Thursday, 22 January 2026

Australian Law Reform Commission
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PO Box 209, Flinders Lane, Victoria, 8009

Dear Commissioner,

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) welcomes the Australian Law Reform Commission's review of human tissue laws and appreciates the opportunity to respond to Question 7 of the Discussion Paper concerning the use of human cell lines in Australia. ASCEPT represents a broad community of medical and biomedical researchers who rely on human cell lines for fundamental, preclinical, and translational research. Our comments are narrowly focused on the regulatory treatment of **established, commercially available human somatic cell lines** and are intended to balance research efficiency with respect for donor rights and community expectations.

We respectfully urge the Commission to recommend that **commercially available, established human somatic cell lines be excluded from the statutory definition of human tissue for the purposes of routine human research ethics review**, provided that the following conditions are satisfied:

- **Source and provenance** — The cell lines are obtained from recognised commercial suppliers or accredited repositories (for example, ATCC or equivalent custodial collections).
- **Privacy and identifiability** — The cell lines are de-identified with no practicable link to personally identifiable information, or, if identifiable, their provenance is already in the public domain, and their use is unlikely to cause harm to the donor or close relatives.
- **Consent compliance** — Researchers comply with any consent conditions or licence terms that accompany the cell line.
- **Non-therapeutic use** — The proposed work does not include development of the cell lines as therapeutic products or clinical cell therapies.
- **Exclusion of embryonic stem cells** — The exemption does not extend to the use or derivation of embryonic stem cells or other materials subject to separate, more restrictive regulation.
- **Gene Technology Regulatory Approval** – That any genetically modified commercially available human somatic cell lines, or their derivatives, have appropriate approvals as per the requirements of the Office of the Gene Technology Regulator.

We emphasise that this recommendation is **limited to the use of established cell lines for research purposes** and is not intended to weaken the robust protections that Australia rightly maintains for the generation of new cell lines from human tissue. ASCEPT strongly supports the strict and necessary regulatory framework that requires informed consent and Human Research Ethics Committee (HREC) oversight when new cell lines are derived from human donors.

We also acknowledge and respect the ethical concerns raised by the family of Henrietta Lacks and others about the commercialisation of biological materials obtained without informed consent. Those concerns underscore the importance of transparency, appropriate consent processes, and, where relevant, fair and ethical approaches to benefit sharing. Our proposed exemption is not intended to

permit commercial exploitation of donor material obtained without consent; rather, it seeks to remove unnecessary regulatory duplication for widely used, well-characterised cell lines whose provenance and consent conditions are already established.

In practical terms, adopting the exemption we propose would:

- Reduce administrative burden and delay for low-risk laboratory research that uses established cell lines;
- Preserve HREC capacity to focus on higher-risk, novel, or donor-identifiable research; and
- Maintain strong protections for donor autonomy and privacy through compliance with consent terms and repository standards.

The administrative burden placed on both researchers and HRECs is significant, and its reduction should be a clear priority in the review. We also recognise that, if an exemption is granted, the community may reasonably expect research institutions to retain the ability to report on the exempt human cell lines used by their researchers. Any revisions to human tissue legislation should therefore adopt the most streamlined and proportionate approach to meeting this expectation.

Thank you for considering ASCEPT's submission. We would be pleased to provide further detail or to discuss how these recommendations could be implemented in a manner that safeguards donors while supporting high-quality biomedical research.

Yours sincerely,

**Associate Professor Nicola J Smith, PhD**
President
Australasian Society of Clinical & Experimental Pharmacologists & Toxicologists (ASCEPT)