

OFFICIAL



Justice Mordy Bromberg
President
Australian Law Reform Commission
PO Box 209
FLINDERS LANE VIC 8009

Cc: Dr Maeghan Toews
Commissioner, Review of Human Tissue Laws
Australian Law Reform Commission

Dear Justice Bromberg

Review of Human Tissue Laws

I am writing on behalf of the National Blood Authority (NBA) in response to the Australian Law Reform Commission (ALRC) Review of Human Tissue Laws Discussion Paper 90 (November 2025) (the Review).

The NBA acknowledges the significant work undertaken by the ALRC to date and would like to thank Dr Maeghan Toews and her team for their engagement with NBA officials and the Australian Red Cross Lifeblood (Lifeblood) staff on 19 January 2026.

The NBA recognises the importance of human tissue donation and strongly supports the harmonisation of existing state and territory human tissue laws to reduce fragmentation and legal uncertainty across jurisdictions.

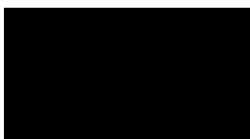
Our mission is to save and improve Australian lives and patient outcomes through a world-class, secure, and affordable supply of blood products, blood related products and services. In this regard, we urge the ALRC take this opportunity to formally recommend the harmonisation of statutory defences relating to blood collection across Australia.

This submission supplements the response provided by the Health Portfolio Reference Group to which the NBA participated as a member. The NBA's views are therefore represented across both submissions.

Attachment 1 is provided for your consideration. If you have any questions or would like to discuss any aspects further, please contact me on [REDACTED] or email at [REDACTED].

We look forward to our continued collaboration on this important initiative.

Yours sincerely



Sandra Cochrane
Acting Deputy Chief Executive, Fresh Blood Products and Business Systems

13 February 2026

Attachment A – Proposals and Questions - Submission from the National Blood Authority (NBA) 12 February 2026

Proposals and Questions	Comments from NBA
<p>National Legislative Framework</p> <p>Proposal 1</p> <p>Retrieval, storage, and use of human tissue in Australia for medical, educational or scientific purposes should be regulated either:</p> <ol style="list-style-type: none"> 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 	<p>The NBA would support a framework uniformly established under Commonwealth legislation to promote and facilitate national consistency.</p> <p>In relation to whether a single National Regulator should be established and responsible for setting codes of practice, guidelines and standards, and for enforcing compliance, the NBA notes that the TGA's existing responsibility for setting standards for the manufacture of blood products and blood related products should be considered in positioning the national regulatory roles.</p> <p>If there is a strong preference for the first option relating to a coordinated and harmonised set of state, territory, the Commonwealth legislation, then the NBA would still support the role of a National Regulator and the TGA.</p>
<p>Proposal 2</p> <p>The regulatory framework established by Proposal 1 should be structured so that:</p> <ol style="list-style-type: none"> 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, 	<p>The NBA agrees with this proposal.</p>
<p>National Regulator / National Body</p> <p>Proposal 3</p> <p>The Australian Government should establish a National Regulator by:</p>	<p>The NBA agrees that there should be a National Regulator that has the suggested powers and functions, however this will need to be considered considering existing regulatory controls of the TGA. Could the TGA powers and functions be extended to cater for the National Regulator roles?</p> <p>The NBA agrees that there is a need to avoid duplication of responsibility for areas that are already regulated; in establishing the National Regulator, regard</p>

Proposals and Questions	Comments from NBA
<p>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</p> <p>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</p> <p>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.</p> <p>The National Regulator could have the following powers and functions:</p> <ul style="list-style-type: none"> • 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. <p>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:</p> <ul style="list-style-type: none"> • Therapeutic Goods Administration; • National Blood Authority; • and the Organ and Tissue Authority. 	<p>should be had to the scope of other regulatory entities in Australia, such as the NBA, the OTA and the NHMRC.</p> <p>The NBA notes that its role extends to national contracting, supply management and associated functions specified in section 8 of the <i>National Blood Authority Act 2003</i> (Cth) (the NBA Act) and incorporated references to parts of the National Blood Agreement. The NBA's role includes supporting and coordinating decision making by all funding government on funding and policy matters, but the NBA does not administer specific statutory regulatory powers in this regard.</p>

Proposals and Questions	Comments from NBA
<p>The Human Tissue Regulator should be adequately funded to carry out its powers and functions.</p> <p>Implementing the National Legislative Framework</p> <p>Proposal 4</p> <p>To implement Proposals 1–3 through national uniform legislation. Achieved through intergovernmental agreement. Structures that could be implemented include:</p> <ol style="list-style-type: none"> Referred legislation. Applied legislation Mirror legislation hybrid (referred/applied or mirror legislation) 	<p>The NBA supports the proposal to implement a nationally consistent legislative framework to reduce legal variation and uncertainty across the jurisdictions. The method of achieving uniformity should be the subject of further consideration having regard to existing models applied across the regulation of therapeutic goods, gene technology and food.</p> <p>The NBA notes ongoing concerns about the lack of harmonisation between state and territory laws on statutory defence for blood collection, as discussed in chapter 15 of the Discussion Paper.</p>
<p>The objects of Human Tissue Laws</p> <p>Proposal 5</p> <p>New human tissue legislation should include an opening section explaining that the objects of the legislation are to:</p> <ol style="list-style-type: none"> 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 increase access to human tissue, and to the benefits of human tissue donation, transplantation and use ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia’s international human rights obligations promote equity and reduce inequities in access to human tissue and the benefits of human tissue use ensure respect for individual dignity and autonomy, and for the human body prevent the exploitation of individuals in relation to how their tissue is removed, and used for medical, educational and scientific purposes; and 	<p>The NBA considers that the proposed new objectives for the new human tissue legislation are consistent with and supportive of the objectives of Australian governments under the National Blood Arrangements (see below).</p> <p>The NBA notes that the purpose of the NBA Act (section 4) is “to establish the NBA as part of the coordinated national approach to policy setting, governance and management of the Australian blood sector as agreed in the National Blood Agreement”.</p> <p>The National Blood Agreement states the following primary and secondary policy objectives of governments:</p> <ol style="list-style-type: none"> The primary policy objectives for the Australian blood sector are: <ol style="list-style-type: none"> to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and

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<p>g. promote public trust in the laws and regulatory frameworks that govern human tissue donation and use for medical, educational or scientific purposes</p>	<p>(b) to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.</p> <p>2. In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:</p> <ul style="list-style-type: none"> (a) to meet international obligations and standards; (b) to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma; (c) to promote national self-sufficiency; (d) to provide products to patients free of charge and based on clinical need and appropriate clinical practice; (e) to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards; (f) to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sector; (g) to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector; (h) to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs; (i) to ensure public support and confidence in the Australian blood sector; and (j) to work towards optimal access to blood products and blood related products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians

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<p>Question 1 Do you agree with the objects listed in Proposal 5 for human tissue legislation?</p>	<p>determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines.</p>
<p>Question 2 Aside from the objects set out in Proposal 5, should new human tissue legislation include other objects?</p>	<p>As above</p>
<p>National Regulator to have regards to objects Proposal 6 In carrying out its functions, including in relation to the creation of guidelines and codes of practice, the National Regulator (or alternative) (Proposal 3) must have regard to the objects of the new human tissue legislation.</p>	<p>The NBA agrees with this proposal.</p>
<p>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?</p>	<p>The NBA agrees that the removal of barriers and promotion of equitable access are pertinent objectives in relation to blood products and blood related products. In this regard, the NBA highlights the need to progress previous recommendations to harmonise statutory defence laws for blood donation, as discussed further below.</p>
<p>Removing barriers Question 4 If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (Question 3), what are the specific barriers that new human tissue legislation needs to address? In considering this question, please ignore:</p>	<p>As above</p>

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<ul style="list-style-type: none"> • definitions of senior next of kin that may be outdated and unsuitable (we address these in Proposal 25); and • disclosure of information provisions that in some jurisdictions prevent the families of deceased donors talking about their family member's experience (we address these in Proposals 46 and 48). 	
<p>Definition of human 'tissue'</p> <p>Proposal 7</p> <p>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.</p>	<p>In so far as the proposed definitions in the new human tissue legislation are expected to relate to blood and blood products within the scope of the national blood arrangements, the NBA provides the following comments:</p> <ul style="list-style-type: none"> • definitions should be broad enough to cover the collection of whole blood or any differentiated blood components including red cells, platelets, and blood plasma; • it should be clear whether blood or its component parts are included or excluded within relevant definitions • the new human tissue legislation definitions relating to blood or blood components should be framed considering relevant comparable definitions within TGA regulatory instruments. <p>The proposed new definitions should expressly include a reference to blood plasma, noting that this is not included in the UK definitions.</p>
<p>Question 5</p> <p>How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?</p> <p>In your response, you might consider the following options:</p> <ol style="list-style-type: none"> tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the Tissue Act 2004 (UK)); or 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)). 	<p>As above</p>

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<p>Question 6</p> <p>In new human tissue legislation, should the word 'tissue' be replaced with another label? In your response, you might consider alternative options such as:</p> <ol style="list-style-type: none"> 'substance of human origin'; 'human material'; or 'cell, organ, and tissue' 	<p>As above</p>
<p>Adjusting the scope of the definition</p> <p>Proposal 8</p> <p>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.</p>	<p>The NBA agrees with this proposal.</p>
<p>Guidelines to support the definition</p> <p>Proposal 9</p> <p>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).</p>	<p>The NBA agrees with this proposal.</p>
<p>Exclusions from the definition</p> <p>Question 7</p> <p>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?</p> <ul style="list-style-type: none"> Human milk. Foetal tissue. Faecal tissue. 	<p>The NBA supports the inclusion of the materials listed here as part of the definition of tissue and in the human tissue laws.</p> <p>National uniform definitions for blood and blood products, donor and blood donations, exempt suppliers, suppliers, tests and diseases need to be addressed in either the new human tissue laws or by the National Regulator.</p>

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<ul style="list-style-type: none"> • Gametes (from deceased donors). • Cell lines. <p>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?</p> <ul style="list-style-type: none"> • 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). 	
<p>New statutory provisions for determining death</p> <p>Proposal 10</p> <p>Statutory provisions for determining death should contain the following:</p> <p>Section X <i>When death occurs</i></p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 iv. accepted medical practice in end-of-life care. v. accepted medical practice in end-of-life care. 	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>2. In this section</p> <p><i>A cessation of the critical functions of a person's brain</i> requires the complete absence of any form of consciousness (wakefulness and awareness) and brainstem functions, including the ability to breathe independently.</p> <p><i>Section Y Determination of death</i></p> <ol style="list-style-type: none"> 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. 4. 	
<p>New statutory location for the determination of death provisions</p> <p>Proposal 11</p> <p>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.</p>	<p>Not Applicable</p>
<p>Consequences of a determination of death provision that applies for all purposes</p>	<p>Not Applicable</p>

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<p>Question 8</p> <p>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?</p> <p><i>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.</i></p>	
<p>Maintaining national consistency</p> <p>Question 9</p> <p>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?</p> <ol style="list-style-type: none"> A 'Uniform Death Act', adopted as national uniform legislation in each state and territory; or New human tissue legislation (Proposal 1); or 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. 	<p>Not Applicable</p>
<p>Post-mortem interventions</p> <p>Proposal 12</p> <p>The following provision should be included in new human tissue legislation:</p> <p>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.</p>	<p>Not Applicable</p>

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<p>For the purpose of determining accepted medical practice, regulations can specify professional standards or guidelines to be complied with.</p> <p>The Dead Donor Rule</p> <p>Proposal 13</p> <p>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:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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. 	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>Consent and authorisation for removal of tissue from living persons</p> <p>Proposal 14</p> <p>New human tissue legislation should provide:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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. 	<p>Lifeblood uses a National Donor Questionnaire for consent and signature by the donors as required under the HITAs.</p> <ol style="list-style-type: none"> 1. The Donor Questionnaire is a national screening tool and legal requirement administered by Lifeblood, which is the sole contracted service provider to collect fresh blood products on behalf of all governments of Australia. 2. Changes to the Donor Questionnaire, which is a national questionnaire, requires separate regulatory approval in each State and Territory. This is not a consistent process - in some jurisdictions, the relevant legislation is a HTA, however in others differing pieces of legislation, such as those governing notifiable diseases, are activated. In some jurisdictions, no legislative change is required, only notification by Lifeblood of the change to the jurisdiction. 3. The types of significant changes that might be made to the Donor Questionnaire, such as a change to a deferral for donors, are also in many cases subject to other regulatory processes such as approval by the Therapeutic Goods Administration and set by a National Regulator. <p>It would be valuable from the NBA's perspective for the new human tissue law to prescribe national requirements for the donor questionnaire, consistent with the relevant therapeutic goods orders.</p>
<p>Additional safeguards</p> <p>Question 10</p> <p>Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?</p>	<p>Uniform national donor declaration for the following areas:</p> <ul style="list-style-type: none"> • the diseases covered under the HITAs • the approval processes for tests • approval of the methods of screening blood donors • special requirements for emergency transfusion (emergency donor panels)

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<p>Definition of 'adult' and 'child'</p> <p>Proposal 15</p> <p>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.</p>	<ul style="list-style-type: none"> human tissue laws under the Defence regime. <p>The NBA notes that any such proposal would need to be nationally consistent.</p>
<p>Donation of blood</p> <p>Proposal 16</p> <p>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.</p>	<p>The NBA notes that any such proposal would need to be nationally consistent. Currently blood donors are 18 years or older. This would need to be considered against Lifeblood's own position on whether it considers this appropriate, and TGA's position (including potentially any consideration of necessary evidence to support a regulatory change).</p>
<p>Donation of tissue by children</p> <p>Proposal 17</p> <p>New human tissue legislation should:</p> <ul style="list-style-type: none"> 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 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. 	<p>Not Applicable</p>
<p>Proposal 18</p> <p>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.</p>	<p>Not Applicable</p>

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<p>Proposal 19</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>Additionally:</p> <ul style="list-style-type: none"> • 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. 	<p>Not Applicable</p>
<p>Question 11</p> <p>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?</p>	<p>Not Applicable</p>
<p>Question 12</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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?</p>	
<p>Donation of tissue by adults who do not have decision-making capacity</p> <p>Proposal 20</p> <p>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</p>	<p>Not Applicable</p>
<p>Proposal 21</p> <p>The Committee (Proposal 20) should have the power to authorise donation if it is in the proposed donor's best interests.</p>	<p>Not Applicable</p>
<p>Proposal 22</p> <p>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:</p> <ul style="list-style-type: none"> • 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; 	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<ul style="list-style-type: none"> the support available for the proposed donor after the removal of their tissue; and the availability of an alternative donor. <p>Additionally, if the proposed donor has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.</p>	
<p>Question 13</p> <p>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?</p>	Not Applicable
<p>Question 14</p> <p>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?</p> <p>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.</p>	Not Applicable
<p>Composition of committee</p> <p>Question 15</p> <p>What is an appropriate composition for a Committee under Proposals 17 and 20?</p> <p>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.</p>	Not Applicable
<p>Consent and authorisation for removal of tissue after death</p> <p>Proposal 23</p> <ul style="list-style-type: none"> New human tissue legislation should provide that: 	Not Applicable

Proposals and Questions	Comments from NBA
<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> a. 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. b. 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. • 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. • Valid consent is: <ul style="list-style-type: none"> 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. • Valid consent is sufficient legal authority for the removal of the specified tissue and for the specified uses. • 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. 	

Proposals and Questions	Comments from NBA
<p>Question 16</p> <p>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?</p> <ul style="list-style-type: none"> If you agree that Designated Officers are no longer necessary, please explain why. <p>If you think the Designated Officer role remains necessary, please explain why.</p>	<p>Not Applicable</p>
<p>Question 17</p> <p>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?</p>	<p>Not Applicable</p>
<p>Question 18</p> <p>Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required?</p> <p>For example, Victoria's legislation allows a person to give consent to donation:</p> <ul style="list-style-type: none"> in writing at any time before their death; or during their last illness, orally in the presence of two witnesses. 	<p>Not Applicable</p>
<p>Proposal 24</p> <p>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.</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>Authorised decision-maker</p> <p>Proposal 25</p> <p>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).</p>	<p>Not Applicable</p>
<p>Question 19</p> <p>How should the hierarchy of decision-makers in Proposal 25 be tailored to the deceased tissue donation context?</p>	<p>Not Applicable</p>
<p>Question 20</p> <p>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?</p>	
<p>Pre-mortem interventions</p> <p>Proposal 26</p> <p>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.</p>	<p>Not Applicable</p>
<p>Question 21</p> <p>Is the definition in Proposal 26 an appropriate definition for pre-mortem interventions? Why or why not?</p>	<p>Not Applicable</p>
<p>Proposal 27</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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).</p> <p>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.</p>	
<p>Question 22</p> <p>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?</p>	<p>Not Applicable</p>
<p>Question 23</p> <p>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?</p>	<p>Not Applicable</p>
<p>Respectful and dignified treatment of deceased body</p> <p>Proposal 28</p> <p>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.</p>	<p>Not Applicable</p>
<p>Proposal 29</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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.</p> <p>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.</p>	
<p>Coronial consent to donation</p> <p>Question 24</p> <p>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?</p>	<p>Not Applicable</p>
<p>Authorisation for non-coronial</p> <p>Proposal 30</p> <p>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.</p> <p>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.</p>	<p>Not Applicable</p>
<p>Question 25</p> <p>Should new human tissue legislation allow for an individual to provide their own consent while alive to a post-mortem examination?</p>	<p>Not Applicable</p>
<p>Question 26</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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?</p>	
<p>Use of tissue removed during a post-mortem examination</p> <p>Proposal 31</p> <p>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.</p>	<p>Not Applicable</p>
<p>Question 27</p> <p>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?</p>	<p>Not Applicable</p>
<p>Consent and authorisation for tissue removal for research – living persons</p> <p>Proposal 32</p> <p>New human tissue legislation should provide that:</p> <ol style="list-style-type: none"> 1. An adult may give valid consent to the removal of tissue from their body for the purpose of research; 2. Valid consent is: <ol style="list-style-type: none"> a. given voluntarily; b. given at a time when the adult who is consenting has decision-making capacity; c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal; d. given after the adult who is consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and 	<p>The NBA supports this proposal.</p> <p>It should be noted that the NBA permits, under contracts with its suppliers, the use of blood and blood products for non-therapeutic research purposes.</p>



Proposals and Questions	Comments from NBA
<p>e. able to be withdrawn in accordance with Proposal 33 or at any time before the removal of the tissue.</p> <p>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.</p>	
<p>Proposal 33</p> <p>New human tissue legislation should provide that:</p> <ol style="list-style-type: none">1. when consent is provided under Proposal 32 in circumstances where all the specific research uses for the tissue are not yet known:<ol style="list-style-type: none">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:<ol style="list-style-type: none">i. the tissue remains usable; andii. 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.	<p>The NBA supports this proposal. Refer Proposal 32.</p>
<p>Proposal 34</p> <p>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).</p> <p>If there are any inconsistencies between new human tissue legislation and the Australian Code for the Responsible Conduct of Research or the National</p>	<p>The NBA supports this proposal. Refer Proposal 32.</p>

Proposals and Questions	Comments from NBA
Statement on Ethical Conduct in Human Research, the terms of the legislation should prevail.	
<p>Proposal 35</p> <p>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 <i>Human Tissue Act 1985</i> (Tas).</p>	Not Applicable
<p>Question 28</p> <p>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?</p>	Not Applicable
<p>Consent and authorisation to remove tissue for research after death</p> <p>Proposal 36</p> <p>New human tissue legislation should provide that:</p> <ol style="list-style-type: none"> 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: 	Not Applicable

Proposals and Questions	Comments from NBA
<p>a. given voluntarily;</p> <p>b. given at a time when the person consenting has decision-making capacity;</p> <p>c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;</p> <p>d. given after the person consenting has been informed about the intended research use(s) of the tissue, insofar as the intended research use(s) are known at the time consent is provided; and</p> <p>e. able to be withdrawn in accordance with Proposal 37 or at any time before the removal of the tissue.</p> <p>f. sufficient legal authority for the removal of the specified tissue for the intended research use(s); and for other research use(s) in accordance with Proposal 37.</p> <p>Proposal 37</p> <p>New human tissue legislation should provide that:</p> <p>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:</p> <p>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;</p> <p>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:</p> <p>i. the tissue remains usable; and</p> <p>ii. the sample is identifiable or, if it has been deidentified, is re-identifiable.</p> <p>2. If consent for future research uses is withdrawn, any unused tissue must be discarded.</p> <p>Consent and authorisation for body donation after death</p> <p>Proposal 38</p>	<p>Not Applicable</p>
<p>Consent and authorisation for body donation after death</p> <p>Proposal 38</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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.</p> <p>The requirements for valid consent should mirror the requirements set out in Proposal 23 regarding deceased donation of tissue.</p>	
<p>Consent and authorisation for research on the recently deceased</p> <p>Proposal 39</p> <p>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:</p> <ol style="list-style-type: none"> adheres to the Australian Code for Responsible Conduct of Research and the National Statement, where applicable; and has received approval by a human research ethics committee formed in accordance with the requirements of the National Statement. <p>The requirements for valid consent should mirror the requirements set out in Proposal 23 regarding deceased donation of tissue.</p>	<p>Not Applicable</p>
<p>Consent and authorisation for use of tissue samples</p> <p>Question 29</p> <p>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</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>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.</p>	
<p>Question 30 If a legal requirement for consent is imposed (Question 29), should there be exceptions to it? If so, what exceptions should exist?</p>	<p>Not Applicable</p>
<p>Regulating stored tissue collections Question 31 Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?</p>	<p>The NBA supports this proposal. Refer Proposal 32.</p>
<p>Question 32 Would it be beneficial to have national regulation, guidance and oversight for:</p> <ul style="list-style-type: none"> a. research biobanks that store and/or distribute human tissue or human bodies; or b. educational collections of human tissue? 	<p>The NBA supports this proposal. Refer Proposal 32.</p>
<p>Question 33 If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:</p> <ul style="list-style-type: none"> 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? 	<p>The NBA supports this proposal. Refer Proposal 32.</p>
<p>Accessing stored tissue Question 34</p>	<p>The NBA supports this proposal. Autologous or directed donations can be provided by Lifeblood.</p>

Proposals and Questions	Comments from NBA
<p>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?</p>	
<p>Prohibiting the exchange of human tissue for reward within Australia</p> <p>Proposal 40</p> <p>New human tissue legislation should prohibit the offering, giving or receiving in Australia of any reward in exchange for human tissue.</p> <p>A reward in relation to the supply of human tissue means:</p> <ol style="list-style-type: none"> any financial payment; or the provision of any valuable property, good, service or advantage; <p>It should not include:</p> <ol style="list-style-type: none"> the reimbursement of any expense or cost; or 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. 	<p>The NBA supports the proposal subject to the exceptions and exemptions outlined in Proposals 42 and 43 below.</p> <p>The NBA notes that the current policy position of Australian governments (as expressed in the National Blood Agreement as a secondary policy objective) is to maintain reliance on voluntary and non-remunerated donations of blood and plasma, and to promote national self sufficiency.</p>
<p>Giving extra-territorial effect to the prohibition</p> <p>Question 35</p> <p>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 <i>Criminal Code Act 1995</i> (Cth)?</p>	<p>Under the national blood arrangements by-products from manufacturing blood or plasma may be excess to Australian needs and there is currently no mechanism to use this precious resource internationally.</p> <p>The NBA suggests that there may need to be flexibility of this policy position changes over time.</p>
<p>Agreement to be void (have no force)</p> <p>Proposal 41</p> <p>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</p>	<p>As above</p>

Proposals and Questions	Comments from NBA
<p>knowing it contravenes, or being reckless about whether it contravenes, the prohibition in Proposal 40.</p>	
<p>Exceptions to the prohibition on the exchange of human tissue for reward</p> <p>Proposal 42</p> <p>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:</p> <ol style="list-style-type: none"> a biological or medical device included in the register under the Therapeutic Goods Act 1989 (Cth); a registered good under the Therapeutic Goods Act 1989 (Cth); human tissue obtained under the 'Special Access Scheme' administered by the TGA; or 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. 	<p>The NBA supports the proposal.</p> <p>However, NBA would suggest that the fourth exception is amended to reflect the following:</p> <ul style="list-style-type: none"> a blood product under the National Blood Authority Act 2003 (Cth) that is listed in the national products price list and traded by the Commonwealth or an entity nominated by the Commonwealth.
<p>Question 36</p> <p>Are the exceptions to the prohibition of the exchange of human tissue for reward listed in Proposal 42 appropriate?</p> <ol style="list-style-type: none"> Should new human tissue legislation include additional exceptions? Should new human tissue legislation include an exception to enable paid plasma donation? 	<p>Refer to Proposal 40.</p>
<p>Proposal 43</p> <p>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.</p>	<p>The NBA agrees that the 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.</p>

Proposals and Questions	Comments from NBA
<p>For example, the National Regulator (or alternative) could be empowered to grant exemptions. These exemptions would supplement the exceptions in Proposal 42.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>The NBA notes that:</p> <ul style="list-style-type: none"> • Lifeblood currently operates within the constraints of the provisions regulating contracting for, or trading in, human tissue, under HTAs in most states and territories. • Lifeblood proposals to expand gifts and rewards programs are currently under consideration by states and territories (with reference to current HTA constraints) through the NBA as part of the donor attraction and retention program. • The potential supply and self-sufficiency benefit of increasing reliance on any form of reward is not robustly established by evidence. <p>The proposal to harmonise legislation (nationally consistent) and the establishment of a National Regulator with the power to grant exemptions would provide sufficient flexibility.</p>
<p>Question 37</p> <p>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?</p> <p>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?</p>	<p>As above</p>
<p>Guidance on cost recovery</p> <p>Proposal 44</p> <p>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.</p>	<p>The NBA agrees that the National Regulator should provide guidance on cost recovery rules.</p>

Proposals and Questions	Comments from NBA
<p>Prohibiting advertising</p> <p>Proposal 45</p> <p>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).</p>	<p>Not Applicable</p>
<p>Question 38</p> <p>Is there a need for a prohibition on advertising that is broader than the prohibition in Proposal 45?</p>	<p>As above</p>
<p>Question 39</p> <p>If a prohibition on advertising is imposed in accordance with Proposal 45, should this prohibition have extra-territorial effect?</p>	<p>Not Applicable</p>
<p>Question 40</p> <p>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:</p> <ol style="list-style-type: none"> 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 A reporting mechanism similar to that contained in the <i>Modern Slavery Act 2018</i> (Cth)? 	<p>Lifeblood imports rare blood groups from the International Blood Exchange program. This is very immaterial but can occur given the differing ethnicity of patients.</p> <p>The NBA contracts for the supply of several imported fractionated plasma products from global suppliers. The NBA is aware also that CSL Behring manufactures certain products in Australia made from imported plasma, for commercial supply overseas and (depending on procurement outcomes) potentially for supply to the NBA in Australia.</p>
<p>Question 41</p> <p>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</p>	<p>As above. Exemptions may be appropriate for importations within the scope of the national blood arrangements.</p>

Proposals and Questions	Comments from NBA
<p>tissue from the prohibition or reporting requirements, and if so, what factors should be considered as a basis for justifying an exemption?</p> <p>For example, relevant factors could include but not be limited to:</p> <ul style="list-style-type: none"> • 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. 	
<p>Improving access to data</p> <p>Question 42</p> <p>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?</p>	<p>Not Applicable</p>
<p>Question 43</p> <p>In relation to Question 42, how should the data be reported? For example, should there be:</p> <ol style="list-style-type: none"> a. voluntary reporting? b. mandatory reporting? 	
<p>Question 44</p> <p>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?</p>	
<p>Prohibiting non-consensual public disclosures of a tissue donor's or tissue recipient's personal information</p>	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>Proposal 46</p> <p>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.</p> <p>'Personal information' is information that identifies an individual, or that makes an individual reasonably identifiable.</p>	
<p>Permission for health practitioners to disclose a tissue donor's personal information in limited circumstances</p> <p>Proposal 47</p> <p>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:</p> <ul style="list-style-type: none"> a. the information is clinically relevant to the potential tissue recipient's decision about whether to accept tissue for transplant; and <p>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.</p>	<p>Not Applicable</p>
<p>Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information</p> <p>Proposal 48</p> <p>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:</p> <ul style="list-style-type: none"> a. the human tissue donor or the human tissue recipient themselves; or 	<p>Not Applicable</p>

Proposals and Questions	Comments from NBA
<p>b. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is deceased; or</p> <p>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.</p>	
<p>Allowing certain people to access and share information for identification and screening purposes</p> <p>Proposal 49</p> <p>New human tissue legislation should use sections 45(4)-(6) of the <i>Human Tissue Act 1982</i> (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.</p>	<p>Not Applicable</p>
<p>Compliance mechanisms</p> <p>Question 45</p> <p>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?</p> <p><i>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.</i></p>	<p>Compliance can be self assessed and should be done through the National Regulator</p>
<p>The timeframe for implementing our reform proposals</p> <p>Question 46</p>	<p>Timeline should be dictated by implementing the best solution that meets the needs of the relevant stakeholders.</p>

Proposals and Questions	Comments from NBA
<p>Do you have views on the timeframe/s within which the reforms set out in this <i>Discussion Paper</i> should be implemented, or on how the implementation of these reforms could be staged or prioritised?</p>	
<p>Are other reforms urgent?</p> <p>Question 47</p> <p>Is there an urgent need for reform of human tissue laws that we have not addressed in this <i>Discussion Paper</i>?</p>	<p>Refer to the below for further information.</p>
<p>Extract from the Discussion Paper</p> <p>15 Reforms we are unlikely to propose</p> <p>Statutory defences in relation to blood collection</p> <p>15.11 Before donating blood or plasma, potential donors are required to complete a donor questionnaire and declaration. This is designed to assess their eligibility to donate, including the risk of their donation transmitting infections through the blood supply. As blood donation is coordinated nationally through Australian Red Cross Lifeblood, the same questionnaire is used throughout Australia. The questionnaire and declaration are updated regularly to reflect changing risk factors to the blood supply. Any proposed changes are reviewed by the TGA to assess the risk and impact that changes might have on Australia's blood supply.⁸ Changes to the donor questionnaire must also be approved by the relevant authorities in each of the states and territories.</p> <p>15.12 In all states and territories except Queensland, there are statutory provisions that provide service providers in the blood sector with a defence to legal actions if blood recipients contract specific infections from the blood supply.⁹ Donor questionnaires and declarations are an important element of these statutory defences. The purpose of the statutory defence provisions is to reduce the risk of blood service providers being exposed to civil</p>	<ol style="list-style-type: none"> 1. All jurisdictions, except for Queensland incorporate some form of statutory defence provisions (as widely scoped in the discussion paper). The provisions generally include reference to prescribed donor declaration forms, offences for donors not completing declarations truthfully, and statutory exemptions from civil liability for Lifeblood if the prescribed declaration form is used. 2. Queensland has provided a non-statutory letter of indemnity to Lifeblood but does not have statutory requirements for a particular donor declaration form. 3. Relevant therapeutic goods orders inform the content and use of the donor declaration form but have no role in providing any element of exemption from liability for Lifeblood. 4. There have been several previous pieces of work undertaken to examine inconsistencies between jurisdictions and the inherent delay and complication in being able to update the donor declaration form. Despite this, work to harmonise the position has not proceeded. 5. Most recently, a recommendation was made to all governments that statutory defence aspects of HTA laws should be repealed, but this

Proposals and Questions	Comments from NBA
<p>litigation relating to the transmission of blood borne diseases where the provider has complied with prescribed donor screening and testing.</p> <p>15.13 Originally introduced in the context of the HIV/AIDS epidemic to address difficulties with insurance and risk management for supplier organisations, the statutory defence provisions also provide clarity for potential litigants regarding when a claim can be made.¹⁰ One requirement of the defence is that the service provider responsible for collecting infected blood must have ensured the donor of the infected blood completed the questionnaire and declaration. Different state and territory Acts define and identify the relevant questionnaire differently. For example: y y in Victoria, it must be in an approved form that is published in the Victorian Government Gazette;¹¹ in the Australian Capital Territory, it takes the form of a 'disallowable instrument', which must be notified and presented to the Australian Capital Territory Legislative Assembly;¹² and in the Northern Territory, it must be approved by the Chief Health Officer and then posted on the Department of Health's website.¹³</p> <p>15.14 There are also differences between jurisdictions related to the types of infections that are covered by the defence, who the defence applies to, and the conditions that must exist for the defence to apply.</p> <p>Problems with current statutory defences</p> <p>15.15 People with knowledge of the sector have told us that the different procedures in the states and territories for approving the blood donor questionnaire can cause delays when the questionnaire is updated.</p> <p>15.16 More broadly, jurisdictional differences between statutory defences for infections acquired through donated blood are in tension with the national coordination of blood collection. The differences create inequalities. Depending on where people live, their rights to receive compensation for transmission of blood borne diseases may be limited by comparison with people in other jurisdictions.</p>	<p>recommendation was referred to individual jurisdictions for action and has not proceeded.</p> <p>Given the above, the NBA views the current coordinated ALRC review as an important and timely opportunity to reiterate and reinforce past recommendations for harmonisation of statutory defence elements of HTA laws (including the introduction and passage of such laws in Queensland)).</p> <p>All blood and blood products manufactured in Australia are covered by robust regulatory requirements of the Therapeutic Goods Administration (TGA). Blood and Blood Products are subject to the highest standards and regulation applicable to therapeutic goods.</p> <p>The NBA suggests that the National Donor Questionnaire requirements are specified in the new human tissue legislation and the form is approved for use by the National Regulator.</p>

Proposals and Questions	Comments from NBA
<p>15.17 Given that blood donation occurs through a national program where donated blood in one jurisdiction might end up being transfused to a patient in another jurisdiction, it may make sense to have a uniform approach to statutory defences for the blood sector.</p> <p>15.18 In 2001, as part of a broader review of the Australian blood supply sector, a report to the Commonwealth Minister for Health and Aged Care called for uniform statutory defence laws ‘as a matter of urgency’.¹⁴</p> <p>15.19 In 2003, a report prepared for the Australian Health Ministers Advisory Committee provided recommendations on what the statutory defence should contain and the need for it to be uniform across Australia. In 2013, an independent review commissioned by the National Blood Authority comprehensively examined the statutory defence laws, making recommendations for legislative models to achieve harmonisation, and endorsing many recommendations from the 2003 report regarding the substance of what the defence should contain.¹⁵</p> <p>Why we are not considering statutory defences</p> <p>15.20 Our focus is on strengthening and harmonising the legislative framework for human tissue donation, transplantation, and use, using the current HTAs as a starting point. Other than in New South Wales, the issue of liability for transmissible infections in the blood supply is dealt with either in dedicated legislation, or as part of broader public health legislation, rather than in human tissue legislation. As such, issues of blood safety or civil liability for actionable wrongs in the supply of blood are not directly raised by our Terms of Reference.</p> <p>15.21 To the extent that these issues are indirectly raised by our Terms of Reference, we do not consider them a central focus of this Inquiry. The problems with the statutory defence laws are longstanding, and previous reports and inquiries have already documented the key issues (including delays in approving donor questionnaires, and disparities across jurisdictions). In light of the wide range of complex matters we are</p>	

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addressing, and given the significant body of work that has already examined the issue of inconsistent statutory defences, we do not propose to consider or recommend additional reforms in this area.	