**Submission to the Australian Law Reform Commission**
**Review of Human Tissue Laws – Question 7 (Commercially Available Cell Lines)**

**Prepared for:** Australian Law Reform Commission (ALRC)
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## Executive summary

This submission responds to Question 7 of the ALRC Discussion Paper on the Review of Human Tissue Laws, which highlights uncertainty about whether (and how) established cell lines are regulated under Australian human tissue legislation. In practice, the absence of an express exclusion for established cell lines can lead to routine requirements for Human Research Ethics Committee (HREC) review, even where the material is commercially available, long-established, and carries negligible risk of harm to donors or their relatives. The resulting administrative burden is disproportionate to the ethical risk and creates avoidable bottlenecks for research that relies on widely used reference models and standardised reagents.[1]

I recommend that research involving established human somatic cell lines be expressly exempt from HREC review when these lines are sourced from recognised commercial suppliers or repositories and meet clear conditions addressing identifiability, consent terms, and excluded high-risk uses. This approach would align Australia with international practice (for example, the UK position that cells created outside the human body, such as cell lines, are not 'relevant material' under the Human Tissue Act) while preserving strong protections for donors where there is a credible pathway to harm (for example, where genomic data could meaningfully re-identify a donor or family).[2,3,11]

A calibrated exemption is feasible to implement using the ALRC's proposed framework: a broad primary definition of 'tissue', paired with a flexible mechanism (delegated legislation) to exclude specific materials or uses, supported by regulator guidelines and flow-chart decision tools.[1] It would also reduce duplication and opportunity costs associated with repeated ethics and governance processes that do not improve participant protection, as documented in Australian studies of multi-site approvals.[8,9] Such right-sized regulation is consistent with Productivity Commission analysis that excessive or duplicative regulation can impose unnecessary compliance costs and hinder innovation and productivity.[5,6]

## 1. Response to Question 7: exemption for established, commercially available somatic cell lines

I support an explicit exemption from HREC review for research using established human somatic cell lines, provided the exemption is confined to low-risk, established materials and does not extend to activities that create new lines, develop therapeutics, or involve embryonic stem cells. The aim is not to reduce ethical standards, but to apply a risk-proportionate governance model so that high-risk activities receive robust oversight and low-risk, standardised inputs do not create systemic delays.

## 2. Proposed exemption criteria

I 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.

## 3. Rationale and supporting evidence

### 3.1 International alignment and coherent scope

Many comparable jurisdictions draw a pragmatic boundary between tissue taken directly from people and cell lines that have been replicated outside the body and distributed as standard research materials. In the UK, the Human Tissue Authority's Code E explains that 'relevant material' does not include material that contains only cells created outside the human body (for example, cell lines).[2] The UK Health Research Authority similarly notes that cell lines are not relevant material under the Human Tissue Act (while primary cell cultures may be).[3] New Zealand adopts a nuanced model: its Human Tissue Act 2008 specifies that cell lines derived from human cells are treated as human tissue for some sections but not others.[4] These examples demonstrate that excluding established cell lines from blanket 'human tissue' treatment is both workable and consistent with donor protection.

### 3.2 Risk-based ethics review and proportionality

The ethical justification for mandatory HREC review is strongest where research involves direct interaction with participants, uses identifiable information, or involves interventions that could create physical, psychological, social, legal, or economic harms. For established cell lines supplied by accredited repositories, the predominant ethical issues are (i) compliance with material transfer and consent terms, and (ii) management of any residual identifiability risks (especially for genomic data). A risk-based approach is consistent with the Australian National Statement on Ethical Conduct in Human Research, which emphasises proportionate review pathways for low-risk research.[19]

### 3.3 Feasibility: implementable carve-outs using delegated exclusions and guidelines

The ALRC Discussion Paper proposes a broad definition of 'tissue', combined with a mechanism to adjust the scope via delegated legislation (Proposal 8) and regulator guidelines (Proposal 9).[1] This architecture is well suited to a targeted carve-out for established cell lines, because it allows exclusions to be expressed precisely (for example, by source and use), and updated as scientific practice evolves. In particular, a consolidated exclusion instrument (or 'scoping order') and accompanying guidelines could include a decision tool that asks whether the material is: (a) an established line obtained from a recognised repository; (b) de-identified or already public without a credible harm pathway; and (c) used only for non-therapeutic research without derivation of new lines.[1]

### 3.4 Avoiding duplication, futile bottlenecks, and delays to research deliverables

Requiring HREC review for each project using broadly available established cell lines creates repeated administrative tasks without improving donor protection. Australian evidence from multi-centre ethics and governance processes shows that

large proportions of time can be spent on repeated or reformatted documentation that does not improve study design or participant safety. Barnett and colleagues found that 75–90% of time in the approvals process was spent on repeated tasks and that approval costs could consume substantial fractions of budgets.[8] Foot and colleagues similarly reported long timelines and inconsistent site requirements that delayed low-risk research, with the approvals pathway taking 230 days in a pragmatic trial (24% of the total project timeline).[9] These findings support streamlining governance where risk is low and the work is already bounded by standardised inputs.

The policy rationale for exemption is even stronger for established cell lines, because (unlike freshly collected tissue) they are already widely distributed, frequently used internationally, and often essential for reproducibility and benchmarking across laboratories. A requirement for repeated ethics approvals at each institution does not change the provenance of the material or improve donor protections; it mainly introduces time delays and duplication.

### 3.5 Productivity, national competitiveness, and opportunity cost

The Productivity Commission has repeatedly emphasised that poor-quality or overly burdensome regulation imposes compliance costs and can deter innovation and investment, reducing productivity growth.[5,6] Biomedical research is an internationally competitive sector where speed, rigour, and access to standardised models influence collaboration, funding success, and translation. Australia already operates in an environment of constrained research resourcing; avoidable regulatory delays therefore have amplified opportunity costs, including delayed deliverables, reduced international competitiveness, and lower return on public investment in research infrastructure.

### 3.6 Rigour, standardisation, and scientific integrity

For established cell lines, the most material risks to research quality are scientific rather than ethical: misidentification, contamination, genetic drift, and poor documentation. The international community has developed mature standards and tools for cell line authentication, including the ANSI/ATCC standard for STR profiling of human cell lines.[15] ICLAC maintains a register of misidentified cell lines to help researchers avoid cross-contaminated or mislabelled materials.[16] NIST similarly notes that contamination and misidentification have plagued the scientific community for decades and highlights STR profiling as a key approach for identification.[17] These controls are concrete, auditable, and directly relevant to reproducibility; they represent a more effective and proportionate governance focus than repeated HREC review of low-risk, widely distributed lines.

## 4. Safeguards, exceptions, and edge cases

An exemption should be coupled to clear safeguards and explicit exceptions to maintain trust and protect donors and families:

- Genomic data and re-identification risk: where research generates or uses whole-genome sequence data from a line that could plausibly implicate donor relatives, additional governance may be warranted. The NIH–Lacks Family Agreement is a prominent example of a tailored oversight model that enables research access while addressing family privacy concerns.[11–14]
- Consent and material transfer conditions: exemption should be contingent on compliance with repository terms, consent conditions (where known), and any usage restrictions communicated with the line.
- No therapeutic development: projects aiming to develop cell-based therapeutics, clinical products, or human application should remain subject to the appropriate therapeutic goods and human application regulatory frameworks (for example, in the UK, cell lines may be subject to the Human Tissue (Quality and Safety for Human Application) Regulations for therapeutic use).[3]

- No new derivation: derivation of new cell lines from human tissue (including from surgical ‘leftover’ tissue) should remain within full ethics and tissue governance pathways, because this is the point at which consent, identifiability, and donor expectations are most directly engaged.
- No embryonic stem cells: embryonic stem cell use or derivation should remain within dedicated ethics and legislative frameworks, reflecting the distinct ethical and community sensitivities.

## 5. Practical implementation options

To implement the exemption while preserving donor protections, I suggest the following practical options consistent with the ALRC framework:[1]

- Delegated exclusion instrument: list ‘established somatic cell lines obtained from accredited commercial suppliers or recognised repositories’ as excluded from the definition of regulated tissue for research purposes, subject to the criteria in Section 2.
- Regulator guidance and decision tool: publish a short checklist/flowchart (aligned to Proposal 9) enabling researchers and institutions to self-assess eligibility for exemption, with escalation triggers (for example, identifiable genomic sequencing, therapeutic development, or new derivation).
- Institutional governance without HREC review: allow institutions to manage compliance through existing research governance controls (material transfer agreements, biosafety, data management plans, and cell line authentication requirements) rather than project-by-project human ethics review.

## Conclusion

A targeted exemption for established, commercially available human somatic cell lines is a proportionate, feasible reform that aligns Australian practice with international approaches while maintaining robust protections where real risks exist. By reducing duplicative low-value administrative steps, the reform would improve research efficiency, support standardisation and rigour, and enhance Australia’s competitiveness in biomedical science without increasing risk of harm to donors or their relatives.

## References

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