# Review of Human Tissue Laws
# Proposals and Questions in the Discussion Paper

This document extracts the 49 proposals and 47 questions contained in the Review of Human Tissue Laws Discussion Paper released by the Australian Law Reform Commission ('ALRC').

Anyone is welcome to use this document when preparing a submission.It is not necessary to respond to all of the proposals or questions — you can answer as many or as few as you wish.

**National legislative framework**

**Proposal 1**

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

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

b. uniformly by Commonwealth legislation.

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

**Proposal 2**

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

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

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

**National Regulator**

**Proposal 3**

The Australian Government should establish a National Regulator by:

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

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

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

The National Regulator could have the following powers and functions:

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

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

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

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

**Implementing a national legislative framework**

**Proposal 4**

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

a. referred legislation;

b. applied legislation;

c. mirror legislation; or

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

**The objects of human tissue laws**

**Proposal 5**

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

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

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

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

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

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

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

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

**Question 1**

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

**Question 2**

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

**National Regulator to have regard to the objects**

**Proposal 6**

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

**Promoting equity**

**Question 3**

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

**Removing barriers**

**Question 4**

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

*In considering this question, please ignore:*

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

**Definition of human 'tissue'**

**Proposal 7**

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

**Question 5**

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

In your response, you might consider the following options:

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

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

**Question 6**

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

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

a. 'substance of human origin';

b. 'human material'; or

c. 'cell, organ, and tissue'.

**Adjusting the scope of the definition**

**Proposal 8**

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

**Guidelines to support the definition**

**Proposal 9**

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

**Exclusions from the definition**

**Question 7**

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

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

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

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

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

**New statutory provisions for determining death**

**Proposal 10**

Statutory provisions for determining death should contain the following:

**Section X** *When death occurs*

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

2. In this section-

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

**Section Y** *Determination of death*

1. A determination that a person has died under **section X** must be made according to accepted medical practice.
2. Regulations may identify professional standards or guidelines for the purpose of determining accepted medical practices under **(1).**
3. To determine the death of a person where the person's respiration is being maintained by artificial means, two registered medical practitioners, one of whom is a specialist and both of whom have been registered medical practitioners for a period of at least five years, must each confirm in writing that they have carried out a clinical examination of the person and, in their opinion, the person has suffered a permanent cessation of the critical functions of the person's brain, within the meaning of **section X**.

**New statutory location for the determination of death provisions**

**Proposal 11**

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

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

**Question 8**

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

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

**Maintaining national consistency**

**Question 9**

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

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

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

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

**Post-mortem interventions**

**Proposal 12**

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

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

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

**The Dead Donor Rule**

**Proposal 13**

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

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

**Consent and authorisation for removal of tissue from living persons**

**Proposal 14**

New human tissue legislation should provide:

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

**Additional safeguards**

**Question 10**

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

**Definition of 'adult' and 'child'**

**Proposal 15**

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

**Donation of blood**

**Proposal 16**

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

**Donation of tissue by children**

**Proposal 17**

New human tissue legislation should:

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

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

**Proposal 18**

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

**Proposal 19**

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

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

Additionally:

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

**Question 11**

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

**Question 12**

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

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

**Proposal 20**

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

**Proposal 21**

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

**Proposal 22**

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

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

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

**Question 13**

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

**Question 14**

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

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

**Composition of committee**

**Question 15**

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

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

**Consent and authorisation for removal of tissue after death**

**Proposal 23**

1. New human tissue legislation should provide that:
2. 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.
    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.
3. If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for transplantation or for other medical, educational or scientific purposes.
4. Valid consent is:
    a. given voluntarily;
    b. given at a time when the person consenting has decision-making capacity;
    c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;
    d. given after the person consenting has been informed about the intended use of the tissue; and
    e. able to be revoked at any time before the removal of the tissue.
5. Valid consent is sufficient legal authority for the removal of the specified tissue and for the specified uses.
6. 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.

**Question 16**

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

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

**Question 17**

Does **Proposal 23** strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach?

**Question 18**

Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required?

For example, Victoria's legislation allows a person to give consent to donation:

- in writing at any time before their death; or
- during their last illness, orally in the presence of two witnesses.

**Proposal 24**

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

**Authorised decision-maker**

**Proposal 25**

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

**Question 19**

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

**Question 20**

How should new human tissue legislation address situations where authorised decision-makers with equal decision-making status in the hierarchy in **Proposal 25** disagree about whether to consent to donation?

**Pre-mortem interventions**

**Proposal 26**

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

**Question 21**

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

**Proposal 27**

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

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

**Question 22**

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

**Question 23**

Should new human tissue legislation have any additional safeguards for the use of pre-mortem interventions beyond the need for valid consent? If so, what safeguards should it have?

**Respectful and dignified treatment of deceased body**

**Proposal 28**

New human tissue legislation should provide that, when removing tissue from a deceased body, any person involved in the removal must treat the body with the highest level of respect and dignity that is practicable in the circumstances.

**Proposal 29**

New human tissue legislation should provide a mechanism enabling medical practitioners and authorised technicians to remove certain types of tissue from deceased bodies, including musculoskeletal, cardiovascular, eye and skin tissue.

The National Regulator (or alternative) should by delegated legislation specify the relevant qualifications required for technicians, and any additional type of tissue that technicians are authorised to remove.

**Coronial consent to donation**

**Question 24**

Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?

**Authorisation for non-coronial post-mortem examination**

**Proposal 30**

New human tissue legislation should provide that it is lawful to conduct a post-mortem examination on the body of a deceased person if the deceased person's authorised decision-maker has given valid consent to it.

In determining whether to consent on behalf of a deceased person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, about the treatment of their body after death.

**Question 25**

Should new human tissue legislation allow for an individual to provide their own consent while alive to a post-mortem examination?

**Question 26**

Should new human tissue legislation contain an exception to the need for an authorised decision-maker to provide valid consent to a post-mortem examination; for example, if the authorised decision-maker cannot be located?

**Use of tissue removed during a post-mortem examination**

**Proposal 31**

New human tissue legislation should provide that tissue removed during a post-mortem examination cannot be used for any purpose other than the post-mortem examination unless valid consent under **Proposals 23** or **36** has been given to use the tissue for another purpose.

**Question 27**

Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?

**Consent and authorisation for tissue removal for research – living persons**

**Proposal 32**

New human tissue legislation should provide that:

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

**Proposal 33**

**New human tissue legislation should provide that:**

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

**Proposal 34**

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

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

**Proposal 35**

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

**Question 28**

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

1 National Health and Medical Research Council, Australian Research Council and Universities Australia, *Australian Code for Responsible Conduct of Research* (2018).

2 National Health and Medical Research Council, Australian Research Council and Universities Australia, *The National Statement on Ethical Conduct in Human Research* (2025).

**Consent and authorisation to remove tissue for research after death**

**Proposal 36**

New human tissue legislation should provide that:

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

**Proposal 37**

New human tissue legislation should provide that:

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

**Consent and authorisation for body donation after death**

**Proposal 38**

New human tissue legislation should provide that an adult may give valid consent to donate their body after their death to a school of anatomy or other licensed facility for medical, educational or scientific purposes.

The requirements for valid consent should mirror the requirements set out in **Proposal 23** regarding deceased donation of tissue.

**Consent and authorisation for research on the recently deceased**

**Proposal 39**

New human tissue legislation should provide that an adult may give valid consent to the use of their body after death for research outside a school of anatomy or other licensed facility if the research:

a. adheres to the Australian Code for Responsible Conduct of Research and the National Statement, where applicable; and
b. has received approval by a human research ethics committee formed in accordance with the requirements of the National Statement.

The requirements for valid consent should mirror the requirements set out in **Proposal 23** regarding deceased donation of tissue.

**Consent and authorisation for use of tissue samples**

**Question 29**

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

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

**Question 30**

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

**Regulating stored tissue collections**

**Question 31**

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

**Question 32**

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

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

b. educational collections of human tissue?

**Question 33**

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

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

b. what types of collections should be regulated?

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

**Accessing stored tissue**

**Question 34**

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

**Prohibiting the exchange of human tissue for reward within Australia**

**Proposal 40**

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

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

a. any financial payment; or

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

It should not include:

a. the reimbursement of any expense or cost; or

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

**Giving extra-territorial effect to the prohibition**

**Question 35**

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

**Agreement to be void (have no force)**

**Proposal 41**

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

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

**Proposal 42**

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

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

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

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

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

**Question 36**

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

b. Should new human tissue legislation include additional exceptions?

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

**Proposal 43**

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

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

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

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

**Question 37**

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

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

**Guidance on cost recovery**

**Proposal 44**

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

**Prohibiting advertising**

**Proposal 45**

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

**Question 38**

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

**Question 39**

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

**Question 40**

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

If so, should the mechanism be:

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

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

**Question 41**

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

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

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

**Improving access to data**

**Question 42**

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

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

**Question 43**

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

For example, should there be:

a. voluntary reporting?

b. mandatory reporting?

**Question 44**

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

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

**Proposal 46**

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

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

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

**Proposal 47**

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

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

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

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

**Proposal 48**

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

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

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

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

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

**Proposal 49**

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

**Compliance mechanisms**

**Question 45**

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

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

**The timeframe for implementing our reform proposals**

**Question 46**

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

**Are other reforms urgent?**

**Question 47**

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