Thursday, 22 January 2026

Australian Law Reform Commission

Dear Commissioner,

I am writing in my capacity as a medical researcher whose work relies extensively on established human cell lines to investigate mechanisms of urinary tract disease. I welcome the Commission's review of human tissue legislation and appreciate the opportunity to comment on Question 7 regarding the regulatory treatment of human cell lines.

In my laboratory, we routinely work with the RT4 and UROtsa cell lines to study urinary tract cystitis and urinary tract infection. These models are central to our efforts to understand host–pathogen interactions and to identify potential therapeutic targets. RT4 cells originate from a well-characterised human bladder cancer line, while UROtsa cells represent an immortalised model of normal human urothelium. Both are widely used, commercially available, and supported by extensive documentation regarding their provenance and characteristics.

Based on my experience, I respectfully recommend that research involving established human somatic cell lines be exempt from ethics review when the following conditions are met:

- The cell lines are commercially available or sourced from recognised repositories such as ATCC.
- The lines are either fully de-identified with no link to personal information, or are publicly identified in a manner that poses no foreseeable risk to the original donor or their relatives.
- Researchers adhere to any consent conditions or usage restrictions associated with the cell line.
- The research does not involve developing the cell lines for therapeutic use.
- No new human cell lines are derived from human tissue as part of the project.
- The research does not involve embryonic stem cells or their derivation.

In my own work, the requirement to obtain Human Research Ethics Committee (HREC) approval for each individual, commercially sourced cell line would create a substantial administrative burden without improving participant protection or research integrity. Preparing multiple applications for routine, low-risk cell lines would divert time away from experimental work and slow the pace of discovery. For HRECs, reviewing large numbers of applications involving well-established, de-identified cell lines would consume committee resources that are better directed toward genuinely higher-risk or donor-identifiable research.

A targeted exemption, framed by the criteria above, would maintain strong ethical safeguards while reducing unnecessary duplication. It would allow HRECs to focus their expertise where it is most needed and support efficient, reproducible biomedical research across Australia.

Thank you for considering this submission and for your ongoing work in modernising Australia's human tissue regulatory framework.

Yours sincerely,

Lu Liu