Children's Cancer Institute

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To whom it may concern,

Children's Cancer Institute – Review of Human Tissue Laws: Issues Paper (2025)

Children's Cancer Institute (CCI) welcomes the opportunity to comment on the Review of Human Tissue Laws: Issues Paper (2025).

Background

Children's Cancer Institute (CCI)

CCI is Australia's sole independent medical research institute, wholly dedicated to pioneering research and innovative treatments to improve the lives of children affected by cancer. The Institute has developed a world-class research environment that merges laboratory-based science with clinical translation pathways for over forty years.

CCI unites researchers, students, corporate leaders, and support staff in a dynamic workplace dedicated to advancing medical research and improving human health.

The Institute has collaborated with the Sydney Children's Hospital Network and the University of NSW (UNSW) to develop the Minderoo Children's Comprehensive Cancer Centre (MCCCC), a state-of-the-art facility set to open in 2025, which will integrate over 900 researchers, clinicians, and support staff to elevate care for children with cancer.

Zero Childhood Cancer Program (ZERO)

CCI co-leads the world-renowned ZERO Childhood Cancer (ZERO) precision medicine program for children with cancer, in partnership with the Kids Cancer Centre at Sydney Children's Hospital, Randwick.

Launched in 2017 as a clinical trial for children with the poorest survival prospects, the national program expanded in November 2023 to include every child with cancer—regardless of type, stage, or risk—and has enrolled 2,500 participants to date.

ZERO uses advanced somatic and germline genomic profiling and precision medicine techniques to identify an individual child's genetic cancer drivers and deliver personalised treatment recommendations.

The program has significantly improved clinical outcomes, transforming care for high-risk and undiagnosable patients in Australia.[1]

Earlier this year, the Federal Government announced $112.6 million over three years to support the program's continuation in its current form and expand access to adolescents and young adults (AYA) with paediatric-type cancers.

Childhood Cancer in Australia

In Australia, over 1,000 children and adolescents are diagnosed with cancer each year, making cancer the leading cause of disease-related death in children. At any given time, more than 2,000 children are undergoing cancer treatment and, tragically, each year 200 of these young patients will not survive.

Two-thirds of childhood cancer survivors experience severe, lifelong side effects, including infertility, cardiac toxicity, chronic pain, developmental deficits, metabolic disorders, and secondary cancers. These issues stem from chemotherapy's non-specific and cytotoxic treatment schedules. The impact extends beyond patients and their families, affecting survivors' ability to work and live independently while placing a significant burden on the healthcare system.

Children are not simply smaller adults with cancer—childhood cancers are unique and require specialised care pathways.

As a rare disease, childhood cancer presents significant inequities in access to high-end diagnostics, therapeutics, and adequate lifelong surveillance and support for survivors.

Despite these challenges, childhood cancer stands as a remarkable example of how medical research can transform outcomes. Advances driven by the collaboration of clinicians and researchers have increased survival rates in developed countries from single digits to over 80 per cent, demonstrating the life-changing potential of ongoing innovation and investment.

Issues Paper Response

CCI welcomes the Federal Government's commitment to comprehensively review human tissue laws, ensuring they remain fit for purpose in our rapidly evolving medical landscape.

We advocate for a nationally consistent, modernised regulatory framework that balances ethical integrity with streamlined access to human tissue for clinical care and research. Such a framework would deliver transformative benefits for all Australians, including paediatric populations.

Our submission addresses critical gaps in the current legislative landscape, offering targeted insights across key areas, including paediatric consent protocols, tissue commercialisation parameters, commercial applications of tissue-derived research models, secondary use provisions, and consent frameworks that accommodate future, emerging applications.

Through these contributions, CCI aims to resolve the ambiguity and jurisdictional inconsistencies that currently hinder both clinical innovation and patient care.

1. *What is your personal experience of how human tissue is obtained or used in Australia?*

As a medical research institute focused on paediatric cancer, CCI works with our clinical partners to obtain tumour and blood samples from children with cancer, under ethical protocols and with appropriate informed consent.

[1] Lau, L. M. S., et al. (2024). Comprehensive genomic profiling for high-risk pediatric cancer patients: Results from the Zero Childhood Cancer Program. *Nature Medicine*.

Tissue is primarily used for diagnostic purposes and research into cancer biology, treatment response, and genomic profiling, particularly through the national ZERO Childhood Cancer Program.

2. *What is your personal experience of how human tissue laws work in Australia?*

As an organisation whose work directly involves human tissue, CCI is bound by these laws and is committed to full compliance and upholding the highest ethical standards across all areas of our work.

While these laws establish an essential ethical foundation, the current framework lacks alignment across states, territories, and the Commonwealth. This jurisdictional fragmentation creates unnecessary complexity and impedes the delivery of coordinated national research programs and cross-border partnerships.

In our experience, the existing legal framework contains significant gaps, particularly in consent protocols for paediatric patients transitioning to adulthood, the boundaries of tissue commercialisation, the commercial use of tissue-derived research models, and consent provisions for future scientific applications that cannot yet be foreseen or defined.

3. *When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?*

Human tissue laws should enable timely, safe, and ethical access to tissue for clinical care and research, removing unnecessary barriers while protecting patient privacy and safety. These laws should facilitate medical innovation and research translation, ensuring discoveries benefit patients rapidly.

The framework must establish clear informed consent processes that respect individual autonomy and accommodate diverse cultural perspectives on tissue use. For paediatric populations, this includes age-appropriate involvement of young patients alongside parental authority.

The laws should promote equitable access to research participation and benefits across all population groups, support national and international research collaboration through streamlined processes, and ensure transparent communication about how tissue is collected, stored, and used.

They must also accommodate future scientific applications, particularly in genomics and emerging technologies, recognising that tissue collected today may unlock tomorrow's breakthroughs.

4. *When we think about reforming human tissue laws, what principles should guide reform?*

Reform should be anchored in respect for persons—honouring individual autonomy, cultural diversity, and human dignity throughout all tissue-related processes. Transparency and accountability must underpin the framework, with clear governance structures that build and maintain public trust.

National harmonisation stands as a core principle, creating consistency that eliminates jurisdictional barriers and administrative duplication. The reform process should embrace flexibility and future-proofing, ensuring laws can evolve alongside scientific advances rather than constraining innovation.

Equity and inclusion must guide reform efforts, actively addressing barriers faced by vulnerable populations and ensuring fair distribution of research benefits.

Evidence-based decision-making should inform any changes, drawing on best practices internationally, while responding to Australia's unique context.

Throughout the review, meaningful engagement with stakeholders, including clinicians, researchers, and patients, remains essential to create laws that reflect community values and expectations, while ensuring practical workability for those conducting research and delivering clinical care.

5. *Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry?*

CCI strongly supports the issues identified in the priority reform areas.

The Institute particularly emphasises the urgent need to address inconsistencies in paediatric consent provisions across Human Tissue Acts. Current frameworks lack clarity on consent authority for children, failing to provide guidance when paediatric donors reach adulthood.

Clear protocols are essential for managing tissue collected during childhood, including specific provisions for when donors turn 18. While young adults should retain the right to withdraw consent for continued research use, mandatory re-consent would create an unsustainable administrative burden and potentially compromise valuable longitudinal studies.

The definition of "tissue" requires comprehensive review, as current legislation inadequately addresses derivative materials such as cell lines, organoids, and other research models created from original samples. This gap creates uncertainty around consent, ownership, and permissible uses of these scientifically valuable resources.

CCI strongly advocates for reformed secondary use provisions that establish clear, practical pathways for ethically approved research while maintaining donor protections. Current jurisdictional inconsistencies create significant barriers—some states prohibit secondary research use even with ethics approval and clear public benefit, while others provide greater flexibility. National reform should enable secondary use through consistent safeguards that maintain public trust while preventing delays to critical research.

The disparities between state, territory, and Commonwealth approaches to regenerative and non-regenerative tissue create unnecessary research obstacles. A unified framework should enable donation of all tissue types for research purposes where donors provide informed consent and ethics approval is secured, removing artificial barriers to scientific progress.

6. *What, if any, other issues should we be focusing on in this Inquiry?*

The inquiry should prioritise establishing clear national pathways for interstate tissue sharing. Despite ethical approval, researchers face significant legal and administrative barriers when collaborating across jurisdictions, impeding critical multi-site studies essential for paediatric cancer research.

Tissue commercialisation requires definitive guidance that recognises the critical role of industry partnerships in advancing research and ensuring sustainability. Commercial applications often provide the necessary resources and expertise to translate discoveries into patient benefits more rapidly. The framework should embrace these opportunities, while maintaining robust ethical safeguards and transparent consent processes.

In addition, the law should provide clarity on the use of models derived from tissue, as the current framework leaves their research and commercial applications uncertain. The review should address these gaps while ensuring appropriate safeguards are in place for donors.

Culturally appropriate tissue practices require specific guidance that honours cultural protocols, spiritual beliefs, and community values. Without clear direction, current practices risk perpetuating harm, undermining cultural sovereignty, and foreclosing opportunities for respectful research partnerships that could deliver meaningful benefits to diverse communities. Reform must address these considerations as distinct from cultural heritage legislation governing ancestral remains,

recognising tissue donation as a contemporary practice requiring its own culturally informed approach.

Consent frameworks must embrace flexibility to accommodate future scientific applications that cannot be anticipated at the time of collection, preventing valuable research opportunities from being lost as technology advances. These frameworks must establish clear precedence where multiple consent regulations intersect, resolving the current legislative conflicts that burden researchers with contradictory requirements and create uncertainty about which standards apply.

As the paper identifies, inconsistencies between state, territory, and Commonwealth legislation create unnecessary complexity that hinders national research efforts. A nationally consistent approach is essential to support multi-site studies, reduce compliance burdens, and enable more efficient, collaborative research, and should be a key focus of this inquiry.

7. *Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?*

N/A

8. *Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?*

While CCI acknowledges these issues are largely addressed under other frameworks, the inquiry should remain mindful of their points of intersection with the Human Tissue Acts to ensure reforms are coherent and future-proof.

Conclusion

The review of Australia's human tissue laws presents a transformative opportunity to modernise and strengthen the national framework governing the retrieval and use of human tissue.

By establishing nationally consistent, ethically robust, and innovation-enabling laws, Australia can strengthen its position as a leader in medical research while ensuring scientific advances translate rapidly into patient benefit.

CCI looks forward to continued engagement throughout this critical reform process.

If you have any questions, please contact Chanel Beynon, Strategy and Government Relations Lead [redacted]

Yours sincerely,

[redacted]

Dr Peter Wejbora
Director, Research Development and Partnerships
Children's Cancer Institute