Friday, 16 January 2026

Australian Law Reform Commission

Dear Commissioner,

I write as a medical researcher of over 25 years experience and as a user of a wide range of human cell lines in preclinical and translational research. I welcome the Australian Law Reform Commission's review of human tissue laws and submit this letter in response to Question 7 concerning the regulatory treatment of human cell lines. My comments reflect day-to-day laboratory practice, publication standards, and the practical constraints faced by researchers and Human Research Ethics Committees (HRECs).

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

- **Source and documentation** — The cell lines are purchased from recognised commercial suppliers or accredited repositories and are documented in accordance with accepted publication standards (for example, those required by the *Nature* publishing group).
- **Privacy and identifiability** — The lines are de-identified with no practicable link to personally identifiable information, or, if identifiable, their provenance is already public and their use is unlikely to cause harm to the donor or close relatives.
- **Consent and licence compliance** — Researchers adhere to any consent conditions, licence terms, or use restrictions that accompany the cell line.
- **Non-therapeutic research use** — The exemption applies only to research uses and does not extend to development of the cell lines as therapeutic products or clinical cell therapies.
- **Exclusion of embryonic stem cells** — The exemption does not cover embryonic stem cells or other materials subject to separate, more restrictive regulation.

My laboratory routinely acquires multiple, well-characterised cell lines from commercial suppliers to study drug mechanisms and target validation. These lines are **documented and authenticated** to the standards required by leading journals, and their provenance and handling are recorded in methods sections and repository accession details. Requiring HREC approval for each new, commercially sourced cell line would impose a substantial administrative burden on both researchers and HRECs. For individual investigators, the cumulative time spent preparing separate HREC applications for dozens of routine, low-risk cell lines would divert effort from experimental work and slow research progress. For HRECs, routine review of well-documented, de-identified lines would consume committee capacity that is better directed to higher-risk, novel, or donor-identifiable research. An exemption, constrained by the criteria above, would

preserve ethical oversight where it is most needed while removing unnecessary duplication for low-risk laboratory research.

I strongly support Australia's rigorous requirements for **informed consent** and HREC oversight when new cell lines are derived from human tissue. Those protections are essential and should remain unchanged. I also acknowledge the legitimate ethical concerns raised by the family of Henrietta Lacks and others about the historical commercialisation of biological materials obtained without informed consent. These concerns underscore the need for **transparency, compliance with consent terms, and ethical approaches to benefit sharing** where appropriate. My recommendation is narrowly focused on the **use** of established, commercially available cell lines for research and is not intended to permit exploitation of donor material obtained without consent.

Adopting the targeted exemption would reduce unnecessary administrative burden, allow HRECs to prioritise higher-risk matters, and support efficient, reproducible biomedical research—while preserving strong protections for donor autonomy, privacy, and ethical oversight where they are most needed. Thank you for considering this submission.

Yours sincerel

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