

# Department of Health



Tasmanian  
Government

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Dr Maeghan Toews  
Commissioner, Review of Human Tissue Laws  
Australian Law Reform Commission  
Via email: [humantissue@alrc.gov.au](mailto:humantissue@alrc.gov.au)

Dear Dr Toews

**Subject: Australian Law Reform Commission - Review of Human Tissue Laws**

Thank you for the opportunity to provide feedback on Discussion Paper 90 of November 2025 regarding human tissue laws in Australia. The Tasmanian Department of Health welcomes the opportunity to improve access to human tissue, clarify complexities in legislation, remove inefficient regulatory burden, and ensure that persons are afforded respect and autonomy in their decisions.

I enclose the Department's submission on the proposals.

Yours sincerely



Sally Badcock  
Secretary

20 February 2026

Enclosed: Tasmanian Department of Health response to the review of human tissue laws in Australia

Proposal Number	Comment
<b>1 and 2 – The legislative model</b>	<p>The Tasmanian Department of Health (“the Department”) supports an approach that achieves a flexible, clear, and concise framework while maintaining ethical and clinical best practice. This would ideally be achieved through model legislation that can be enacted by individual jurisdictions, with the assistance of guidelines and other instruments to inform its operation.</p> <ul style="list-style-type: none"> <li>• The Department supports proposal 1.a – substantial consistency across states and territories through a coordinated and harmonised set of state, territory, and Commonwealth legislation.</li> <li>• The Department partially supports proposal 2 – the substance is dealt with in legislation and any necessary detail is dealt with by codes of practice, guidelines or standards. The Department notes that model delegated legislation is not strongly supported due to the administrative inflexibility.</li> </ul>
<b>3 – National Regulator</b>	<p>The Department supports Proposal 3 in principle.</p> <p>A National Regulator would contribute to a flexible regulatory landscape where guidelines can be updated to maintain best practice and research. A system that requires sustained legislative amendment and subordinate legislation can become a burden and potentially leave gaps in regulation and compliance in this space. Option 3.a (expanding the powers and functions of the Organ and Tissue Authority by amending the <i>Australian Organ and Tissue Donation and Transplantation Authority Act 2008</i> (Cth)) is supported as the most appropriately scaled entity for the development of clinical guidelines.</p> <p>As part of its in-principle support, the Department welcomes further information on the National Regulator’s funding model and whether licensing requirements would apply to state providers.</p>
<b>5-6 – Objects of framework</b>	<p>There is utility in incorporating legislative objects to assist in the interpretation of human tissue laws, especially to ensure that the legislation maintains human autonomy, respect, and dignity as paramount concerns. These objects should be sufficiently broad to allow jurisdictions the flexibility to deal with emerging issues, and to incorporate guidelines or regulations that are consistent with those objects. The Department supports the proposed objects.</p> <p>No issues of equity have been identified.</p>

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<b>7 – Definition of human tissue</b>	<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>On Question 6, neither “substance of human origin” nor “human material” are considered to be of sufficient clarity to be supported, as on their plain meanings could include inorganic manufactured items.</p>
<b>8 – Adjustments to definition of human tissue</b>	<p>The Department supports the ability for the definition of tissue to be adjusted where necessary through subordinate and delegated legislation, or guidelines.</p>
<b>9 – Guidelines to support definition of human tissue</b>	<p><b>Question 7 – Exclusions from definition of human tissue</b></p> <p><b>Gametes</b></p> <p>Excluding posthumous gamete extraction from the framework would have the effect of deregulating this process, and accordingly, is not supported at this time. This issue should be put to a wide public audience for consultation given the intrinsic ethical issues it raises and the need to hear the lived experience of persons born through assisted reproductive technology (ART).</p> <p>The extraction of gametes from deceased donors carries significant ethical and legal considerations, that are best dealt with by courts of the relevant jurisdiction (when required) and legislation specific to assisted reproductive technology.</p> <p><b>Human milk</b></p> <p>From a public health perspective, the Department supports using human tissue legislation to restrict trade in human derived milk. This is the current approach under the <i>Human Tissue Act 1985</i> (Tas) (‘Tasmanian HTA’) whereby human milk is only permitted to be traded for valuable consideration under certain circumstances, including where:</p> <ul style="list-style-type: none"> <li>- The sale or supply is made for use, in accordance with the direction of a medical practitioner for therapeutic or scientific purposes, or</li> <li>- In special circumstances the sale or supply is approved by the relevant Minister.</li> </ul>

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	<p>This approach maintains and enables donation and supply of human derived milk and milk products (such as colostrum) for important therapeutic purposes, but limits donated human milk supplies from being diverted to other general commercial purposes (such as body building supplements, or production of alleged ‘superfoods’ etc).</p> <p>The <i>Food Act 2003</i> (Tas), which adopts the Australian and New Zealand Food Standards Code, regulates food safety and suitability relevant to food for sale. However, as there are no human milk standards, the Tasmanian Food Act cannot regulate human milk. Therefore, if human milk is omitted from the operation of human tissue legislation, the Department would be unable to regulate the trade of human milk and ensure its availability for vulnerable babies.</p>
<b>10 – Provisions for determining death</b>	<p>The Department agrees with a national approach to the determination of death and no issues were identified with the associated definitions contained within the proposal.</p>
<b>11 – Statutory location for determining death provisions</b>	<p>A nationally consistent legal standard for determining death in model legislation is supported.</p> <p>The Department does not believe a national agreement is required in addition to national adoption of uniform provisions on determining death.</p> <p><b>Question 8 – What are the consequences of a national determination of death provision?</b></p> <p>A consistent and clear approach to determining death would be beneficial for clinical staff and medical practitioners in complex scenarios involving individuals who may satisfy the criteria for death but require a healthcare decision maker (such as family and loved ones) to permit cessation of life supporting measures. Having a clear and consistent approach gives certainty to medical practitioners and clinical staff to have respectful discussions about when a patient may satisfy the definition of death and the issue of tissue donation.</p> <p>The definition should also ensure that it is sensitive to the diversity of Australian views while being practical in hospital settings.</p> <p><b>Question 9 – Maintaining national consistency</b></p>

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	<p>The Department supports continuing to contain the definition of death within model human tissue legislation.</p> <p>To reduce administrative and regulatory burden, the Department does not support a standalone Uniform Death Act model legislation approach.</p>
<b>Proposals 12-15</b>	No issues identified.
<b>16 – Donation of blood by a child aged 16 or over</b>	The Department agrees with the proposal as it would bring blood donation into closer alignment with accepted medical practice regarding <i>Gillick</i> competency.
<b>17-19 – Committee to determine donation of tissue by children</b>	<p>While the Department supports clarifications to the framework regulating donation of tissue by children, the proposal to “<i>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</i>” may be problematic for two reasons:</p> <ol style="list-style-type: none"> <li>1. The phrase “a child with decision-making capacity” adds a qualifying test that the decision-making body would find difficult to determine in advance of the application. It is suggested that the wording more plainly represent a child making their own application; and</li> <li>2. The Department does not support the establishment of another decision-making Committee. The relevant body for such decisions in Tasmania should be the Tasmanian Civil and Administrative Tribunal.</li> </ol> <p>Question 12 – the Department submits there <u>are</u> situations where the removal of tissue from a child should not require approval by an oversight body, and any new human tissue legislation should require only parental consent, or individual consent where a child has decision-making capacity. An example is for the removal of blood, where a child has decision-making capacity in relation to minimal impact compatibility testing. Further, a mature minor with decision-making capacity should be supported in their choices where medical practitioners are satisfied that those choices have been made freely and with understanding of the consequences.</p>

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<p><b>20-22 – Role of Committee where an adult does not have decision-making capacity</b></p>	<p>The Department supports the intent of these proposals in principle, noting that all members of the community should have access, as far as possible, to full participation in the community – including in relation to altruistic donation. The Department’s support is subject to the Department not supporting a new Committee (as noted above) and suggesting that the relevant decision-maker should be the Tasmanian Civil and Administrative Tribunal.</p> <p>Further, the Department notes that proposal 22 lacks detail regarding any safeguards that limit its operation to supporting the views, wishes and interests of the adult who lacks decision-making capacity, such as those contained in section 9 of the <i>Guardianship and Administration Act 1995 (Tas)</i>.</p> <p>Situations where an adult who lacks capacity should not need the authorisation of an oversight body are any that are already provided for by jurisdictional laws.</p>
<p><b>23 – Consent and authorisation for removal of tissue after death</b></p>	<p>The Department supports proposal 23, outlining the consent and authorisation for removal of tissue after death.</p> <p>The Department notes that the designating of officers is not an administrative policy that is adding value. It is difficult for the Designated Officer to discharge the obligations to make the inquiries required under the Tasmanian HTA. The Department accepts that the role of Designated Officers appears diminished in any case, with the functions primarily undertaken by a patient’s care team, or DonateLife with the assistance of the individual, or, if they are deceased, their family. Furthermore, health practitioners are overseen by Ahpra, which also acts as a mechanism for complaints or conduct issues where regulated health professionals do not act in the best interests of their patients.</p> <p>Potential donors who fall within the category of reportable deaths should continue to have the independent oversight of the coroner with forensic pathologists assisting. This would ensure that forensic pathological evidence is not affected by any potential donation of human tissue (see question 24).</p> <p><b>Question 17 – Does proposal 23 strike the balance between individual rights and unforeseen circumstances?</b></p> <p>The proposed objects emphasise a need to ensure the wishes of a potential donor are respected. This should be the primary consideration in determining whether donation can occur. It should be a matter of policy to ensure that families and loved ones of individuals who have consented to donation are supported and informed. Tasmania’s legislation</p>

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	<p>currently allows individuals to state their intentions in relation to donation while they have the capacity to do so, with consent consistent with the Tasmanian HTA removing the need to refer to family or friends. However, this does not prevent DonateLife from working with a donor's loved ones in these circumstances.</p> <p><b>Question 18 – What form should consent to deceased donation take?</b></p> <p>The Department supports the Victorian approach as described, and suggests that witnesses to an oral consent should be independent and not part of an organisation responsible for or involved with human tissue donation.</p>
<b>24 – National Regulator protocols</b>	<p>The Department supports the making of nationally consistent protocols by the National Regulator.</p>
<b>25 – Authorised decision maker</b>	<p>The Department supports contemporising the definition of substitute decision maker or next of kin. In practice, family units/relationships can be complex, and traditional definitions may not always capture these appropriately.</p> <p>Consideration should be given to jurisdictions' varying definitions of relationships, and what that means for human tissue donation and HTAs.</p> <p><b>Question 20 – Hierarchy of authorised decision makers</b></p> <p>This is a complex issue and could be resolved with legislative hierarchies on next-of-kin in the event that decision makers in the same category are unable to agree on whether to consent to human tissue donation. However, recognising the evolution of diverse family units and relationships in Australia, the incorporation of guidelines to allow regulatory flexibility is desirable.</p>
<b>26-27 – Pre-mortem interventions</b>	<p>The Department has not identified any issues with the proposed definition of pre-mortem interventions.</p> <p><b>Question 22 – Minor procedures and consent</b></p> <p>No. Consent should be obtained from authorised decision makers, exhausting the hierarchy in the event consent is unable to be obtained from the potential donor. In the event that there is no authorised decision maker (and if</p>

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	<p>absolutely necessary), the process of obtained consent should be through the Public Guardian, where the person's wishes can be considered.</p> <p><b>Question 23 – Additional safeguards for pre-mortem inventions</b></p> <p>Good practice would be to ensure and document that the potential donor understands what a pre-mortem intervention involves, and is able to comprehend its risks and benefits and why it may be necessary.</p>
<p><b>28-29 – Respectful and dignified treatment of deceased body</b></p>	<p>The Department supports the new legislation providing 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>The Department supports the proposal ensuring that only appropriately trained, skilled and qualified practitioners should remove certain types of tissue in accordance with the new framework, to ensure the dignity of the donor.</p>
<p><b>30 – Authorisation for non-coronial post-mortem examination</b></p>	<p>The Department supports new human tissue legislation providing 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><b>Question 25 – Allowing individuals to consent to post-mortem examinations</b></p> <p>Yes, individuals with capacity should be able to consent to this.</p> <p><b>Question 26 – Exceptions to consent for post-mortem examinations</b></p> <p>No, an exception to the consent rule inherently conflicts with the stated objects as proposed by the Review. It is exemptions like this that led to the unlawful retention of human tissue, public inquiries, and ultimately the repeal of the <i>Human Tissue Act 1961</i> (UK) and the implementation of the <i>Human Tissue Act 2004</i> (UK).</p>

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<p><b>31 – Use of tissue removed during a post-mortem examination</b></p>	<p>The Department supports the proposal that 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 has been given to use the tissue for another purpose.</p> <p><b>Question 27 – Exceptions to consent for removal of small samples of human tissue</b></p> <p>No. Exceptions to the consent requirement for removing or retaining tissue does not align with the objects of the Review or the <i>NHMRC National Statement on Human Research</i>.</p> <p><b>Question 29 – Legal requirement to obtain consent for the use of human tissue in research</b></p> <p>Yes, there must be a legal requirement to seek consent for the use of human tissue. To use human tissue for research in a way that a participant/donor has not consented to does not align with the objects proposed or the <i>NHMRC National Statement on Human Research</i>.</p> <p><b>Question 30 – Exceptions to the legal requirement to obtain consent for the use of human tissue in research</b></p> <p>No, there should not be an exception to the requirement to obtain consent or substitute consent.</p>
<p><b>32-34 – Removal of tissue from living donors</b></p>	<p>No issues identified.</p>
<p><b>35 – Model provision of removal of human tissue from children for research</b></p>	<p>The Department supports the new human tissue legislation allowing tissue to be removed from children for use in research using a provision modelled on section 22B of the <i>Human Tissue Act 1985 (Tas)</i>.</p> <p><b>Question 28 – Tissue removal for research from adults without capacity</b></p> <p>The Department supports the intent of a framework that permits tissue to be removed from adults without decision-making capacity for use in research if the consent is obtained in accordance with consent legislation and the provision otherwise follows the <i>NHMRC National Statement on Human Research</i>. Tasmania already has these provisions in the</p>

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	<i>Guardianship and Administration Act 1995 (Tas)</i> , to allow adults who lack decision-making capacity to access clinical trials.
<b>36 – Consent and authorisation to remove tissue for research after death</b>	The Department is supportive of this proposal. Research should still be subject to the <i>NHMRC National Statement on Human Research</i> .
<b>37 – Consent and research use</b>	The Department is supportive of this proposal. However, it should be noted that if gametes are included in the definition of tissue in HTAs, consideration should be given as to whether deidentification should be possible in the event an individual born through ART wishes to know the identity of the gamete donor. Currently, in jurisdictions without legislation, the <i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i> apply. This area should be subject to further, targeted, public consultation to capture lived experience perspectives.
<b>38 – Consent and authorisation for body donation after death</b>	No issues identified.
<b>39 – Consent and authorisation for research on the recently deceased</b>	<p><b>Question 33 – Is it beneficial to have national regulation of stored tissue collections</b></p> <p>Yes, especially regarding commercialisation of human tissue through research and data. Where robust regulation regarding the use, storage, and sharing of human tissue exists, this assists in preventing human tissue from being used for purposes not contemplated by a donor. For example, a donor provides human tissue for research but does not understand that the research may be commercialised.</p>

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<b>40-41, 43-44 – Prohibiting the exchange of human tissue for reward and similar regulation</b>	No issues identified.
<b>42 – Exceptions to the prohibition on the exchange of human tissue for reward</b>	<p>The Department supports the proposal to prohibit the exchange of human tissue for reward, other than in the case of human tissue:</p> <ul style="list-style-type: none"> <li>• donated to or obtained by a tissue bank or</li> <li>• lawfully traded for a medical, educational, or scientific purpose otherwise authorised under the HTA.</li> </ul> <p>However, it would be ethically prudent that the legislative mechanism ensures the origin of the tissue is known at all points of exchange.</p> <p><b>Question 36 – Is proposal 42 appropriate?</b></p> <p>B. Should it include additional exceptions? No, it should not include additional exceptions to the exchange of human tissue.</p> <p>C. Should it include an exception for paid plasma donation? No, jurisdictions should operate within the bounds of the donation schemes.</p>
<b>45 – Prohibiting advertising</b>	<p>The Department is supportive of a proposal to prohibit the public dissemination of information that invites, promotes, or seeks to induce a person to engage in a prohibited exchange of human tissue.</p> <p><b>Question 39 – Extra-territorial effect on the prohibition of advertising</b></p> <p>Yes, it should have extra-territorial effect for the purposes of human rights law.</p>

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	<p><b>Question 40 – Mechanisms to help ensure imported tissue is ethically sourced</b></p> <p>Yes, the Department is supportive of a framework that ensures imported tissue is ethically sourced.</p>
<p><b>46 – Prohibiting non-consensual public disclosures of a tissue donor’s or tissue recipient’s personal information</b></p>	<p>Tasmania has already amended its framework to address and allow for disclosure of personal information/public identification by families, including for the purposes of publicly sharing stories/media, community-based events to support raising awareness of donation in the community.</p>
<p><b>47-49 – Information sharing</b></p>	<p>No issues identified.</p>
<p><b>45 – Compliance</b></p>	<p>Generally, compliance operations in Tasmania for the health sector are undertaken by Ahpra (registered professions) or the Health Complaints Commissioner (unregistered professions).</p> <p>Collection/removal of donated material is likely to fall within the scope of the <i>Health Complaints Act 1995</i>. It is noted that under this legislation, <i>health service</i> includes “a service provided at a hospital or health institution for the temporary storage of human remains as defined in the <i>Burial and Cremation Act 2002</i>” (Schedule 1). For clarity and consistency, there may be value in adding the HTA to this definition as well.</p> <p>The Department also notes that the Health Complaints Act framework:</p> <ul style="list-style-type: none"> <li>• is a negative regulation model, relying on post-incident intervention, which may be too late for some breaches; and</li> </ul>

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	<ul style="list-style-type: none"> <li data-bbox="488 225 2085 304">• focuses on “significant issues of public safety or public interest” or “significant questions as to the practice of a health service provider”, which may not cover the breadth of potential breaches.</li> </ul> <p data-bbox="434 336 2123 560">Tasmania does not have an area dedicated to prosecutorial support for violations under the Human Tissue Act and, without offending behaviour that would amount to criminal sanctions, Tasmania Police are unlikely to be involved with complex medical issues. Significant offending would be referred to the Director of Public Prosecutions, who would have the discretion of whether to devote resources to bringing the matter to court. Unless support is provided via the National Regulator, Tasmania will continue to rely on those limited and disparate resources.</p>
<b>46 – Implementation</b>	<p data-bbox="434 595 2096 719">As noted above, there are several issues that should be considered for further targeted consultation with persons with lived experience. Tasmania has recently made minor amendments to its HTA to allow donor families to consent to the public disclosure of a donor’s information.</p>