work expeditiously and we would advise the ALRC to consult paediatric transplant Haematologists in paediatric tertiary hospitals in each state for further advice on existing protocols and processes. (We can advise the ALRC on relevant individuals and provide their contact details if required).

The global unrelated HSC exchange system functions well for Australians, with 80-85% of all unrelated HSC being sourced from international registries. The ABMDR has however to be exempted from the provisions of the current HTAs by the Ministers in each state in order to be legally allowed to operate.

ABMDR thus suggests that Paired Kidney donation be allowed in the Act only within the protocols operated by the OTA, and by analogy unrelated HSC exchange should be allowed in the Act only within the national unrelated donor registry protocols operated by the ABMDR.

The ABMDR believes the case has not been made that the current distinction between regenerative and non-regenerative tissues should be changed beyond creating uniformity across the country.

Donation of tissue by adults who do not have decision-making capacity

Proposal 20

New human tissue legislation should enable a legally authorised substitute decision-maker or guardian of an adult who does not have decision-making capacity to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the person's body for the purpose of transplantation or for other medical, educational or scientific purposes.

Proposal 21

The Committee (**Proposal 20**) should have the power to authorise donation if it is in the proposed donor's best interests.

Proposal 22

New human tissue legislation should provide that in determining if a donation is in the best interests of an adult who does not have decision-making capacity, the Committee (**Proposal 20**) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the proposed donor's views, given, where appropriate, directly by the proposed donor, or from sources reflecting the proposed donor's views from a time when they had decision-making capacity;
- the proposed donor's physical and psychological wellbeing;
- the proposed donor's level of understanding;
- the proposed donor's relationship with the intended recipient;
- the support available for the proposed donor after the removal of their tissue; and
- the availability of an alternative donor.

Additionally, if the proposed donor has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

Question 13

Are the considerations listed, and the guidance provided, in **Proposal 22** appropriate? Are there additional considerations that the Committee (**Proposal 20**) should take into account?

Question 14

Are there situations where donation from adults who do not have decision-making capacity should not require approval by a Committee and where new human tissue legislation should require only consent by a legally authorised substitute decision-maker?

See also **Question 28** where we are seeking feedback on whether specific consent requirements should exist to allow adults without decision-making capacity to donate tissue for research purposes.

Composition of committee

Question 15

What is an appropriate composition for a Committee under **Proposals 17** and **20**?

We are seeking input about the qualifications and/or experience of people who should be on the Committee; and also if there should be a national Committee or multiple state and territory Committees.

Questions 13 and 14

Is an incarcerated prisoner to be included as a person without decision making capacity? See comments in response to Question 4 above please.

Question 15

The critical problems with such committees are: time constraints; ability to interview the individuals involved to gain an independent view of the circumstances; expertise in addressing the issues; consistency of decision making; transparency in decision making; and the risk of lobbying, suborning or otherwise influencing the committee members. The latter being a major and persistent problem in many countries where these committees have been established. Establishing state-based committees, while bringing decision making closer to the individuals whose cases are being determined, would lead to the almost inevitable reality that there will be different decisions made in different states. This would lead to 'state hopping' to get the decision the individuals want. State committees would also have many fewer cases to review and thus have less expertise and be less able to respond quickly to clinical timelines. Thus, there should be a national committee, but that committee would have to be resourced to solve the other problems identified above.

Scope will need to be carefully determined to ensure the role of the Committee does not creep beyond acting in the role of decision maker for those without the capacity to make a decision.

The Committee might need to sit ad hoc in the middle of the night for deceased organ donors if the remit extends to deceased donation.

The Committee must not be inserted into current clinical practice to be the arbiter of all unrelated donation suitability particularly for HSCT. The delays, additional bureaucracy and costs could not be justified. We advise the solution identified in Q 11 above.

Potential Membership of The Committee

A principle for membership should be to ensure an independent clinician with expertise in the recipient's disease and its treatment.

Paediatrician specialising in care of neurological conditions
Paediatric Psychiatrist
Adult Psychiatrist

Probation Officer (if remit includes Prisoners)
Solid Organ Transplant surgeon
Solid Organ Transplant physician
Paediatric Haematologist
Adult Haematologist (if recipient is an adult or a donor is an adult without decision making capacity)
HLA/Tissue Typing Scientist
Nominee from the NHMRC Ethics Committee
Lawyer with an interest in human tissue acts
Lawyer with an interest in family law/guardianship
Chair – selected by the Human Tissue Regulator

The opportunity should be taken to spread the membership across the states and territories.

7. Reforms relating to deceased donation

These issues are outside the direct purview of the ABMDR Board.

8. Reforms relating to tissue donation for research

The majority of this section and the proposals relate to the physical use of donated material. The provision that consent cannot be retroactive is important because it would limit the research unreasonably if any product of that research were to be subject to retrospective withdrawal from a research study. What has not been addressed clearly is retrospectivity of withdrawal of data that has been derived from the consented material. In the context of clinical transplantation one cannot 'unknow' a test result that is known, even if it was derived from a research test. Withdrawal of consent to future use of the known data would create a great logistical problem.

Clarity is needed about the rights of an individual recipient of a 'tissue' donation with respect to the ownership of the organ. It is clear that once donated a living donor cannot seek the return of the organ, cell or tissue. However, there are now circumstances in which a decision of the recipient may have implications for the donor and their family that could not have been considered at the time of consent to donate.

The implication of 'donation' is that ownership of the organ, tissue or cells that have been donated, transfer to the recipient. In transferring ownership, the recipient presumably has rights to test the donated material, especially when transplanted and

functioning, for whatever purpose they, as the recipient, consent to. To suggest otherwise would be to suggest ongoing rights of the donor. The vast majority of these tests are related to assessing the material for rejection and functional elements needed to maintain the organ in the best clinical condition. Thus a biopsy of the donated organ for any reason – be it clinical or research – is subject to the consent of the recipient not the donor. If this is the position in law, then if the recipient and their clinicians determine that a genetic test of the donor material is deemed necessary to rule in or out a genetic disease in the transplanted organ cell or tissue, then there is no compulsion (over and above the existing requirements of pathology services) to take into consideration the implications for the donor's family, nor to inform them of a result that may potentially be of clinical importance to the donor's relatives, such as whole genome screening which might indicate the potential for genetic disease. Is this correct?

The paper is silent on genetic testing of donor-derived material. We note that the UK Act prohibits testing of donated 'bodily material' without donor consent, with some exceptions, in an effort to deter "surreptitious" or "unauthorised" genetic testing (e.g. paternity, family risk) via donated tissue. A similar provision to deter specific tests but permit clinically important tests might be considered. Clearly, consent by a deceased donor provides a substantial complexity for such a provision.

Further consideration is needed to determine the legal, family and community consequences of donation followed by post transplantation genetic testing, to ensure that clinical decisions required to maintain the viability and function of the organ cells or tissue in the recipient are not impeded. It is also important to encompass the tests that may be needed to contribute to the welfare of the recipients, who may be impacted by donor derived disease needing investigation. Finally, tests may be sought on transplanted material to explore the possibility that an adverse reaction resulting from the transplant could have been related to a donor factor, in order to identify risks and prevent such events in future transplants.

Consent and authorisation for tissue removal for research – living persons

Proposal 32

New human tissue legislation should provide that:

1. An adult may give valid consent to the removal of tissue from their body for the purpose of research;
2. Valid consent is:
    a. given voluntarily;
    b. given at a time when the adult who is consenting has decision-making capacity;
    c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal;
    d. given after the adult who is consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and
    e. able to be withdrawn in accordance with **Proposal 33** or at any time before the removal of the tissue.
3. Valid consent is sufficient legal authority for the removal of the specified tissue for the intended research use(s); and for other research use(s) in accordance with **Proposal 33**.

Proposal 33

New human tissue legislation should provide that:

1. when consent is provided under **Proposal 32** in circumstances where all the specific research uses for the tissue are not yet known:
    a. the person providing their tissue has a right to access information about how their tissue is being used, if at the time of the information request the sample is identifiable or, if it has been deidentified, is re-identifiable;
    b. the person providing their tissue has a right to withdraw consent for any future research uses, if at the time of the consent withdrawal:
        i. the tissue remains usable; and
        ii. the sample is identifiable or, if it has been deidentified, is re-identifiable.
2. If consent for future research uses is withdrawn, any unused tissue must be discarded.

National regulation would be desirable since research and education into rare diseases in Australia often requires collection of specimens from more than one HTA.

Proposal 33. a) The need for HTA specific approval, such as the need for PHA approval in Queensland alone, should be removed, and a singular nationwide regulation should apply.

b) There needs to be consideration of the circumstance where the individual who gave consent in life has now died – these samples are often the most important samples since they are, almost by definition, from transplants that were not successful and thus

about which most must be learnt and certainly not specifically excluded. Providing consent prospectively for research questions yet to be detailed is of great importance.

c) Provision for all types of collections should be made in the legislation, to avoid ambiguity and intentional misclassification in order to avoid scrutiny of any collection.

Proposal 34

New human tissue legislation should provide that tissue removed from a person's body for research in accordance with **Proposal 32** must be removed, and the research conducted, in a manner that is consistent with the Australian Code for the Responsible Conduct of Research[1] and the National Statement on Ethical Conduct in Human Research (the National Statement).[2]

If there are any inconsistencies between new human tissue legislation and the Australian Code for the Responsible Conduct of Research or the National Statement on Ethical Conduct in Human Research, the terms of the legislation should prevail.

A blanket right to access stored material or tissue is not supported. Storage processes often render a tissue or human material suitable for only some types of subsequent analytical process, and this is likely to reduce utility for subsequent diagnostic and research use. The complexity of testing and continued evolution of analytic techniques directly affects the value of these stored specimens to any individual and grounds the lack of support for a universal right to access.

Proposal 35

New human tissue legislation should allow tissue to be removed from children for use in research using a provision modelled on section 22B of the *Human Tissue Act 1985* (Tas).

Question 28

Should new human tissue legislation contain a similar provision to **Proposal 35** that allows tissue to be removed from adults without decision-making capacity for use in research? If so, what safeguards are appropriate to enable legitimate research while protecting participants from harm and exploitation?

Consent and authorisation to remove tissue for research after death

Proposal 36

New human tissue legislation should provide that:

1. An adult may give valid consent to the removal of tissue from their body after their death for the purpose of research;
2. If an adult is close to death and does not have decision-making capacity, or dies without having provided valid consent, the adult's authorised decision-maker may give valid consent to the removal of tissue from the adult's body for the purpose of research.
3. When deciding whether to give consent, the authorised decision-maker must have primary regard to the adult's known beliefs, values, and preferences regarding the use of their tissue in research, if any, and make the decision they believe the adult would have made in the circumstances.
4. If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for the purpose of research.
5. Valid consent is:
    a. given voluntarily;
    b. given at a time when the person consenting has decision-making capacity;
    c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;
    d. given after the person consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and
    e. able to be withdrawn in accordance with **Proposal 37** or at any time before the removal of the tissue.
    f. sufficient legal authority for the removal of the specified tissue for the intended research use(s); and for other research use(s) in accordance with **Proposal 37**.

Proposal 37

New human tissue legislation should provide that:

1. When consent is provided under **Proposal 36** by an authorised decision-maker on behalf of someone else in circumstances where the all the specific research uses for the tissue are not yet known:
    a. the person who provided consent has a right to access information about how the tissue is being used, if at the time of the information request the sample is identifiable or, if it has been deidentified, is re-identifiable;
    b. the person who provided consent has a right to withdraw consent for any future research uses, if at the time of the consent withdrawal:
        iii. the tissue remains usable; and
        iv. the sample is identifiable or, if it has been deidentified, is re-identifiable.
2. If consent for future research uses is withdrawn, any unused tissue must be discarded.

9. Reforms relating to donation and use of deceased bodies

This is beyond the purview of the ABMDR Board

10. Reforms relating to stored tissue collections

Consent and authorisation for use of tissue samples

Question 29

Should there be a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes that they did not consent to?

You may want to consider **Question 27**, where we ask about secondary uses of tissue samples taken during a post-mortem examination.

Question 30

If a legal requirement for consent is imposed (**Question 29**), should there be exceptions to it? If so, what exceptions should exist?

Consent before tissue samples are used in research remains an important principle, but the catch all phrase "or other purposes" may be seen to restrict appropriate use for clinical purposes. An example is when an adverse event has occurred after transplantation and there is a need to test donor material to determine if the origin of the adverse event was from the donor,

Regulating stored tissue collections

Question 31

Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?

Question 32

Would it be beneficial to have national regulation, guidance and oversight for:

a. research biobanks that store and/or distribute human tissue or human bodies; or

b. educational collections of human tissue?

Question 33

If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:

a. what aspects of tissue collection, storage, use, transfer or disposal need to be regulated?

b. what types of collections should be regulated?

c. are there types of collections that should not be regulated?

Accessing stored tissue

Question 34

Should new human tissue legislation provide that individuals have a right to access their stored tissue? If so, what should 'access' entail in this context and who should be granted the right?

For HSC donation, ABMDR does not support the right of the donor to access stored 'tissue/cells' that have been donated. Once donated, the cells must be for the exclusive use of the recipient to whom they were donated. The concept that the donor could seek the return of the donated material runs counter to the concept of a gift as discussed above.

11. Reforms relating to the prohibition of trade

Prohibiting the exchange of human tissue for reward within Australia

Proposal 40

New human tissue legislation should prohibit the offering, giving or receiving in Australia of any reward in exchange for human tissue.

A reward in relation to the supply of human tissue means:

a. any financial payment; or

b. the provision of any valuable property, good, service or advantage;

It should not include:

a. the reimbursement of any expense or cost; or

b. the recovery of any loss or damage that was reasonably and lawfully incurred or suffered in connection with the donation, procurement, storage, processing or distribution of human tissue for a purpose permitted by the legislation.

Giving extra-territorial effect to the prohibition

Question 35

Should the prohibition on exchanging human tissue for reward have extra-territorial effect? If so, what would be the best mechanism to achieve this? For example, an amendment in new human tissue legislation, or an amendment to the *Criminal Code Act 1995* (Cth)?

Human tissue legislation should ensure human tissues and organs are ethically sourced, however for the example of human plasma, prohibition as per statement a) would render Australia with insufficient ability to service plasma needs, therefore this restriction could not be applied to all human materials. A reporting mechanism similar to that contained in the Modern Slavery Act is supported.

Agreement to be void (have no force)

Proposal 41

New human tissue legislation should provide that an agreement for the exchange of human tissue is not enforceable by any person who enters the agreement either knowing it contravenes, or being reckless about whether it contravenes, the prohibition in **Proposal 40**.

Exceptions to the prohibition on the exchange of human tissue for reward

Proposal 42

New human tissue legislation should provide that, other than human tissue donated to, or otherwise procured by, a tissue bank, the prohibition of the exchange of human tissue for reward (**Proposal 40**) does not apply to human tissue traded for a medical, educational or scientific purpose that is also:

a. a biological or medical device included in the register under the *Therapeutic Goods Act 1989* (Cth);

b. a registered good under the *Therapeutic Goods Act 1989* (Cth);

c. human tissue obtained under the 'Special Access Scheme' administered by the TGA; or

d. a blood product under the *National Blood Authority Act 2003* (Cth) that is traded by the Commonwealth or an entity mentioned in the national products price list as a supplier.

Question 36

a. Are the exceptions to the prohibition of the exchange of human tissue for reward listed in **Proposal 42** appropriate?

b. Should new human tissue legislation include additional exceptions?

c. Should new human tissue legislation include an exception to enable paid plasma donation?

Proposal 43

New human tissue legislation should include a mechanism to allow for the exemption of exchanges, or categories of exchanges, of human tissue from the prohibition of exchanges for reward in **Proposal 40**.

For example, the National Regulator (or alternative) could be empowered to grant exemptions. These exemptions would supplement the exceptions in **Proposal 42**.

In deciding whether to exempt exchanges or categories of exchanges, new human tissue legislation should require the National Regulator (or alternative) to consider certain factors, including but not limited to:

- the public interest in permitting the exchange;
- the nature or form of the material that is the subject of the exchange and the extent of the nexus to human tissue;
- the source of the human tissue; and
- the risk of exploitation, coercion, or the commodification of human tissue.

Proposal 42 could include unrelated HSC exchanged under the control and using the protocols of the ABMDR. As discussed above there is a current exclusion of the ABMDR in its entirety by each of the State jurisdiction ministers of health. If unrelated HSC is not included in proposal 42 then other arrangements need to be provided in the legislation to exclude the activities of the ABMDR from the operation of the prohibition in Proposal 40.

Question 37

a. Are the factors listed in **Proposal 43** that the relevant decision-maker must consider when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue appropriate?

b. Should the relevant decision-maker be required to consider any other factors when deciding whether to exempt exchanges or categories of exchanges from the prohibition of trade in human tissue?

Guidance on cost recovery

Proposal 44

The National Regulator (or alternative) should be authorised to provide guidance about what expenses, costs, loss or damage can be reimbursed or recovered by persons that retrieve, process, use, and/or distribute human tissue.

The complexity of this issue is exposed in unrelated HSC exchange globally – which Australia currently depends upon for 80-85% of all unrelated HSC transplants. Payments are made to the originating Registry according to their fee schedule over which an Australian regulator would have no authority or visibility. This fee schedule and each registry is subject to the accreditation of the World Marrow Donor Association. To fashion the Act to accommodate the complexity of global unrelated HSC exchange would likely distort provisions for other 'tissues' and make continued operation of the ABMDR and WMDA global exchange more expensive and potentially delay time critical transplants. The ABMDR thus re-emphasises the proposal to exclude exchange of 'tissues' if undertaken under the protocols of the OTA for Paired Kidney Exchange and the ABMDR for unrelated HSC.

Reforms relating to advertising the trade of human tissue

Prohibiting advertising

Proposal 45

New human tissue legislation should prohibit the public dissemination of information that invites, promotes, or seeks to induce a person to engage in a prohibited exchange of human tissue (**Proposal 40**).

Question 38

Is there a need for a prohibition on advertising that is broader than the prohibition in **Proposal 45**?

Question 39

If a prohibition on advertising is imposed in accordance with **Proposal 45**, should this prohibition have extra-territorial effect?

There is importance in preserving valid promotion of a donation of organs, cells or tissues in general, which is undertaken routinely by many national and governmental and charitable agencies and organisations such as OTA, Driving Licence Authorities and

the ABMDR, Transplant Australia and the Leukaemia Foundation. Problematic is the promotion of donation to a specific individual, which in other countries (such as the USA) has led to billboards and social media requests for donation to a particular individual, favouring the photogenic and wealthy and encouraging unrelated donation for covert reward. Yet individuals are routinely identified in calls for general recruitment to the ABMDR register in the hope of a donor suitable for the individual and families routinely publicly seek donor registrations in the hope of finding an unrelated HSC donor. Legislating to allow these uses of promotion while preventing appeals for an individual needing a liver or kidney will require careful drafting. The internet ensures that extra territorial access to advertising is routine as is national access to extra territorial media. The important issue is the control on utilisation of potential donations derived from these media activities, In the case of organ transplants in Australia these are undertaken in public government run hospitals with appropriate controls on all unethical and illegal activity such that the advertising derivation of a transplant is nullified if unethical or illegal. In the case of recruitment to the ABMDR register, search of the register is standardised and routine irrespective of the family/friends originated media used to encourage recruitment and uses standard Tissue Typing criteria, uninfluenceable by the mode of recruitment.

Question 40

Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced?

If so, should the mechanism be:

a. A prohibition of the importation into Australia of human tissue that was originally obtained without the consent of the donor, or in exchange for reward or profit? or

b. A reporting mechanism similar to that contained in the *Modern Slavery Act 2018* (Cth)?

This is an important issue that needs to be addressed. Based on the large range of alternative sources for donation of HSC it would be more appropriate for this to be managed through delegating the responsibility to the protocols of national organisations (OTA and ABMDR) and through Therapeutic Goods regulation or other regulator as identified above.

Question 41

If a prohibition is legislated of the kind described in **Question 40(a)**, or reporting requirements introduced of the kind described in **Question 40(b),** should new human tissue legislation include a mechanism to exempt importations of human tissue from the prohibition or reporting requirements, and if so, what factors should be considered as a basis for justifying an exemption?

For example, relevant factors could include but not be limited to:

- the health needs of Australians;
- if it is possible to meet the health needs of Australians through domestic supply of the relevant tissue; and
- the risk that the people from whom the tissue was originally obtained were coerced or exploited.

The ABMDR could not operate to provide unrelated HSC donations, currently for around 500 Australians needing HSC Transplants each year, if there was additional burden placed on overseas unrelated HSC registries to report specifically to an Australian Regulator. “The health needs of Australians” and “the inability to meet the health needs of Australians through domestic supply” both apply to these HSC donations. The ABMDR ensures, through Accreditation of registries to the World Marrow Donor Association (WMDA), that donation of HSC in all accredited registries is undertaken under strict WMDA protocols including ethical, legal and quality provisions. Additional reporting requirements would not further increase the ABMDR’s capacity to ensure ethically sourced donations. Exempting Unrelated HSC importations under the protocols of the ABMDR would resolve this issue.

Improving access to data

Question 42

We have heard there is a need for data from donation agencies, tissue banks and other tissue product manufacturers, distributors, and sponsors to better understand the demand for tissue and inform future policy development.

If you agree there is a need for data, what type of data is needed?

Question 43

In relation to **Question 42**, how should the data be reported?

For example, should there be:

a. voluntary reporting?

b. mandatory reporting?

Question 44

In relation to **Question 43**, if you support mandatory reporting, should the National Regulator (or alternative) have the power to conduct mandatory inspections of records?

Collection of data covering product usage, demand and trends over time is supported. Data to validate cost recovery calculation could also be collected, though this is encompassed by the Independent Hospital and Aged Care Pricing Authority (IHACPA) on a routine basis. National outcome registries are uniformly collecting such data for organ transplants, HSC transplants and cornea transplants. Extending that voluntary process to a mandatory mechanism for all donated material would be complex and costly. We question whether this needs to be included in the Act.

11. Reforms relating to how information can be disclosed and shared

Prohibiting non-consensual public disclosures of a tissue donor's or tissue recipient's personal information

Proposal 46

New human tissue legislation should prohibit the public disclosure of a human tissue donor's or human tissue recipient's 'personal information', unless consent to disclosure has been provided in accordance with **Proposal 48**.

'Personal information' is information that identifies an individual, or that makes an individual reasonably identifiable.

Permission for health practitioners to disclose a tissue donor's personal information in limited circumstances

Proposal 47

New human tissue legislation should provide that it is permissible for medical practitioners to disclose a human tissue donor's personal information to a potential human tissue recipient provided:

a. the information is clinically relevant to the potential tissue recipient's decision about whether to accept tissue for transplant; and

b. the information is disclosed in a manner that mitigates the risk of the donor being identified to the greatest extent possible without compromising the ability of the potential recipient to make an informed decision.

Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information

Proposal 48

New human tissue legislation should provide that consent to the disclosure of a human tissue donor's or human tissue recipient's personal information may be given by:

a. the human tissue donor or the human tissue recipient themselves; or

b. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is deceased; or

c. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is a child or an adult who does not have decision-making capacity.

Allowing certain people to access and share information for identification and screening purposes

Proposal 49

New human tissue legislation should use sections 45(4)–(6) of the *Human Tissue Act 1982* (Vic) as a model to ensure that medical practitioners, health authorities, and DonateLife staff can access and share with each other relevant information for donor identification and screening.

The definition of personal data needs to be carefully thought through and described in the Act. There is an important distinction between data that is important for clinical treatment and for decisions made by the potential recipient (eg a Hepatitis B positive donor) and data that identifies the donor (name, age, address etc). The second distinction is whether the individual is alive and a competent adult, or deceased, or a child. The ABMDR has a protocol for allowing donors of HSC to offer to make their personal identifying data available to the recipient, just as the recipient can offer to make their identifying data available to the donor. The ABMDR has protocols which permit the exchange of these data via the ABMDR if both independently provide consent, but only after a certain period post-transplant has elapsed (such that the potential need for a second donation from the same donor has lapsed). Exchange of data is also dependent upon the individuals receiving counselling of the potential negative aspects of data exchange, but in the end two consenting adults cannot be validly prevented from making their own data public. The complexity of extending this right to families of donors or recipients needs to be carefully considered and is not currently included in the ABMDR protocols. The ABMDR understands the public pressure in the Organ Donation/Transplantation environment for this right to be extended to families. ABMDR would need to consider carefully the application of any change in the law extending the right from the individual themselves to the family of the individual. While the vast majority of such interactions end in positive outcomes, that is not unfortunately universally true, since there are also negative outcomes.

Definitions used in this provision should align with existing definitions in other legislation such as the Privacy Act 1988 (Cth) and the Health Records and Information Privacy Act 2002 (NSW).

Compliance

Compliance mechanisms

Question 45

Do you have views about the best mechanisms to encourage or enforce compliance with the obligations and prohibitions that we are proposing should be included in new human tissue laws, regulations or standards?

In your answer, you may wish to focus on particular obligations or prohibitions that we are proposing, and the best way of encouraging or enforcing compliance with these.

14. The timeframe for implementing our reform proposals

The timeframe for implementing our reform proposals

Question 46

Do you have views on the timeframe/s within which the reforms set out in this *Discussion Paper* should be implemented, or on how the implementation of these reforms could be staged or prioritised?

The major concern that the ABMDR has is if the jurisdictional budgets do not permit funding of a regulator and either remove the concept of a new regulator or allow it to proceed but fail to fund it sufficiently to undertake the roles envisaged, then what reforms will be able to proceed? There are no proposed reforms that are critical to the current functioning of the ABMDR and unrelated HSC donation and transplantation providing that the ABMDR remains excluded from the provisions or retains State Ministerial exclusions.

Are other reforms urgent?

Question 47

Is there an urgent need for reform of human tissue laws that we have not addressed in this *Discussion Paper*?

The considerations are very thorough