

Submission on ALRC Review of Human Tissue Laws DP90

Bellberry Response to Selected Proposals and Questions

Bellberry Limited is a national, private not-for-profit organisation providing streamlined scientific and ethical review of clinical and social science research projects across Australia.

Bellberry is Australia's single largest reviewer of clinical research, providing specialist HREC oversight to 40% of CTN registered clinical trials across all phases of clinical and device trials as well as for social and behavioural studies.

Bellberry commends the ALRC on the publication of the Review of Human Tissue Laws: Discussion Paper (2025) and makes submissions on those proposals and questions considered to be of greatest relevance to the ethical acceptability of research involving human tissue.

Bellberry's submissions are made specifically in the context of collection and use of human tissue in the course of conducting human clinical research as approved by an appropriate HREC.

Bellberry notes that a number of the proposals and questions in the DP seek to regulate the collection and use of human tissue for 'research' and 'research purposes', and recommends that the ALRC include an appropriate definition of "these terms.

Responses to specific proposals and questions are set out below:

Proposal/question	Bellberry response
Proposal 1	Bellberry supports this proposal
Proposal 2	Bellberry does not have a view on the most appropriate regulatory model for achieving the aim of Proposal 1
Proposal 3	<p>Bellberry supports in principle the proposal to establish a national regulator for human tissue, with functions including setting national policies, creating binding codes of practice, providing guidelines for medical researchers and others, providing educational material about tissue donation, accrediting and licensing entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors, and monitoring, investigating and enforcing compliance.</p> <p>Bellberry notes that any such policies and codes of practice should be consistent with the NHMRC <i>National Statement on Ethical Conduct in Human Research</i>. Guidelines for HRECs would be a useful inclusion in this scope.</p>
Consent and authorisation for tissue removal for research – living persons	
Proposal 32	Bellberry supports this proposal

Proposal 33	<p>Bellberry supports the intent of Proposal 33; however, questions whether the right to access information may need to be limited to circumstances in which it is feasible or reasonably practicable for the sample to be reidentified and discarded.</p> <p>Should such a responsibility be implemented, the National Regulator or another authority should provide clear guidance to researchers and others on how to balance their privacy and confidentiality responsibilities with facilitating participant requests to access information about how the tissue is being used and to withdraw consent and request destruction. This guidance will be especially important where the samples have been shared beyond the original research team.</p>
Proposal 34	Bellberry supports this proposal
Proposal 35	Bellberry supports the introduction of clear provisions that would allow tissue to be removed from children for use in research where such removal and use is consistent with ethical research standards. Section 22B of the <i>Human Tissue Act 1985</i> (Tas) provides a useful model for such provisions. Bellberry suggests that tissue donation for research by children must be authorised by an HREC registered with the NHMRC (as compared with a low-risk panel).
Question 28	Bellberry supports the introduction of clear provisions that would allow tissue to be removed from adults without decision-making capacity for use in research where such removal and use is consistent with ethical research standards. Any new provisions in human tissue laws also should be consistent with state and territory guardianship laws. This may include a requirement for research involving the removal of tissue from an adult without decision-making capacity to be reviewed by the relevant state or territory guardianship tribunal as well as an HREC registered with the NHMRC (for eg, s 45AA(2)(e) of the Guardianship Act 1987 (NSW)).
Consent and authorisation to remove tissue for research after death	
Proposal 36	Bellberry supports Proposal 36
Proposal 37	Bellberry supports Proposal 37
Question 29	Bellberry supports a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes to which they did not consent. This is consistent with general principles of bioethics, including upholding autonomy and respect for persons. It would also promote national consistency on this important issue.
Question 30	An exception to the requirement for consent may be required for certain quality assurance activities. This could be addressed by inclusion of an exception to the requirement for consent for secondary uses directly related to the primary purpose of collecting the tissue sample (broadly akin to Australian Privacy Principle 6.2 for use and disclosure of personal information).
Regulating stored tissue collections	
Question 31	Bellberry supports the introduction of legal rules to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks. Given the overlap between human tissue

	samples and personal information, Bellberry suggests Australian privacy laws could provide a useful foundation for the relevant legal rules.
Question 32	Bellberry supports national regulation, guidance and oversight for research biobanks to ensure human tissue is being stored and distributed in accordance with legal and ethical requirements.
Question 33	Bellberry does not have a view on specific aspects of tissue collection that require regulation or types of collections that should be regulated.
Accessing stored tissue	
Question 34	<p>Bellberry supports a right of access to stored tissue. This would be consistent with the right to obtain access to personal information under Australian privacy laws. Access may be especially important where a stored tissue sample has been obtained through an invasive medical procedure and access to the sample can prevent the procedure from having to be conducted another time.</p> <p>Bellberry would support such a right including testing the tissue sample or transfer to a research biobank or pathology laboratory. The tissue holder may warrant a right to charge the tissue donor for reasonable expenses in carrying out the request for access.</p>