

I am writing in response to the Australian Law Reform Commission's Review of Human Tissue Laws.

With respect to Question 7 (should cell lines be exempt from human tissue laws?), I recommend that somatic cell lines be exempt from the human tissue laws once they have been established. Once a cell line is established, it can be propagated outside human body, distributed, and manipulated for research and manufacturing purposes. For example, HEK293 cells are routinely used for the production of recombinant products, including vaccines (eg Vaxzevria to prevent COVID-19). Many commercially available cell lines have been subject to modification and are protected by patents as they are considered 'something new' that has been created by humans. As they do not occur naturally, jurisdictions such as the UK, define cell-lines as a manufactured product and are no longer considered human tissue.

Exemption of the use of established commercially available cell lines for research purposes would bring Australian legislation in line with other jurisdictions including the US, UK, and Canada. It will remove an unnecessary and, to date un-enforced, regulatory burden on researchers, while ensuring best practice without increasing the risk of harm to the donors and their relatives.

I recommend that research involving the use of established human somatic cell lines be made exempt from review if 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.

Regards,

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