Thursday, 22 January 2026

Australian Law Reform Commission

Dear Commissioner,

I write as a medical researcher 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.

I respectfully recommend that research involving the use of established human somatic cell lines be made exempt from review provided that they meet the following criteria:

- The established cell lines are commercially available or can be obtained from established repositories (e.g., ATCC). and;
- The cell lines are either de-identified and not linked to any personally identifiable information or are identified and available in the public domain, and unlikely to cause harm to the original donor or their relatives.
- The researcher will comply with any consent terms attached to the use of the cell line.
- The proposed research will not develop the cell lines as therapeutics.
- The proposed research will not use human tissue to develop new cell lines.
- The proposed research does not involve the use or derivation of embryonic stem cells.

Requiring Human Research Ethics Committee (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.

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 sincerely,

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