

NHMRC RESPONSE TO ALRC ISSUES PAPER 51: REVIEW OF HUMAN TISSUE LAWS

List of questions

1. What is your personal experience of how human tissue is obtained or used in Australia?

NHMRC: No comment.

2. What is your personal experience of how human tissue laws work in Australia?

NHMRC: No comment.

3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?

You might think about aims such as:

- *increasing the amount of tissue available for transplantation and/or other uses;*
- *creating a transparent and easy to navigate tissue donation system;*
- *making sure tissue donation happens safely;*
- *making sure people have a good understanding of what is involved in donating tissue;*
- *making sure people understand how their tissue will be used;*
- *equity, and removing barriers faced by some individuals or groups to human tissue donation or transplantation;*
- *making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

NHMRC: All of these aims are appropriate. Nothing to add.

4. When we think about reforming human tissue laws, what principles should guide reform?

You might consider principles such as:

- *respect for persons and for the human body;*
- *equity;*
- *the importance of public trust in the framework that governs how human tissue is obtained and used in Australia;*
- *the importance of laws that are well designed and effective.*

NHMRC: Extending the last bullet point, the importance of laws that are fit for purpose and not unnecessarily restrictive of legitimate activities using human tissue, such as quality, training and approved research.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

NHMRC: In the first heading under Priority reform areas (p.10), there is a question related to definition of tissue. In the Issue Paper Glossary (p. iv) the definition does not include cells, cell lines or cell products. While paragraph 50 notes that 'tissue' can include 'sperm and egg cells', paragraph 52 notes the problem that arises from definitions of tissue for research. This paragraph notes that the definition may include 'cell lines'. We recommend that the Review strongly consider full consultation on the definition of tissue with an emphasis on ensuring that all Australian tissue acts and laws are clear and consistent on whether cells, cell lines or, potentially, certain cell

products fall under the definition of tissue for purposes of enabling or restricting research activity. We note that for some types of cell lines there are established laws that govern their movement and use. The review should ensure that these are fully considered if cell lines are included in the definition of tissue.

Included in the scope of this question should be any distinctions that should be made arising from the degree of attenuation associated with cell lines/cells and taking into consideration that there may be a meaningful distinction between cell lines/cells that are (a) prospectively collected for research, (b) collected originally for non-research purposes and (c) available from existing inventory that is under the control of pathology labs, biobanks or other repositories, both domestic and international.

This issue is related to another question (on p.11) that asks, 'What tissue should be used in research?' Noting paragraphs 56 and 57, we suggest that any ambiguities or gaps related to use and sharing of tissue obtained for valid clinical purposes for research and/or other additional purposes should be resolved in revised HTAs or other laws relating to human tissue.

On page 18, under the heading 'What are some other uses ...' paragraph 96 raises the issue of the ambiguity of the meaning of 'scientific purposes.' We suggest that the Review encompass the need to clarify the meaning of this phrase to include quality, training and research and any other appropriate inclusions and that all Australian HTAs employ the term consistently.

6. What, if any, other issues should we be focusing on in this Inquiry?

You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about:

- *if there are issues caused, or likely to be caused, by current or emerging technology that we haven't identified in this Issues Paper; and*
- *if there is a need to update the HTAs to account for contemporary community values, in ways that we haven't identified elsewhere in this Issues Paper.*

NHMRC: No comment, other than to note that NHMRC published its *Ethical guidelines for cell, tissue and organ donation and transplantation in Australia*, co-authored with the Organ and Tissue Authority, in May 2025 and recommends this document for use by the ALRC in its review.

7. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

NHMRC: No comment.

8. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

NHMRC: No. We consider the exclusions to be appropriate so long as other law governing these areas is scrutinised to ensure that no inconsistencies between modified HTAs and the laws governing these areas have arisen.