Response from the BMDI Cord Blood Bank to Australian Law Reform Commission, Review of Human Tissue Laws: Discussion Paper (2025).

Responses (shown in black text) are to selected questions relevant to public cord blood banking (clinical biobanking) and research.

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.*

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.*

We believe that a new national regulatory body would allow clarity and consistency for both the public and the medical/research sectors. This body could perhaps include existing bodies such as the Organ and Tissue Authority, the National Health and Research Council (NHMRC). Other bodies may need to be included as departments or as different branches to reduce fragmentation and overlap of existing regulations and could include the Therapeutic Goods Administration (TGA) and Office of the Gene Technology Regulator (OGTR).

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?*

Yes, we believe that this is an area that needs consistency at a national level and that the Objects of the legislation for HTA as per Proposal 5 above need to be made more publicly available. The Proposal outlined above and provided in the Discussion paper is clear and consideration should be given to more public access to these Objects of Human Tissue Laws than in the documentation alone. Including the objects of new human tissue legislation in an opening section clearly identifies and signals the importance of these objects and provides an accessible guide to interpreting the legislation. This may contribute to greater public trust in how human tissue is used, and in the organ and tissue donation and transplantation system, leading to greater access for clinical and research purposes and an increase in people willing to donate their tissue without fear of exploitation.

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?*

We suggest that the definition of tissue in **regulatory** terms should include materials that include cells, tissue organoids and organs from a human source. A possible definition could include whether DNA / genetic material is included in the tissue definition (whether as cells or cell products such as exomes) and a functional component i.e. does this material derive from functional tissue in a human body?

Question 6: *In new human tissue legislation, should the word 'tissue' be replaced with another label?*

The term "Material of Human origin" has been a suggestion and would fit a broader definition, but the terms "tissue" and "tissue components" are more recognisable terms for the public, donors, and medical professionals. If the intentions of the bill include greater public understanding and engagement then this may need to be considered. Material of human origin may be too broad.

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.*

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).*

We believe that guidance and clarity about the process of the definition and scope of what is a human tissue is as important as understanding the reasons for the guidelines themselves; the ability to adjust the scope will ensure consistency with the objects of the new human tissue legislation. A consistent definition is needed across all the governing bodies that could potentially be included under the umbrella of a National Regulator, such as the NHMRC and Organ & Tissue Authority. Such guidelines could also clarify whether some human tissues/materials or classes of material are better regulated by another area of law for ethical or social reasons.

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?*

i *Human milk.*
ii *Foetal tissue.*
iii *Faecal tissue.*
iv *Gametes (from deceased donors).*
v ***Cell lines.***

Derivative materials like cell lines and organoids should be included in the definition of tissue. The term “tissue” (or whatever term is finally agreed upon) should be used to include solid organs and cells, including blood and cord blood. All the above materials contain at least some part of DNA/cell content which could be considered a marker in the broader definition discussed. Whether cells lines should be excluded from human tissue laws may need to be defined by circumstance. While the need to protect from exploitation exists, the inclusion of cell lines as human tissue may need to take into account the amount of cellular manipulation, how far they are from the source tissue and the purpose of the lines; are they for non-human research, clinical application or production of secreted materials? It would be helpful to clearly state in the new Regulations what does or does not meet the remit of being classified as human tissue. For example, exosomes, although the cells from which they are derived are classified as tissue. This could be in a similar format to that used for the OGTR regulations that define what are or are not genetically modified organisms (GMOs), or the TGA Biological regulations that describe what does and does not fall into the different Biological Class categories.

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?

Proposal 14: *New human tissue legislation should provide:*
1. That an adult may give valid consent to the removal of tissue from their body for the purpose of transplantation into the body of another person, or for other medical, educational, or scientific purposes.

2. Valid consent is:
***a**. given voluntarily.*
***b**. given at a time when the adult who is consenting has decision-making capacity.*
***c**. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal.*
***d**. given after the adult who is consenting has been informed about the intended use of the tissue after it has been removed; and*
***e**. able to be withdrawn at any time before the removal of the tissue.*

3. Valid consent is sufficient legal authority for the removal and use of the specified tissue for the specified purpose(s).

4. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in Proposal 32 must be met.

Question 10: *Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?*

We feel that consideration of the data (personal and genetic information) related to the samples or their clinical usage should be considered. This is relevant to the use of cord blood or other tissues for banking and donation for transplantation. Currently in the cord blood banking/research sector these requirements are addressed by an international body, the Foundation for the Accreditation of Cellular Therapy (FACT) Standards and NHMRC but would significantly benefit through being coded nationally through a National Regulator. New data privacy concerns and transparency requirements need also to be considered, to ensure National and International understanding and consistency.

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, as far 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.

We wish to raise the possibility of retroactive change of consent to broad unspecified consent for banked samples if the donor cannot be reached? We do not suggest adding permissions for research or the potential of commercial use to materials where the donor has specifically refused/rejected these options. We are however wondering if the definition of research that has already been consented to can be expanded upon, by extending permissions that already exist to cover previously unthought-of research in the areas that the tissue was donated/collected for? i.e. If you have a sample donated for one type of cancer research, but a different cancer type/condition /clinical trial that the sample is suited for is proposed at a later date, possibly years later, is that in the spirit of the donor's original consent? This is a concern relevant to many types of cell and tissue bank collections.

In terms of consent, at the Cord Blood Bank we have found that adding a sentence into the Donor Consent and Information Sheet stating that any research using the samples in the future would be approved by a nationally registered HREC gives the donors increased confidence and understanding on how the samples are treated as well as increased transparency. This may be an additional ethical guideline to consider.

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.

We agree with this statement, and it should be considered in conjunction with Question 42.

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

These caveats are appropriate and currently in use in our Bank. However, these caveats can only be applicable to samples or tissues that are the original donation, not cell lines or possibly organoids that have been derived from the consented material, especially if the work has progressed or cell lines shared significantly over time. The right to withdraw consent should only be allowable until the donated tissue is used, which in collections such as cell and tissue banks may be an extended period; the BMDI Cord Blood Bank has cord blood units that have been in clinical cryostorage for more than 29 years. There may be a need for considered time limits in long term existing tissue depositories to moderate the ability to honour these principles.

10. Reforms relating to stored tissue collections: Access to stored tissue collections for purposes that differ from the original purpose of the tissue collection.

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?*

We believe legislation is warranted to mandate consent from people who provide tissue samples before their tissue is used for research or other purposes but that the scope of the research or other purpose should not be legally binding. Reconsent of donors for a different use of their tissue to that which they have consented to may not be possible or realistic. Factors such as the length of time since original consent was obtained are important, especially in long running or legacy collections, where the donor may have died, or the number of donors / samples may be larger than is feasible to trace/contact. An attempt to contact and reconsent the donor **could** be made, but this should be more of a guideline than mandatory.

In the national *AusCord Cord Blood Consent for cord blood collection, banking and use*, we have separate checkboxes to consent to research or commercial use of cells, along with a clause stating that any research using the samples in the future would be approved by a nationally registered HREC, with the onus on the HREC as to whether they consider the new research to be an ethical use of a donated sample. We feel this is a positive approach to the situation improving transparency as well as improving sample access.

Question 30: *If a legal requirement for consent is imposed (Question 29), should there be exceptions to it? If so, what exceptions should exist?*

This feeds into the previous discussions above. A legal requirement to consent should be imposed, with guidelines for reconsent and stated consideration for exceptions or modification should apply for samples that have existed for an extended period of time (years) before the potential new use existed, provided they had consent for research, do not affect privacy constraints and that a nationally recognized HREC has approved the project

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?

There is a strong need for national regulation, guidelines and governance in the sector to ensure sound and appropriate research, ethical governance and to allay privacy, transparency, and exploitation concerns. Rules and guidelines already exist but they can vary state to state, and we need a clear, simplified, and consistent system under National regulations to ensure relevance to National and International standards for clinical and research use.

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?

All aspects: collection, consent, storage, use and data management, could be regulated by guidelines at a national level. Areas such as ethics, research storage and disposal are key areas requiring consistent and flexible guidelines. Data storage should be protected. Currently FACT play a key role in providing international Standards for consent and accreditation of cord blood banks (clinical biobanks) who collect, store and use human tissue for cellular therapies; it is a TGA manufacturing licence requirement that all cord blood banks in Australia adhere to the FACT Cord Blood Standards. There is clearly a role for a national regulatory body for human tissue use.

b. *what types of collections should be regulated*?

We feel that collections and biobanks for transplantation, clinical use research collection would most benefit from consistent national regulation. Private collections such as non-government cord blood banks and stem cell banks may also benefit.

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?*

Access to their samples in most cases would be of no real use to most individuals, perhaps the better question is should they be able to access the benefits of any research in terms of treatment or transplantation, not monetary. If the idea is to be like the private Cord Blood Banks where it is predominantly a storage unit as a form of insurance, then access would be appropriate if under limited guidelines. A consideration/ exception could be made if they were accessing their donation to move it from the private banks to a research collection.

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.*

We strongly believe there should be guidelines that show what can and cannot be considered for calculating cost recovery. There needs to be flexibility in these guidelines to take into consideration of the circumstances or use of the donation. One suggestion could be for cost recovery to have a weighted scale approach or with a scaled approach to categories such as non-profit research organizations, research institutes, and commercial entities.

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?

We feel that there is a need for more information about what the actual and predicted patterns of use is for various sample types and a clearer breakdown of the role of entities in clinical research/ trials that are not funded by the government. It would also be helpful for a list of exceptions to tissue laws and cost recovery policies be made public so that the sponsors and public can understand that in many cases no profit is or ever will be made.

Question 43: *In relation to Question 42, how should the data be reported? For example, should there be:*
a. voluntary reporting?
b. mandatory reporting?

Given the requirement for transparency and the possibility of delay or lack of compliance in voluntary reporting, mandatory reporting such as exists under external body or existing state laws where relevant, should be required.

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?*

Yes, at discretion and with reasonable timing and notice. Otherwise, it is easy to overlook maintaining proper documentation.

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?*

Priority is a national governing body rather than state, followed by consistent version of what constitutes human tissue and standardised ethical approval requirements for tissue and biobanks towards broad, unspecified consent. Recovery cost guidance would then follow on from these.

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Response submitted 21st January 2026