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PERTH BONE & TISSUE BANK INC.

100% DONATED IN AUSTRALIA

15 January 2026

Advisory Committee
Review of Human Tissue Laws
Australian Law Reform Commission

Dear Committee Members,

Re: Review of Human Tissue Laws - Discussion Paper

PlusLife is Western Australia's only bone and tissue bank and one of a small number of tissue banks in Australia. PlusLife has operated continuously as a not-for-profit service since 1992. In PlusLife's long history we have been involved in several reviews and improvements to the legislation and ethical frameworks for human tissue donation and transplant.

The current review's discussion paper was encouraging for the breadth and depth of the considerations that the committee was seeking to invite commentary on and make recommendations about.

At PlusLife, we screen, collect, process, store and distribute donated human bone and tissue allografts. We pride ourselves on exclusively retrieving 100% Australian donated bone and tissue to produce the highest quality allografts in our facility located in Midland, Western Australia.

As a Therapeutic Goods Administration licensed tissue bank, we are committed to providing medical professionals with safe and effective allografts for use in surgical procedures to treat patients with conditions such as spinal deformities, arthritic joint disease, bone cancers, sports injuries; and facial and dental reconstructive surgeries.

We exist to enhance Australian lives through the precious gift of human bone and tissue donation. We are a not-for-profit service delivering on our commitment which is centred around the needs of each recipient, supported by uncompromising respect for every donation.

In the last ten years with the emergence for-profit actors trading in musculoskeletal human tissue it has become increasingly difficult to maintain a sustainable and independent not-for-profit tissue banking service. PlusLife is hopeful that this review provides outcomes that re-balance Australian systems of donation, processing, allocation and use of human tissue towards the objectives proposed in the discussion paper in a sustainable manner.

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PlusLife has laid out responses to the recommendations and questions at Appendix 1. Should any of the response require additional explanation please do not hesitate to seek further information by contacting info@pluslife.org.au.

This review is a once in a generation opportunity and we look forward to the committee's Final Report later this year. Thank you for your attention to this submission.

Yours sincerely,

[redacted]

Hal Borohovskis
Chief Executive Officer

Appendix 1

ALRC Discussion Paper Proposal and Questions	PlusLife Response
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.	*PlusLife is supportive of a proposal for uniform legislation and a national regulator. The current state is one of substantially consistent legislation with a limited ability to regulate activity inter jurisdictionally in a consistent manner.*
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.	*The governance hierarchy of proposal 2 is supported with an acknowledgement that a mechanism for the National Regulator to allocate responsibilities to other agencies should exist within a framework of agency and organisational responsibility that is established within the legislation.*
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); 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.	*The three pathway options to creation of a National Regulatory Authority presented in the discussion paper are not supported.* *The discussion paper proposes an expanded definition of tissue and a requirement to extend and regulate tissue donation, retrieval, processing, allocation, distribution and implantation as the primary objectives of the legislative reform. There needs to be a separation of responsibilities between funding, regulation and delivery service arms to ensure effective governance and remove the possibility for conflicts of interest to arise.* *Presently the Organ and Tissue Authority (OTA) is doing important work in improving the systems of organ donation, allocation and transplantation. To date it has been unable to effectively deliver on its responsibilities for improvement in tissue donation. The task may be too large for one service. The OTA is presently involved in less than 30% of donation and retrieval activity, less than 3% of allocation, distribution and transplantation activity and is not involved in processing or storage of any tissue.* *In addition, there are priority areas for reform that require the OTA's immediate attention that may be delayed if OTA's functions were restructured and expanded. For further information please refer to the response to Question 46.* *Establishing a new statutory regulatory body that incorporates the Organ and Tissue Authority as a branch may not provide sufficient distance and separation of interests to enable the effective promotion of improvement in tissue donation. For example, the current National Strategy for Organ Donation, Retrieval and Transplantation does not include tissue that is not an organ. Establishing any alignment to this document would be limiting.* *An independent regulatory authority that has powers and functions that can be both delegated or retained would be supported as it would enable independence, good governance and reduce the likelihood of duplication and conflict of interests emerging;* *Powers and Functions that might be retained or delegated:* • *set and delegate the creation of 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; and*

	• *accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors.* *Powers and functions that should be retained* • *monitor, collect data, investigate, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.*
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.	*PlusLife has no comment on the method of legislative alignment.*
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?	*PlusLife supports the objects of the legislation proposed with the proposed informed consent model of authorisation within Proposal 14.* *In light of funding challenges discussed further in response to Proposals 40 to 44 and the disproportionate economies of scale with commercial or altruistic donation that can be achieved across different metropolitan, rural or international settings. It is possible to achieve these objects in an unbalanced way that would have a very negative impact on Australian systems of human tissue donation, processing and allocation with limited impact on public trust in the laws and regulatory frameworks that govern human tissue donation.* *Consideration should be given to inserting reference to the sustainability of Australian systems of donation, processing, allocation and use of human tissue.*
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. **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?	*The barriers to equitable donation and transplantation access are systemic and may be unresolvable. There will always be capacity and logistics constraints that limit access to donation opportunities for people that live in locations that cannot support certain services in a sustainable way.* *It is appropriate to include in the legislation the flexibility and capacity to redress barriers and promote equitable and sustainable improvement in access to human tissue donation, transplantation, and use.* *A multi layered context for access must define what is equitable and sustainable in a way that accommodates differing viewpoints of equity from healthcare providers, the public, authorised persons and their families, the donor, and tissue banking services at each stage of the donation lifecycle from donation, retrieval, processing or allocation to allocation and use. It is recognised that this is a difficult challenge.* *The proposals within this paper go a long way towards improving most of the current barriers.* *Some extension of the proposals as a pathway to improved equity is required within the following:* • *Establishing mandatory reporting and national registries for implantation of biologicals of human origin (Question 43 & 44 commentary).*

	• *Establishing a national inventory of the altruistically donated human tissue available for implantation. It is a national community asset and should be managed in a similar way to the management of blood.* • *Establishing a consistent and fair funding model for donation to enable equitable access (Proposal 40 to 44 commentary).* • *Establishing a consistent and fair funding model for transplantation activity to support equitable access (Question 47 commentary).* • *Extension of the discussion on the concept of consent authority to include authorised consenting officer (Proposal 14 commentary).* • *Extend the Coroner's capacity to consider and support donation within Coroner's decision-making remit (Proposal 29 commentary).*
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'; c. Or 'cell, organ, and tissue'.	*PlusLife supports broadening of the definition.* *The label 'substance of human origin' is more inclusive than 'tissue', and would be PlusLife's preferred term, however it is recognised that this may encounter greater difficulty when translated into public awareness campaigns, leading to a duality in reference language emerging. Considering this potential challenge, the definition based on section 7 of the Human Tissue Act 2008 (NZ) is preferred.*
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.	*PlusLife supports this proposal.*
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). **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? a. Human milk. b. Foetal tissue. c. Faecal tissue. d. Gametes (from deceased donors). e. 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).	*PlusLife supports the proposal to have facility to improve clarity and guidance. It is unclear why with an extended definition (Proposal 8) and a capacity to provide interpretive guidance (Proposal 9) there would be a need to provide limits on the context of the objectives of the legislation (Question 7).*

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.

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.

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.

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.

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.

PlusLife is supportive of proposals 10, 11 and 12.

In relation to question 8 this is the current position for Western Australia.

PlusLife does not have comment for the statutory approach (Question 9) taken to achieve and maintain consistency.

For the purpose of determining accepted medical practice, regulations can specify professional standards or guidelines to be complied with.	
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.	*It is critical to ensure these sections of the legislation are well crafted to provide the necessary safeguards.* *PlusLife notes the intention to remove the designated officer and the extension of the purposes of tissue donation to include scientific purposes and cautions that the construction of these clauses should not inadvertently limit the Coroner in the normal function of the role in some Coronial settings.*
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. **Question 10** Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?	*PlusLife notes that Proposal 14 lays out a framework for achieving informed consent and that this includes both living and deceased tissue donation. PlusLife is supportive of the proposed framework for achieving informed consent with the following additional comments.* *PlusLife is in agreement that there is a need for greater legal and ethical safeguards and supports valid consent including informing the donor or the donor's authorised decision maker:* • *whether the donated tissue will be used to generate profit; and* • *whether the donated tissue will be sent to another country.* *Presently there is no consideration within the discussion paper of who is appropriately qualified to facilitate the 'informed consent' process. With the proposal to remove the designated officer role in tissue donation it is appropriate to consider additional safeguards that would ensure that the consent process is conducted by appropriately qualified or authorised people. PlusLife suggests there is a need to define what makes a practitioner authorised to confirm, secure or receive valid consent.* *With the removal of the designated officer role, the locations deceased tissue donation can occur is likely to extend beyond the current hospital and coronial settings. Oversight of the validity of consent for deceased donation should be maintained to ensure opportunities to donate in new settings are managed in accordance with the objectives of the legislation.* *Consideration should be given to who will be responsible for the consent process noting the broader definition of tissue and OTA/DonateLife service involvement levels in deceased and living donation activity.* *Consent should be facilitated by a practitioner authorised to secure consent. Presently who is involved in facilitating valid consent can be dependent on the tissue being consented, the jurisdiction of the donation and whether the donation is living or deceased.* *It will also be necessary to connect the ability to access information (Proposal 49) with authorised practitioners who might also be responsible for managing the screening and consenting processes.*

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.	*PlusLife supports this proposal.*
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.	*PlusLife supports this proposal.*
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.	*PlusLife has no comment on this proposal.*
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.	*PlusLife has no comment on this proposal.*
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?	*PlusLife has no comment on this proposal.* *In relation to question 12 Pluslife currently consents for femoral head donation for donors who are not yet 18, in practice consent is obtained from the child and their NOK. Consideration needs to be given to the reason for removal and the types of tissue that can be removed with consent without the need for referral to a committee. Pluslife believes it is not the intent of these proposals to include routine donation of tissue.*
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.	*PlusLife has no comment on this proposal.*
PROPOSAL 21	*PlusLife has no comment on this proposal.*

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. **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.	*PlusLife has no comment on this proposal.*
PROPOSAL 23 1. New human tissue legislation should provide that: a. An adult may give valid consent for the removal of their tissue after their death for the purpose of transplantation or for other medical, educational or scientific purposes. b. 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 transplantation or for other medical, educational or scientific purposes. 2. When deciding whether to give consent, the authorised decision-maker must have primary regard to the adult's known beliefs, values, and preferences regarding tissue donation, if any, and make the decision they believe the adult would have made in the circumstances. 3. 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 transplantation or for other medical, educational or scientific purposes. 4. 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 use of the tissue; and e. able to be revoked at any time before the removal of the tissue. 4. Valid consent is sufficient legal authority for the removal of the specified tissue and for the specified uses. 5. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in Proposal 36 must be met.	*PlusLife supports this proposal.* *The designated officer is an important safeguard to ensuring the validity of consent within a Hospital setting. The Coroner performs a similar role exercising oversight by authorising tissue donation to proceed in the coronial setting. As currently described it is also a role that limits the locations that donations can be facilitated. It is incorrect to state that these functions are now primarily undertaken by DonateLife.* *If the intention is to move this activity to DonateLife then, additional resourcing will be required with a transfer of work effort from tissue banks and research institutes to DonateLife. Alternately to improve access to donation opportunities for Australian's it will be necessary to more broadly define who is able to facilitate 'valid consent' in addition to extending access to information sources (Proposal 49).* *Outside of hospitals and the coroner it is currently possible for donation opportunities to arise without access to a way of authorising consented tissue donation to proceed. Tissue donation requires oversight to ensure it meets the objects of the legislation. Without a designated officer how will oversight of valid consent be managed in the future in;* • *Hospitals;* • *Aged care facilities;* • *Funeral homes;* • *Research institutes; and* • *The community.* *PlusLife suggests that consideration be given to the following to support the objects of the legislation in the absence of a specified independent role such as the designated officer:* • *recognising an authorised 'consent' practitioner role in the donation process;*

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. **Question 17** Does Proposal 23 strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach? **Question 18** Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required? For example, Victoria's legislation allows a person to give consent to donation: • in writing at any time before their death; or • during their last illness, orally in the presence of two witnesses.	• *requiring mandatory reporting on donation activity inclusive of tissue retrieved; and* • *establishing and managing an independent complaints mechanism.* *The designated officer also performs a role in authorising post-mortems. Will the designated officer retain this role? Consideration needs to be given to how voluntary post-mortems might be actioned within the proposed legislation in the absence of the designated officer.* *PlusLife believes that it will be necessary to specify the form that consent to deceased donation should take in order to meet the objects of the proposed legislation. To improve access to donation opportunities for Australian's it will also be necessary to more broadly define who is able to facilitate 'valid consent' in both living and deceased tissue donation contexts.*
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.	*PlusLife supports this proposal.*
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? **Question 20** How should new human tissue legislation address situations where authorised decision-makers with equal decision-making status in the hierarchy in Proposal 25 disagree about whether to consent to donation?	*PlusLife supports a proposal to modernise and extend the authorised decision maker hierarchy.* *The current senior available next of kin framework is workable and accommodates for availability in addition to prioritising seniority of the next of kin. PlusLife requests that any extension of the hierarchy to include additional flexibility should also maintain the concept of availability as an influence on the seniority of the next of kin.* *A significant portion of donation opportunities are missed due to the limited time available to manage the screening, consent and retrieval process after death.* *The legislation should only seek to intrude so far into the decision-making process as to ensure that the decision is informed be it informed consent or informed objection. If the objection is informed, then it must be respected.*
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?	*Proposal 26 should replace the word organs with tissue. In context of Proposal 14, 23, 27 and 13, proposal 26 is supported.* *It is suggested that additional safeguards may be required to regulate and maintain the currency of pre-mortem interventions that are considered appropriate in order to promote the objects of the legislation and maintain consistent access to pre-mortem interventions across Australia.*
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. **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? **Question 23** Should new human tissue legislation have any additional safeguards for the use of pre-mortem interventions beyond the need for valid consent? If so, what safeguards should it have?	*In context of Proposal 23, 26 and 13 proposal 27 is supported.* *It is current practice that procedures such as drawing of bloods undertaken for the benefit of the potential donor can also be used for additional tests after valid consent has been gained. PlusLife does not support the idea that any procedures that are not for the benefit of the patient can be performed without valid consent being given prior.* *It is suggested that additional safeguards may be required to regulate and maintain the currency of pre-mortem interventions that are considered appropriate in order to promote the objects of the legislation and maintain consistent access to pre-mortem interventions across Australia.*

PROPOSAL 28 New human tissue legislation should provide that, when removing tissue from a deceased body, any person involved in the removal must treat the body with the highest level of respect and dignity that is practicable in the circumstances.	*This is current practice and is essential to maintain in the new legislation, PlusLife supports this proposal.*
PROPOSAL 29 New human tissue legislation should provide a mechanism enabling medical practitioners and authorised technicians to remove certain types of tissue from deceased bodies, including musculoskeletal, cardiovascular, eye and skin tissue. The National Regulator (or alternative) should by delegated legislation specify the relevant qualifications required for technicians, and any additional type of tissue that technicians are authorised to remove. **Question 24** Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?	*PlusLife supports this proposal noting that it could include any tissue and therefore any person removing tissue for a broad range of reasons. The new legislation should include both the type of tissue removed and the reason for the tissue removal. This would enable appropriate accommodation for tissue donation and other activity such as the work of the Coroner.* *This a highly specialised field with a variety of pathways to be deemed competent. Movement towards a nationally recognised 'relevant qualification' will need sufficient runway of time to enable currently qualified authorised practitioners to be recognised.* *Presently in WA the Coroner does not have a remit for decision making for non-coronial purposes. It is appropriate that the proposed legislation improve the capacity of the coroner to support donation. The proposed framework at 7.94 of the discussion paper may be limiting to individual instances of consent. In each coronial consent instance, the three step framework of forensic needs, benefit and wishes of the proposed donor and their family is reasonable.* *There is a need to enable consideration of this framework as part of strategic or tactical process changes the Coroner might be considering. It could prevent or better inform decisions that impact cohorts of potential future donors.* *The legislation should consider the relationship between Proposal 36 and the Coroner's consent for donation activity to proceed.*
PROPOSAL 30 New human tissue legislation should provide that it is lawful to conduct a post-mortem examination on the body of a deceased person if the deceased person's authorised decision-maker has given valid consent to it. In determining whether to consent on behalf of a deceased person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, about the treatment of their body after death. **Question 25** Should new human tissue legislation allow for an individual to provide their own consent while alive to a post-mortem examination? **Question 26** Should new human tissue legislation contain an exception to the need for an authorised decision-maker to provide valid consent to a post-mortem examination; for example, if the authorised decision-maker cannot be located?	*The intent of this proposal as described in 7.100 and 7.101 of the discussion paper is supported as it encourages informed decision making. With removal of the designated officer role consideration must be given to how this proposal might be implemented including:* • *where an individual might record their consent or objection to a post-mortem;* • *who will check for the record of consent or objection and facilitate the informed decision making of the authorised-decision maker.* *In context of the intent of this proposal, the current powers of the Coroner and the time-lines for post-mortems to be conducted it is not clear why there would ever be a need to proceed with a voluntary post-mortem in the absence of the authorised decision-maker.*
PROPOSAL 31 New human tissue legislation should provide that tissue removed during a post-mortem examination cannot be used for any purpose other than the post-mortem examination unless valid consent under Proposals 23 or 36 has been given to use the tissue for another purpose. **Question 27** Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?	*PlusLife has no comment on this proposal.*
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;	*It is not clear why this is proposed separately from Proposal 14, 23 and 39.*

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.	*PlusLife supports this proposal and cautions that it has implications for:* *1. Secondary sale of tissue and movement of tissue internationally;* *2. Economic loss for the research collection entity or tissue bank; and* *3. All tissue that is collected primarily for transplantation but is subsequently unusable for transplantation but has been validly consented for research, training and other scientific purposes.* *Pluslife requests that the language around discarding tissue be changed to 'disposed of appropriately'.*
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 and the National Statement on Ethical Conduct in Human Research (the National Statement). 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.	*PlusLife supports this proposal.*
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?	*PlusLife has no comment regarding this proposal.*
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; a. given at a time when the person consenting has decision-making capacity; b. given after the person consenting has been informed about the nature and effect of the removal of the tissue;	*PlusLife supports the intent of this proposal and makes the following comments for consideration.* *It is not clear who will facilitate the valid consent. Refer to previous commentary in response to Proposal 23.* *It is not clear whether practitioners involved in retrieving research tissue will be subject to Proposal 29.* *It is not clear where retrieval of tissue for research might occur and how that can interact with consent for tissue donation for transplantation.*

c. 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. d. 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: 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.	*PlusLife has no additional comment relating to this proposal.*
Proposal 38 New human tissue legislation should provide that an adult may give valid consent to donate their body after their death to a school of anatomy or other licensed facility for medical, educational or scientific purposes. The requirements for valid consent should mirror the requirements set out in Proposal 23 regarding deceased donation of tissue. Consent and authorisation for research on the recently deceased	*PlusLife has no comment relating to this proposal.*
PROPOSAL 39 New human tissue legislation should provide that an adult may give valid consent to the use of their body after death for research outside a school of anatomy or other licensed facility if the research: a. adheres to the Australian Code for Responsible Conduct of Research and the National Statement, where applicable; and b. has received approval by a human research ethics committee formed in accordance with the requirements of the National Statement. The requirements for valid consent should mirror the requirements set out in Proposal 23 regarding deceased donation of tissue. 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? **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? **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?	*It is unclear why this proposal is presented separately from Proposal 14, 23, 32 and 34.* *In response to the questions 29 to 34.* • *The introduction of new legislation and regulations should strive for consistency in support of the Australia's international and national obligations for ethical practice around donated human tissue.* • *Where tissue has been donated with valid consent, individuals have a right of access to information regarding the tissue. Individuals should also have right of access to the tissue that supports the purpose of the initial donation. Access rights should not extend so far as to impede on the original purpose of the donation and the compliance obligations for management of the tissue in storage imposed by the Therapeutic Goods Orders.*

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.

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)?

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.

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.

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?

PlusLife has considered the discussion in chapter 11 and believes the Proposals 40 to 44 will not be adequate to resolve the underlying issues discussed in Chapter 11.

As previously advised existing legislation has varying forms of prohibition on trade in tissue and cost recovery guidance and this does not prevent the presence of for-profit operators in the sector and perversion of the market demand for implantable human tissue towards economic rather than clinical drivers.

Questions relating to the option of paying plasma donors and exempting transactions or classes of tissue need a context of what is sustainable.

- *Should Australia be a net exporter or self-sustaining?*
- *If Australia cannot be self-sustaining what is a reasonable level of importation and how can the donation system be designed to achieve the desired level?*

This should include establishment of a position supported by data on how Australia will position the systems of tissue donation to support its international obligations for ethical practice with human tissue.

Exporting of human tissue is desirable into countries with developing health systems and tissue implantation demand, to enable clinicians and the population access to high quality tissue. As demand grows so to do local donation systems to support that demand. There is a tipping point where continued importation of tissue is harmful to growth of the donation system within a country. There is also a point where the economics of importation from larger populations, larger economies of scale with different donation system incentives driven by commercial rather than clinical imperatives, will seek profit maximisation through importation over the establishment and sustainment of local donation models.

Australia cannot compete with the economies of scale that can be achieved internationally within larger donating populations. Better regulation for compliance with the prohibition on trade in tissue and cost recovery guidance is required to meet our international obligations and current legislated directives.

What should we be regulating towards? A sustainable donation system and/or a sustainable implantation system. Where is the balance?

How should we ensure that Australians are afforded the opportunity to donate?

PlusLife makes the following comments in relation to the Chapter 11 discussion.

- *The PWC Report was prepared and released in draft in 2009. In 2016 it was released without significant change as a Final Report. It is a dated analysis of the sector.*

- *At 11.80 – States that 9000 allografts were imported over a 3-year period. Importation has risen to between 13,000 to 23,000 units per annum (refer to the table below). Note this data does not include tissue implanted in out of hospital settings.*

Activity	Data Source	Comments	Volume*
Tissue Donated in Australia (Donations)	Reported monthly to ANZETDATA	Donation activity well captured.	3000 to 3500 donations per annum
Australian sourced eye and tissue allograft implanted (Public Hospital)	Reported monthly to ANZETDATA	ANZETDATA does not separate public private hospital activity within its reporting total volume approximately 13000	13000 allografts per annum

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?

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.

		per annum split across public and private hospitals.	
Australian sourced eye and tissue allograft implanted (Private Hospital)	Reported monthly to ANZETDATA Reported retrospectively through Prosthesis Health Claims (PHC) through benefits claimed on the PHI List Part B	ANZETDATA does not separate public private hospital activity within its reporting total volume approximately 13000 per annum split across public and private hospitals. PHC data does not separate benefits claimed for Australian versus internationally sourced human tissue. Total reported approximately 26000 allografts per annum.	13000 allografts per annum 26000 allografts claims per annum
Internationally sourced eye and tissue allograft implanted (Private Hospital)	Reported retrospectively to DoHA through Private Health Cover (PHC) activity through benefits claimed on the PHI List Part B	Current reporting does not separate benefits claimed for Australian versus internationally sourced human tissue. The difference is approximately 13,000 allografts per annum.	13000 allografts per annum
Internationally sourced eye & tissue allograft implanted (Public Hospital)	Not reported. May be available at individual bank/importer level	Estimated up to 10000 to 15000 units of allograft per annum. PHI benefit is not claimed therefore no national reporting on implantation volume. No aggregation of data for implantation volume at allograft, donor, recipient level or jurisdiction level.	Unknown

**Note all table data are approximate annual figures.*

- *11.7 - PlusLife agrees that there is a need for ethically appropriate forms of tissue exchange. To maintain legal, ethical and international obligations these exchanges must remain as reasonable cost of service recovery only. Guidance, regulation and mandatory reporting would be welcomed in support of these obligations.*

- *11.19 to 11.24 - A definition of tissue bank is required. It is currently possible to import human tissue that is either processed as a final implantable product or unprocessed in which case it does not meet any proposed classes of exempted material in Proposal 42 until it has been manufactured into a registered product. It is therefore possible to establish a for-profit holding company to take profit at any point in the donation importation manufacturing process prior to the tissue becoming a finished product. It is also possible under the proposals to establish and operate a donation service that supplies donated tissue at cost-of-service provision to a commercial entity for downstream processing activity and profit. PlusLife believes this would not support the objects of the legislation. PlusLife requests that the prohibitions on trade should apply to upstream transactions occurring from donation to receipt at a tissue bank for processing unless the entities are recognised as exempt tissue banking entities that are operating on a cost recovery basis.*

- *11.13 to 11.17 - A decision on what is a sustainable level of donation and implantation activity is required this will assist in guiding exemptions that may be granted, such as paid plasma donation or AKX donations. PlusLife agrees that there is from time to time a need for exemptions and suggests that the ability to grant exemptions in Proposal 43*

	should be extended to a capacity to grant, monitor and revoke exemptions. Additional considerations that the National Regulator might need to be influenced by should include: *a. the public interest in permitting the exchange;* *b. the nature or form of the material that is the subject of the exchange and the extent of the nexus to human tissue;* *c. the source of the human tissue; and* *d. the risk of exploitation, coercion, or the commodification of human tissue. and* *e. the clinical need for the tissue exchange;* *f. the maturity of Australian donation and tissue banking services for the proposed tissue exchange to be exempted;* *g. the length of time of the proposed exemption;* *h. the model of supply proposed, is it pull (driven by clinical demand) or push (seeking to drive clinical demand);* *i. any conditions that may need to be applied to the exemption; and* *j. any accompanying proposals towards improving Australian tissue banking in order to remove the need for the exemption in the future.* • *Plasma is used as an example for paid donation, and it is unclear whether this is for out-of-pocket costs or commercial reward for the act of donating. PlusLife highlights that an agreed payment scheme for out-of-pocket costs to surgeons, patients, hospitals for femoral heads removed during total hip replacement surgery has the potential to increase donation 3-fold. This would translate to a 250% increase in available high quality musculoskeletal processed allograft. At this level Australia could be self-sufficient. The decision to import rather than invest in Australian donation systems is an economic and commercial one driven only partially by structural constraints within Australian legislation.* • *The existing cost recovery occurring at implantation funding model is very constraining. PlusLife as a not for profit is mission driven to support Australian donation systems. This capacity to support Australians to donate would be greatly improved by allowing for alternate models of tissue exchange funding.* • *11.27 - PlusLife is in agreement that there is a need for greater legal and ethical safeguards and supports valid consent including informing the donor;* o *whether the donated tissue will be used to generate profit* o *whether the donated tissue will be sent to another country* • *11.28 - It is no longer a true statement to say 'the PHI lists sets prices in public and private hospitals for payment of tissue provided by tissue banks'. Tissue providers must charge the PHI List price in private settings. For profit operators charge a range of prices for tissue supplied into public hospitals and do so to capture new business both with bundled sales of part A prosthesis and sales mix of high profit allograft weights alongside discounted allograft weights.* • *11.29 – This remains a true statement largely driven by capacity and lack of mechanisms to monitor and enforce compliance with the requirement not to profit from human tissue exchanges. These legislative parameters already exist however there is trading of tissue for profit.*
PROPOSAL 45 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).	*PlusLife supports this proposal.*

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?	
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 valid 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)? **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. **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?	*PlusLife is supportive of a mechanism for prohibition as proposed in part a to ensure compliance with our international obligations and current legislated mandates on ethical practices with human tissue.* *In response to question 41 PlusLife restates previous commentary.* *A decision on what is a sustainable level of donation and implantation activity is required. This will assist in guiding exemptions that may be granted, such as paid plasma donation or AKX donations.* *PlusLife agrees that there is from time to time a need for exemptions and suggests that the ability to grant exemptions in Proposal 43 should be extended to a capacity to grant, monitor and revoke exemptions. Additional considerations that the National Regulator might need to be influenced by should include:* *a. the public interest in permitting the exchange;* *b. the nature or form of the material that is the subject of the exchange and the extent of the nexus to human tissue;* *c. the source of the human tissue; and* *d. the risk of exploitation, coercion, or the commodification of human tissue. and* *e. the clinical need for the tissue exchange;* *f. the maturity of Australian donation and tissue banking services for the proposed tissue exchange to be exempted;* *g. the length of time of the proposed exemption;* *h. the model of supply proposed is it pull (driven by clinical demand) or push (seeking to drive clinical demand);* *i. any conditions that may need to be applied to the exemption; and* *j. any accompanying proposals towards improving Australian tissue banking in order to remove the need for the exemption.* *In response to questions 41 through 44 PlusLife submits the following. Two types of data are required:* • *Activity data - should include donation, implantation, processing, manufacturing, allocation, inventory and importing/exporting activity.* • *Financial data - should include a standard suite of revenue and operating costs sufficient to show costs of service provision against the supply of services revenues to validate that tissue exchanges are not occurring for the purpose of generating profit or generating demand for future profit.* *PlusLife is supportive of mandatory reporting, with powers of inspection.*
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.	*PlusLife supports this proposal.*
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	*PlusLife supports this proposal.*

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.	
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; c. or 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.	*PlusLife supports this proposal.*
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.	*Further consideration is needed for the recognition and authorisation of screening/consenting officers and care should be taken to capture all tissue screening activity in the construction of the clauses.* *As the Victorian legislation is framed, anyone in a named institution or service has the right to access information and this may need to be more tightly defined.*
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.	*The proposed laws are not substantially different from the existing laws. There is a gap in capacity to consistently regulate, monitor and enforce compliance. Laws establishing and enabling a National Authority with powers to regulate, monitor and enforce compliance is the obvious pathway.*
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?	*Areas that should be considered higher priority are:* • *Provision of clarity around use of pre- and post-mortem validly consented procedures and in particular access to normo-thermic perfusion for the donation after cardiac death pathway. This has the capacity to double the number of organs that can be successfully retrieved and transplanted from this cohort of donors (Year 1).* • *Establish guidance on sustainable management in use of human tissue (Year 1).* • *Regulate commercial activity in the tissue banking and importation sector (Year 1-2).* • *Establish mandatory reporting and national inventories for tissue similar to the model for blood (Year 1-2)*
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 establishment of an appropriate funding model for tissue donation and transplantation in Australia. Presently there is no consistent and adequate funding for many of the activities that occur in tissue donation and transplantation. This constrains growth of donation and transplant activity.*