WEHI Response to the ALRC Review of Human Tissue Laws

23 January 2026

Executive Summary

The Walter and Eliza Hall Institute of Medical Research (WEHI) welcomes the Australian Law Reform Commission (ALRC) review of human tissue laws and strongly supports the goal of a modernised, nationally consistent framework that safeguards human rights, fosters public trust, and futureproofs the laws to accommodate advances in biomedical research.

Our submission consolidates feedback from key WEHI stakeholders, including clinical research scientists, ethics experts, legal experts and the VBDR program (Volunteer Biospecimen Donor Registry, a WEHI-operated biobanking and tissue access for research service). It draws on operational experience and expertise managing core aspects relating to use of tissues in research, including consent, governance, biospecimen handling, data stewardship and collaborations.

In summary, WEHI supports:

1. a single national legislative framework overseen by a dedicated National Regulator
2. alignment of new legislation with the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research to avoid duplication and/or inconsistencies
3. a broadened definition of 'human tissue' to include derivatives (such as faecal matter), coupled with tailored treatment of 'human-derived research tools' (such as cell lines)
4. practical, workable consent laws that respect the autonomy of individuals to provide broad consent for use of tissues in medical research, and HREC-approved waivers for low-risk or impracticable scenarios (including archival samples)
5. clear, nationally consistent guidance on biobank operation and cost recovery, and
6. modernised legislation on advertising considering the evolving media landscape

In the following pages are WEHI's detailed responses against the subset of key proposals and questions of relevance to biomedical research.

The ALRC can also expect separate submissions from WEHI stakeholders (individuals and groups, including the VBDR) with their unique perspectives.

National legislative framework and Regulator (Proposals 1 and 3)

WEHI supports uniform Commonwealth legislation as the most effective means to eliminate current cross-jurisdictional inconsistencies and reduce administrative burden for research collaborations.

We support establishing a new, adequately funded National Regulator with the powers and functions described in Proposal 3.

The Regulator should be advised by key stakeholders that refer to the Human Tissues Act (HTA) including consumers, and coordinate with existing bodies (e.g. TGA, National Blood Authority, Organ and Tissue Authority) to avoid duplication.

Licensing should be tiered and risk-based (e.g. clinical use in routine medical care vs experimental use in clinical trials vs preclinical research; scale of operation) to avoid bottlenecks and unnecessary costs. We do not support merely expanding existing agency powers (e.g. OTA/TGA/NHMRC) as this risks fragmented oversight.

Implementation should consider a referred/applied legislative model that secures national consistency while enabling transparent expert guidance to evolve with science.

Definition of human tissue and scope (Proposal 7, Questions 5–7)

WEHI supports a clear legislative definition of 'human tissue' and does not support delegating power to the National Regulator to change core definitions without legislation. The Regulator should issue interpretive guidance as needed.

Preferred definition: a broad definition to capture the diversity of human materials and derivatives, aligned with NZ Human Tissue Act (Question 5(b)), and inclusive of acellular bodily materials that originate from or are altered by human cells (e.g. saliva, urine, faecal matter), unless regulated elsewhere.

However, we propose that there should be a separate definition of "human-derived research tools" or "human biospecimen derivatives", being materials created outside the human body that are derived from human material, and which are primarily intended for use in medical research (e.g. cell lines, organoids, patient-derived xenografts and models). This would allow for different treatment of those tools in some contexts, recognising their value in knowledge creation for public good, and the desirability for dissemination to maximise benefit. Further comments on this are below in relation to proposals 32, 33, 34 and 42.

Label (Question 6): the term 'human tissue' could be updated to "human material", "human biospecimen", or "human-derived biological material" to reflect the diversity of human materials and derivatives that this Act will cover.

Recommended inclusions/exclusions and clarifications (Question 7):

› Human milk: include within Act to standardise practice and deter illicit trade/exploitation.

- Foetal tissue and gametes: exclude embryos and Assisted Reproductive Technology gametes regulated under other Acts (Prohibition of Human Cloning for Reproduction Act 2002, Research Involving Human Embryos Act 2002). Where foetal material is obtained in clinical care (e.g., surgery), regulate under this Act with control resting with the pregnant person.

  Expert Advice

  WEHI clinical research scientist:

  Foetal tissue generated by Assisted Reproductive Technology should be excluded, as they are regulated elsewhere. It is important to make the distinction that if the foetal cells are from within the body (e.g. a conceptus present at the time of surgery e.g. for a failed pregnancy involving a female genital tract malignancy), this should come under the control of the pregnant person and thus should be regulated by this Act as it may become part of research related to associated medical conditions.

- Faecal material: include within Act - while faecal matter is currently regulated by the TGA, these regulations do not consider the use of faecal matter that may be collected and banked for research purposes. Faecal matter may be utilised in medical research or for faecal transplantation as a therapy (e.g. for Inflammatory Bowel Disease).

  Access to faecal matter will be under a HREC process. As the presence of the donor's cells in faecal samples (as well as other human derivatives like saliva and hair follicles) could be used to identify the individual (using genomics), some guidelines about what information can be accessed from faecal samples would be implicit through inclusion in the definition (and with HREC oversight).

- Human-derived research tools (e.g. cell lines, organoids, patient-derived xenografts and models): as introduced above (Question 5), these should be excluded (aligning with the UK HTA) or treated as a special class of human-derived materials with tailored provisions.

  Expert Advice

  WEHI human research ethics advisor:

  Consider exclusion of established human cell lines meeting defined criteria provided they are ethically derived with consent addressing immortalisation, dissemination, commercial use and unforeseen future research.

  "Established" should mean lines created in vitro that show sustained propagation and phenotypic stability and are not intended for transplantation, so that brief cultures of fresh tissue cannot be misclassified as unregulated cell lines.

  The legislation should acknowledge that many legacy lines were derived without clearly documented consent and now function as standard, widely available research tools.

- Hair and nails from living persons: exclude (aligning with UK HTA approach).

Post-mortem samples and 'small sample' exceptions (Proposal 31, Question 27)

We support requiring valid consent for use of tissue removed during post-mortem for purposes beyond the examination, with limited exceptions for 'small samples' using existing, well-established ethical review pathways to protect participants. This includes provisions for a waiver of consent, which requires a risk-based assessment of the potential impacts on research participants, and alignment with the requirements outlined in the National Statement on Ethical Conduct in Human Research.

We recognise the substantial scientific and public health value of access to archival pathology collections (including for rare diseases and longitudinal analyses).

Consent for tissue removal for research – living persons (Proposals 32–35, Question 28)

We support Proposal 32 with some recommendations. The legislation should:

(i) make clear that donors may consent to the use of their donated material for specific research or for future unspecified research, in accordance with the National Statement on Ethical Conduct in Human Research. It may be preferable for specific consent to be required for donated material to be used for the creation of human-derived research tools
(ii) clarify that material removed for clinical purposes may be used secondarily for research with valid consent, and
(iii) ensure wording accommodates archival samples and acellular bodily materials like faecal matter, as these will not be "removed from the body", as they are already outside the body

Additionally, if valid consent cannot be provided during the lifetime of an adult, a research program with an HREC-approved waiver of specific consent in line with the NHMRC guidelines, can use this waiver to request access to stored tissue.

Proposal 33: We support the right to withdraw consent for future uses where the sample remains usable and identifiable/re-identifiable. To ensure workability, we recommend excluding widely disseminated human-derived research tools from ongoing 'use notification' obligations.

Proposal 34: Where a research project involves the use of human-derived research tools that were created with HREC approval, we suggest additional HREC review should not be required for their routine use. The widespread (often international) nature of use of human-derived research tools would make mandating HREC review for routine use highly impracticable. Additionally, as previously raised, the legislature wording should cover archival samples and urine/faeces samples which need not be "removed from the body", as they are already outside the body.

Proposal 35: We support this proposal.

Question 28: We support similar provisions for adults without decision-making capacity with the following proposed safeguards:

(i) an authorised decision-maker acting in accordance with the donor's known values/preferences
(ii) HREC approval and/or a waiver of specific consent in line with the NHMRC guidelines
(iii) appropriate governance to mitigate vulnerability to exploitation

Consent to remove tissue for research after death (Proposals 36 and 37)

Proposal 36: We support this proposal but repeat our comments in relation to clarifying that consent may be given to future unspecified research (see Proposal 32).

Proposal 37: Similar to our comments on Proposal 33, we see merit in this proposal, but raise concern about the potential for this proposal to be onerous to implement in practice. In particular, human-derived research tools may be widely disseminated and used for a large number of research projects over many years. We suggest that human-derived research tools should be excluded.

Consent for research on the recently deceased (Proposal 39)

We support in principle a pathway allowing HREC-approved research with the recently deceased outside schools of anatomy or licensed facilities where aligned with the Australian Code and National Statement and under robust consent processes. While not a core WEHI activity, research programs involving procedures like warm autopsies can deliver transformative scientific value when conducted with rigorous governance and sensitivity.

Expert Advice

WEHI clinical research scientist:

Warm autopsies performed for research programs like CASCADE (CAncer tiSsue Collection After DEath), are typically done within 24 hours of death and are performed at the Coroner's Office with assistance from research staff. The consent is given prior to death – preferably weeks to months prior, rather than hours to days, to ensure that family will be aware, to reduce surprise and distress. This involves a detailed, documented consent process, performed by specialist researchers who are not involved in either the patient care or the subsequent research.

Research programs requiring warm autopsies are best managed by their processes being HREC approved, ensuring that the research program has the required understanding and resources. HREC consent should be withheld if the committee believes that sufficient care has not been taken to prevent family distress.

Consent for use of tissue samples (Questions 29 and 30)

Questions 29–30: Consent should be required for research use, and it should be possible to provide broad consent to future unspecified research (i.e. medical research generally), with HREC power to waive consent for low-risk research where obtaining consent is impracticable (e.g. some archival samples), in accordance with the National Statement.

Expert Advice

WEHI clinical research scientist:

Consent and future use: Most donors who consent to research are comfortable with additional use. An opt-out could be included for future unspecified research to respect individual preferences.

When future use isn't addressed: Permit inclusion only where justified by the greater good and HREC approval, and prefer alternatives where a comparable donor with broad consent exists. For rare diseases, HREC-approved inclusion may be warranted to advance health outcomes.

Waivers: Allow HREC-approved waivers of specific consent (per the NHMRC National Statement) for low-risk or impracticable scenarios, including archival or post-mortem tissue, with safeguards to minimise potential harms (e.g. managing incidental genetic findings).

Regulating stored tissue collections (Questions 31–33)

We favour nationally consistent guidance and oversight rather than new prescriptive obligations which may pose operational challenges or restrictions. National coordination will streamline collaboration between biobanks, reduce delays, and improve consistency of practice. Within what is regulated by law, we suggest there is a layer of flexibility for expert groups e.g. NHMRC or HREC to adapt for change in certain contexts.

We suggest the national regulations focus on consent, access/transfer, storage, disposal, and associated data governance (including Data Transfer Agreements and minimum data stewardship standards).

Where additional legislation is contemplated, the term 'biobank' should be carefully defined.

Expert Advice

WEHI legal counsel:

We note that the current Victorian approach in relation to cost-recovery by tissue banks is overly restrictive from WEHI's perspective (and is different to the approach in other states):

- *(i) only "prescribed tissue banks" have the benefit of the cost-recovery defence*
- *(ii) there is no clear definition of "tissue bank" (e.g. WEHI's VBDR is probably not a tissue bank, because it involves provision of samples "on demand" not from storage)*
- *(iii) the process for a tissue bank to become "prescribed" is unclear*
- *(iv) Ministerial approval is required for advertisements related to the donation of tissue (which in practice means that WEHI's VBDR is unable to post social media content to encourage donors).*

Accessing stored tissue (Question 34)

We do not support a general statutory right for donors to access physical samples, noting the compliance burden and practical risks. Donor protection is sufficiently achieved through rights to withdraw consent leading to destruction of unused material.

Where access is sought for clinical benefit (e.g. additional diagnostic testing when clinical blocks are exhausted), a controlled release pathway to the treating pathology service - not directly to individuals - can be accommodated under documented chain-of-custody and provenance procedures. Release to an accredited third-party lab may occur if consistent with the original consent/ethics and governance requirements.

If direct-to-patient release is permitted, they should be provided with clear information about storage/handling risks prior to release. We suggest obtaining consumer input on this approach.

We also recommend safeguards be implemented to prevent misuse (e.g. tissue trafficking) and uphold donor welfare.

Exceptions to the prohibition on the exchange of human tissue for reward (Proposals 40 and 42, Question 36)

Proposal 40: We support prohibiting the offering, giving or receiving of reward in exchange for human tissue, while clearly distinguishing cost recovery from trade. We suggest that 'costs' are clearly defined as reasonable and directly attributable to collection, processing, storage, handling and transport to avoid excess recovery under the broad term "costs".

As currently worded, "reward" could be broadly defined and this could impact the contractual terms on which medical research institutes might receive human material. Victorian law currently restricts the sale and purchase of human tissue. "Sale" and "purchase" are somewhat narrower concepts than the proposed prohibition on the exchange of human material for "reward" – i.e. this proposal is likely to render some existing research arrangements unlawful. For example, some collaborative research agreements allow IP revenue sharing tied solely to human material provision. New legislation should avoid unintended barriers to collaboration while deterring commodification of human tissue.

Proposal 42, Question 36: We support the existing exceptions and recommend adding an explicit exception for human-derived research tools to allow appropriate exchange for research purposes.

We assume clinical trial participation is not expected to be impacted as payments typically relate to participation, not tissue provision.

Question 36c: As plasma donation is currently on a volunteer basis, some organisations fail to recruit sufficient volunteers which can limit research activity, so incentivising donation could help to address recruitment issues. However, if the money to pay for the donation would come from research budgets, this would deplete research potential. We suggest any payment made should be modest and reflect the time and effort involved in making the donation. We also note payment may encourage individuals to not declare their medical conditions which may be contraindications.

Guidance on cost recovery (Proposal 44)

We support empowering the National Regulator to publish binding guidance on reimbursable costs and losses (e.g. operational costs of removing, processing, storing and distributing tissue to provide certainty and financial sustainability for research biobanks.

Prohibiting advertising (Proposal 45, Question 38, 40 and 41)

We support prohibiting advertising that induces prohibited exchanges, while modernising rules to cover current and emerging media platforms (including social media).

Question 38: Victoria's current blanket ban on advertising for tissue donation does not cover social media, and imposes a labour-intensive 4–6-month permit process, hindering biobanks from recruiting diverse, informed donors. We recommend new legislation, overseen by the National Regulator, should have the capacity to evolve with time as the media landscape changes.

Question 40: We support the policy objective of ensuring imported tissue is ethically sourced. We do, however, note the operational burden if rigid prohibitions or broad reporting are imposed.

We raise the concern that this could impact using some externally sourced human materials, e.g. commercial cell lines, if the information around the primary sourcing of the material did not contain evidence regarding ethical standards being maintained. This could limit some research and collaborations.

We also note that global health research programs rely on local ethical approvals and standards that may differ across jurisdictions, and it would be difficult to impose different obligations on clinical operations in other countries.

We also raise the concern that samples obtained in exchange for profit or reward may have compromised the supply chain in some regard and/or fostered illegal or coercive behaviour. An exception to this could be judged by a HREC for the rare circumstances where there were clear rationales for reward or profit was reasonable.

Question 41: We agree with the proposed exemptions, and recommend some considerations for additional exemptions:

(i) rare diseases where samples are unavailable within the population of Australia
(ii) whether the research will benefit the people of the source country (e.g. global health studies)
(iii) the nature of the tissue and the nature of any risks associated with collection (e.g. the risk of blood donation compared to organ donation)