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The Transplantation Society of Australia and New Zealand

TSANZ Chair – Professor Nicole Isbel

The Transplantation Society of Australia and New Zealand (TSANZ) welcomes the opportunity to comment on the ALRC Review of the Human Tissue Laws. It is a very comprehensive and far-reaching paper, and we would be happy to have further discussion on any aspect of the feedback contained in this response or any other area of concern.

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.

Comment: Consistency is vital and how this is achieved is the secondary issue for the clinical sector. As long as it works!

A single national body with oversight would be a reasonable approach and TSANZ would suggest that partnership with TSANZ as the peak clinical representative body would be necessary. TSANZ have a track record of setting codes of practice, guidelines and standards through our collaborative work with the Organ and Tissue Authority (OTA) on the TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors (Clinical Guidelines).

However, enforcing compliance is not an area that has been undertaken previously by either OTA or TSANZ and is complex given that neither group has the structures to undertake this work currently. It is made even more complex in that, each of the health services reports to the state health departments within state legal systems. The remit of the proposed laws is very broad and will involve many aspects of transplantation of organs and tissues across a very large number of health services. Audit and benchmarking at a national level are critical and with infrastructure development and support are achievable. We suggest that a national approach to setting codes of practice, guidelines and audit can be done but that compliance regulation will be done at a state level with the assistance of the state health bodies.

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



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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

Comment: This proposal is reasonable.

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.*

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.

Comment: TSANZ would support a national regulator by providing additional clinical expertise that is likely to be required. TSANZ would respond that it is essential that in order to set policies and standards that it is critical that clinicians experienced in organ donation and transplantation are involved in the establishment of the policies, standards, etc. The OTA is well placed to develop the educational materials for the general public on organ donation and TSANZ well placed to develop the education for clinicians in the transplant sector.

Research: policies regarding research must be done in collaboration and with wide consultation with stakeholders such as the patient community, the National Health and

Medical Research Council (NHMRC), established research groups and the TSANZ to ensure that the policies are fit for purpose and forward thinking – these policies must remain appropriate but do not constrain advances in the field.

We have some concern about what is meant about the requirement to licence and accredit tissue retrieval and storage and the impact that will have on research programs. Where donor family consent has been given for research, it needs to be possible for research to continue outside of centralised biobanks.

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*

Comment: Transplantation in Australia becomes an increasingly national undertaking – with shipping of organs across state boundaries frequently occurring that the harmonisation of laws is critical.

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*



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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?

Comment: Yes.

Question 2

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

Comment: Yes. Include a requirement that the safety of the recipient of the organ or tissues is also a material concern and that, when information about a donor may have an impact on the recipient health outcomes it does need to be disclosed to both the treating clinicians and the recipient in a way that protects the privacy of the donor. This allows for informed consent of the recipient and implementation of interventions/therapies that are required to safeguard the health of the recipient.

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

Comment: TSANZ supports equity of access to assessment for donation and transplantation as a founding principle of organ transplantation.

Barriers to donation –

- Deceased donation – ability to optimise donor organs to increase the opportunities for donation. These would include ability to proceed with antemortem donor care as per standard care and more invasive investigations and therapies following consent of the family.
- Living donation – improving the financial support for donors

Barriers in access to transplantation are not really occurring because of gaps in the law. Eg human rights, antidiscrimination, Australian Charter of Healthcare Rights are all covered by existing laws/regulations.

We agree with the statement in the report that barriers exist because of lack of structures and funding (including workforce) to bring transplantation to groups that have difficulty in accessing assessment and post-transplant care. For example, access to transplantation for First Nations Australians particularly for non-kidney transplants is of concern through lack of

data, lack of structured assessment and structures for culturally appropriate care for patients who often live remotely. So, there is probably not a need to legislate beyond supporting what is already in existence.

Access to transplantation as a therapy will always be constrained by a tension between

1. The disparity between numbers of donors and potential recipients.
2. Some consideration of utility to be undertaken such that a scarce and precious community resource is used with respect to achieve a reasonable outcome for the majority.
3. That access to assessment for transplantation is very different to access to transplantation. Patients who may hope for a transplant as treatment for their end stage organ failure may not always be medically suitable, or benefit from for transplantation.

In the discussion paper (2.11) there is a comment that there are 1,850 people on the transplant waiting list and that there are 13,000 people on dialysis who could benefit from a transplant. While there are many people on dialysis who would benefit from a transplant, this number is very much less than 13,000. The lack of data to fully determine this is an issue, but the predominant reason for lack of wait listing is that comorbidity is such that transplantation is likely to be unsuccessful or be associated with very poor outcomes including death.

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’.*

Comment: Greater granularity is very important. Option c; Human cells, organs and tissues would be the best term. The law, regulations, guidelines will apply differently to each of these components.



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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.

Comment: Yes – it is important that the structure that is created to provide oversight has the ability to facilitate changes in definitions as the field moves forward. And that the structure be constituted of the appropriate stakeholders for this to occur.

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).

Comment: Yes – but this may better sit outside of government so that it can be structured to be receptive to input from the regulator, experts and other stakeholders and that it doesn't create a barrier to innovation. Adequately funded and resourced so that it is a flexible structure and able to provide timely advice.

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?

Comment: Gametes from deceased donors – this should be included. This issue comes up frequently enough for a legal clarification. The ability to have directed donation of deceased donor gametes where the wishes of the donor are known, needs to be considered as a separate topic and provide clear guidance that is uniformly applied across states and territories. Every year this issue causes great distress for families and outcomes are variable and inconsistent.



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Similarly, the governance of cell lines and foetal tissue from deceased donors need special and separate consideration.

The other human materials listed – milk, faecal tissue (and others not included – urine, bile, etc) should be excluded from this legislation.

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

b. 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



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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?

Comment: It is important that the definition of death applies for all purposes as a key foundation to enabling public trust in donation and transplant sector.

The definition of death as given above is very different to what is standard clinical practice for most deaths (those not related to donation) both in hospital and the community which are based on absence of circulation (no pulse, no heart sounds) no respiration, not able to rouse and no pupillary response.

The wording is complex and hard to completely understand the intent – simplification would help.

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.*

Comment: Option a - A uniform death act would be preferred which is adopted by states and territories.

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,*



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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.

Comment: This is not feasible in the intensive care situation as the recipient of the organ may be cared for by an intensivist who is involved in the declaration of death in both the immediate and future. Limitations would be unworkable and potentially place the recipient at risk.

Consent and authorisation for removal of tissue from living persons

Proposal 14

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.

Comment: This depends on the definition of tissue and this needs to be very carefully worded. The donation of blood/ bone marrow is very different ethically than the donation of organs due to the balance of risk versus harm.

The TSANZ and the Living Donor Working Group Steering Committee is strongly opposed to the removal of organs from living children for purposes of donation.

The donation of organs by living children (and adults who lack competence) is outside Australian societal and clinical practice norms and is discouraged by most international guidelines. It is so rarely practiced that there is no data on the safety – both in terms of physical consequence in children and psychological harm in children and adults that lack



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decision making capacity. If the intent is to support the donation of organs from living children, there is a very serious risk of adverse impact on donation overall as the practice is not supported by the general population or the clinical community.

There is a rare exception of domino transplantation. The case where a child with a genetic disorder has an organ removed so they can receive an organ (usually the liver) which contains the missing gene. The child's liver can then be used for a person in desperate need as the impact of the missing gene is only apparent after many years.

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*

Comment: The donation of cells/bone marrow does not need to be approved by a legislated committee.

The TSANZ does not support living organ donation from children. There are always other options for managing the needs of patients who are suitable for transplantation from a deceased donor but have other complex issues such as sensitisation.

The risk to the sector from over emphasis on this issue and loss of public trust is a concern.

Question 11



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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?

Comment: No. Parents and guardians may have extraordinarily difficult conflicts of interest (e.g. in supporting the donation of organs between siblings or to themselves).

Further research is required before donation of organs by living children can be considered.

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?

Comment: It is impossible to think of any medical, educational or scientific purposes where there would be adequate benefit to the child or adult without capacity to remove anything more than cells. Suggest great clarity what human components are being referred to here.

It is likely to facilitate distrust and unhelpful discussion for what must be almost no societal benefit or return.

The need for such a committee should be so rare, and the qualifications required would vary so much that it could be convened by the Australian Chief Medical officer in consultation with stakeholders such as the National regulator, OTA, relevant patient advocacy groups (e.g., Transplant Australia), and peak clinical representative groups (e.g. TSANZ, Transplant Nurses Association, etc). To set up a committee in advance is tacit approval to the practice which should be strongly avoided.

Consent and authorisation for removal of tissue after death

Question 16

Proposal 23 removes the role of the Designated Officer, who under current legislation is required to authorise tissue removal when a person dies in a hospital. Do you agree the role of the Designated Officer is no longer necessary?

- *If you agree that Designated Officers are no longer necessary, please explain why.*
- *If you think the Designated Officer role remains necessary, please explain why*

Comment: There will remain a role of a designated officer at transplanting hospitals. It is an important link between the hospital's executive, state health departments and will remain part of the local oversight of donation. They will be an important and independent resource urgent advice for complex cases. They would also be an important role in local oversight of the law and the application and enforcement.

Proposal 24

The National Regulator (or alternative) should develop protocols or guidelines for deceased tissue donation by people accessing voluntary assisted dying, and people who have decision making capacity and who are requesting withdrawal or cessation of life-sustaining therapy.

Comment: Unnecessary for this level of detail to be specified in the new laws. The process/guidelines for donation in circumstances such as Voluntary Assisted Dying (VAD) are already in place and working well. Need to be careful not to create a bureaucratic and unwieldy structure. Needs to have a clear focus and operate at a high level.

Authorised decision-maker

Proposal 25

New human tissue legislation should replace current HTA definitions of ‘senior available next of kin’ with a definition of ‘authorised decision-maker’ that sets out a hierarchy of decision-makers modelled on section 13 of the Health Care Decision Making Act 2023 (NT).

Question 19

How should the hierarchy of decision-makers in Proposal 25 be tailored to the deceased tissue donation context?

Comment: The hierarchy of decision makers should be consistent across all jurisdictions and purposes.

Pre-mortem interventions

Proposal 26

New human tissue legislation should define pre-mortem interventions to mean any activity, procedure or investigation that is performed on a living person solely for the purpose of tissue donation after death, including to assess, maintain, or improve the viability of organs for transplantation.

Question 21

Is the definition in Proposal 26 an appropriate definition for pre-mortem interventions? Why or why not?

Comment: Very broad and probably unworkable. For example, the giving of intravenous fluids, measurement of blood pressures and temperatures, continuance of antibiotics after it is determined that treatment is futile and end of life care is commenced could all be included in this definition. It would be usual practice to stop all of these once the decision to commence end of life care for patients who are nondonors. It is critical to continue support of the possible donor until the decision is made by the family as whether to proceed or not. Otherwise, opportunity to be a donor will be lost. It would be a preferred standard of care

that support is continued until the patient is determined to be unsuitable on medical grounds or the family have declined to consent.

Proposal 27

New human tissue legislation should provide that a pre-mortem intervention is prohibited unless valid consent has been given to it. If the person to whom the intervention will be administered does not have decision-making capacity, valid consent can be provided by the person's authorised decision-maker (Proposal 25).

In determining whether to consent on behalf of an adult person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, and make the decision they believe the person would have made in the circumstances.

Comment: The decision to commence end of life care is separate from the discussion of organ donation. The gap between the discussion to withdraw futile treatment and consent for donation can be some hours/days and this is very important for the donor family. The management of the potential donor during this time would be very difficult if basic measures as listed above are not able to be continued. And most DCD donors would probably not be viable. The wording needs to be substantially changed. Once consent for donation is obtained – it needs to be broad enough to cover the suite of interventions that are appropriate for the workup of that donor. Approaching the families for additional consent should only occur in exceptional circumstances to avoid unnecessary distress.

Question 22

We have heard that it is sometimes necessary to conduct a minor procedure such as a

blood test to determine a person's suitability to donate tissue after their death, and that it may not be practical to obtain prior consent. Should new human tissue legislation contain an exception to the need for consent? If so, how should the exception be expressed, and what limits should there be on it?

Comment: In continuance with the comments above – basic support of the donor and minor procedures could all be exempt from consent.

Regulated stored tissue collections

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?*

Comment: No. Guidance already exists through the National Statement on Ethical Conduct and additional regulation and oversight is not required. Education and certification programs to develop best practice are encouraged.

Care needs to be taken that over-regulation does not occur.



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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)?

Comment: Travel for purposes of transplantation where it is of a transactional basis is unethical and should absolutely be strongly discouraged.

Presumably, in a similar way that the child sex tourism act protects international children a similar law could be enacted by amending the criminal code. But the implementation of such a law would be very difficult – having the treating physicians responsible for reporting what they can only suspect as a case of exchange of money for an organ transplanted overseas would mean that a therapeutic relationship with that patient would be compromised. Mostly it is found out after the fact that such a transplant (or is suspected) to have occurred. Suggest that more work be done on this proposal. In general, supportive but needs to be able to be enforced.

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

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?

Comment: Clinical trials conducted both by pharmaceutical companies and independent researchers will collect tissue samples as part of that research. Patients are consented for both the collection and the sharing of the material (de-identified) as part of the research protocol. Re-imburement of costs to the trial site (rather than reward) occurs as standard practice.

It may be worth adding as an exemption tissues collected as part of a clinical research trial that has been approved by the standard ethical governance procedures.

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



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Is there a need for a prohibition on advertising that is broader than the prohibition in

Proposal 45

Comment: TSANZ supports proposal 45 and that it apply in overseas jurisdictions.

Reforms relating to tissue importation ethics and oversight

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)?

Comment: TSANZ supports that all tissues sourced overseas be obtained ethically and with the consent of the donor.

Exemptions should be determined for organ sharing with New Zealand. The Australian Paired Kidney exchange will exchange kidneys with New Zealand. Also, on occasions deceased donor organs are shared between the countries. It can be assumed that the organs have been ethically sourced. Additional regulatory review would be a barrier that may delay or prevent this process.

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?

Comment: There is a need for data, and the national regulator should have a role but likely that this sits outside a legal framework. Mandatory reporting and inspection should be limited to aspects covered by the tissue laws around donation.