Children's Cancer Institute

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Australian Law Reform Commission (ALRC)
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ALRC Online Survey Portal

To whom it may concern,

Children's Cancer Institute – Review of Human Tissue Laws: Discussion Paper

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

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 officially open in early 2026, 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 nearly 3,000 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]

In 2025, 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.

[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*.

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.

Discussion Paper Response

CCI appreciates the opportunity to contribute to the next stage of consultation on the reform of human tissue laws.

As a medical research institute focused on paediatric cancer, CCI works closely with our clinical partners to access tumour and blood samples from children with cancer under robust ethical frameworks and appropriate informed consent. The Institute also operates a human tissue bank and is part of a national network of paediatric tumour banks.

Human tissue is used to support diagnosis and to advance research into cancer biology, treatment response, and genomic profiling, including through ZERO.

CCI supports a nationally consistent, modernised regulatory framework that upholds ethical integrity while enabling timely and streamlined access to human tissue for medical research.

Reform in this area has the potential to deliver significant benefits for patients and the broader community, including children with cancer.

However, it is paramount that any changes do not introduce unnecessary additional regulatory burden for medical research institutes, which already operate within extensive legislative and regulatory frameworks, and that such measures do not inadvertently hinder medical research that delivers patient benefit.

Question 1

CCI agrees with the objects listed in Proposal 5. Collectively, they strike an appropriate balance between respect for human dignity, autonomy and consent, and the need to enable ethical, timely access to human tissue for medical, educational and scientific purposes.

In particular, the Institute supports the emphasis on adaptability, equity, and public trust - critical in the context of rapidly advancing medical research, including precision medicine - as well as the focus on consistent laws and regulatory frameworks, which is essential for research involving rare pathologies that often requires access to tissue samples across multiple jurisdictions.

These principles provide a necessary foundation for a modern regulatory framework capable of responding to evolving scientific practices while maintaining strong community confidence.

Question 2

While Proposal 5 provides a strong foundation, CCI recommends that the objects be strengthened to ensure the framework fully supports contemporary and future research needs. In particular, CCI suggests that:

- Object b explicitly recognises the importance of *timely* access to human tissue.
- Include additional objects to:
    - Support national and international research collaboration, including streamlined interstate tissue sharing;
    - Future-proof the regulatory framework by recognising that tissue collected today may enable unforeseen scientific applications and breakthroughs; and
    - Ensure clear governance, transparency, and accountability.

Question 3

CCI supports the inclusion of explicit provisions to remove barriers and promote equitable access across the full tissue lifecycle, from donation and collection to research use and translation.

Current legislative fragmentation across jurisdictions creates inequities in who can participate in research, how tissue can be accessed, and how benefits are distributed.

Embedding high-level equity-focused provisions in the legislation would ensure that all Australians, including children with cancer, have fair opportunities to contribute to and benefit from tissue-based research.

Question 4

CCI identifies the following key barriers that new human tissue legislation must address:

- Jurisdictional inconsistency across state, territory, and Commonwealth laws, which impedes interstate tissue sharing and multi-site research essential for paediatric cancer studies.
- Unclear paediatric consent frameworks, including a lack of guidance on the management of tissue when paediatric donors reach adulthood. CCI's position is that mandatory re-consent at age 18 is not required. However, individuals should retain the right to request that their tissue no longer be used for future research if they so choose.
- Restrictions on secondary use of tissue, even where ethics approval exists, and public benefit is clear, resulting in delays or loss of valuable research opportunities.
- Barriers to culturally appropriate tissue practices, particularly for Aboriginal and Torres Strait Islander communities and culturally and linguistically diverse populations, where the absence of clear guidance risks harm and disengagement.

Addressing these barriers is essential to promoting equity, efficiency, and public benefit.

Question 5

CCI supports a broad and inclusive definition of "tissue", aligned with Option (b), encompassing the human body and any constituent material, substance, or part removed from a human body that includes or derives from human cells.

More explicit wording to capture derivative materials, such as cell lines, organoids, xenografts, and other models, would be welcome, as these are foundational to modern paediatric cancer research and are not consistently addressed in existing legislation.

However, clarity and inclusiveness alone will not necessarily increase the appropriate use of these resources. If derivative materials are treated as fully equivalent to primary tissue for all regulatory purposes, this may unintentionally increase perceived barriers to use, particularly for low-risk, de-identified research materials. It is therefore critical that any expanded definition is accompanied by proportionate and risk-based regulatory treatment.

CCI supports a flexible, future-proofed definition, supported by mechanisms that allow regulatory requirements to be calibrated over time in line with scientific practice and risk.

Question 6

CCI does not recommend a change in terminology, provided the definition of “tissue” is sufficiently broad, clearly articulated, and future proofed. If alternative terminology is adopted, “human material” would be appropriate, as it more readily captures contemporary research practice and derivative materials.

Regardless of terminology, the framework must clearly distinguish between different stages of use. In particular, materials derived from tissue, such as cell lines and other models, should be clearly in scope, while recognising that derivation and distribution present higher ethical and governance risks than downstream use of established, de-identified materials.

Question 7

CCI does not support blanket exclusions for scientifically relevant materials such as cell lines, as this would create regulatory gaps and uncertainty.

However, CCI strongly cautions against regulatory approaches that treat all uses of derivative materials as equivalent to primary tissue. In particular, it would not be pragmatic or proportionate to require individual ethical approval for the downstream use of de-identified human somatic cell lines.

As such, the Institute supports a risk-based, purpose-specific framework, with greater regulatory stringency applied to the derivation and distribution of cell lines and other models, and proportionate, streamlined pathways for low-risk, de-identified end-use. Clear national guidance would be essential to ensure consistency and avoid unintended barriers to research.

Question 8

CCI considers that national consistency in the determination of death is essential to reduce legal uncertainty and support safe research practice.

If national uniformity cannot be achieved through harmonised state and territory legislation, any alternative approach should avoid creating parallel or conflicting legal standards and should prioritise clarity for clinicians, researchers, patients, and families.

Question 9

CCI strongly supports option (a): the adoption of a Uniform Death Act through national uniform legislation. This approach offers the most effective and durable means of achieving national consistency, preventing divergence over time and providing clear, legally certain standards across health, research, and coronial systems.

The creation of a Uniform Death Act should not introduce any additional administrative burden. If it replaces fragmented state and territory provisions with a single, consistent standard, it would simplify compliance, reduce legal uncertainty, and avoid duplication, particularly for health and research professionals operating across jurisdictions.

Question 10

CCI supports the safeguards in Proposal 14 for adult consent but considers that additional, child-specific safeguards are required for paediatric research contexts. These should include clear, nationally consistent provisions on consent authority for children, including the respective roles of parents or guardians and minors, supported by age-appropriate information.

Safeguards are also needed to manage tissue collected during childhood as donors transition to adulthood. CCI does not support mandatory re-consent at age 18. However, young adults should retain the ability to request that their tissue not be used for future research.

Consent frameworks should explicitly support ethically approved secondary and future use of paediatric tissue to enable longitudinal research, supported by appropriate governance, transparency, and oversight.

The legislation should also clearly specify acceptable forms of consent.

Question 11

CCI supports the considerations outlined in Proposal 19, including the requirement that a child’s consistently expressed unwillingness must be determinative.

The broad interpretation of “best interests” appropriately reflects the medical, psychological, and relational factors relevant to decisions involving children.

We recommend that the Committee also consider:

- The provision of age-appropriate information and appropriate psychosocial support for the child and their family;
- Recognition of the importance of maintaining flexibility within the consenting process, including staged or delayed consent where appropriate, to ensure sample integrity while responding appropriately to the significant emotional and psychological burden experienced by children diagnosed with cancer and their families;
- The long-term implications of tissue removal, storage, and potential future or secondary use; and
- The need for nationally consistent decision-making to avoid variable outcomes for children across jurisdictions.

These additional considerations would strengthen protections for children while enabling ethically approved paediatric research to proceed proportionately and consistently.

Question 12

CCI supports the removal of tissue for ethics-approved research without Committee approval, consistent with Proposal 35.

Requiring Committee approval in these cases would impose unnecessary delays without improving participant protection.

Question 13

CCI considers the considerations set out in Proposal 22 to be appropriate for adults without decision-making capacity. CCI recommends that these be strengthened by:

- Explicitly recognising any previously expressed preferences regarding research participation.
- Acknowledging minimal-risk research contexts where participation has received ethics approval, to support proportionate decision-making.

Question 14

CCI considers that ethics-approved research conducted in accordance with the National Statement should not require additional Committee approval beyond existing Human Research Ethics Committee processes.

Question 15

CCI supports a multidisciplinary Committee composition that includes legal, clinical, research, and community representation.

Where decisions involve children, the Committee should include appropriate paediatric expertise.

CCI also supports a national committee model, supported by consistent guidance, to promote nationally consistent decision-making and avoid jurisdictional divergence.

Question 16

CCI supports reforms that improve clarity and efficiency in consent and authorisation frameworks.

Where valid consent and authorised decision-maker arrangements provide clear legal authority, CCI agrees that additional authorisation requirements should not be necessary, provided appropriate safeguards remain in place.

Question 17

CCI considers that Proposal 23 provides an appropriate balance between individual autonomy, flexibility where consent has not been expressly recorded, and respect for the role of next of kin. By prioritising the known wishes of the deceased and providing clear authority for authorised decision-makers, the proposal supports timely and ethical tissue donation for medical and research purposes.

The main advantage of this approach is increased clarity and efficiency in consent and authorisation processes. However, a possible disadvantage is the risk of uncertainty where the deceased's preferences are not documented, which reinforces the importance of clear guidance and sufficient consent documentation.

Question 18

CCI supports legislation that provides clarity about acceptable forms of consent to deceased donation.

Clear guidance on consent supports consistency, transparency, and public confidence.

Recognising written consent as a primary form, while allowing flexibility for other forms of consent, such as verbal, where appropriate and properly documented, would ensure the framework remains practical and responsive without creating unnecessary barriers.

It should also recognise digital consent as a valid and increasingly common mechanism, ensuring the framework remains contemporary and technology enabled.

Question 19

CCI supports a clear and nationally consistent authorised decision-maker hierarchy that prioritises the deceased person's known wishes and promotes timely, consistent decision-making in deceased tissue donation contexts.

Question 20

CCI supports a legislative approach that prioritises the deceased person's known wishes and values where authorised decision-makers of equal status disagree. Where those wishes are clearly documented or can be reliably established, they should guide the decision.

In the absence of clear evidence of the deceased person's preferences, the framework should promote timely and proportionate resolution, recognising the time-sensitive nature of donation decisions.

Where disagreement cannot be resolved within a reasonable timeframe, CCI considers it appropriate that the donation does not proceed, to maintain public trust and provide certainty for clinicians and researchers.

Question 21

CCI considers the definition of pre-mortem interventions in Proposal 26 to be appropriate, as it clearly distinguishes procedures undertaken solely for the purpose of post-mortem tissue donation from activities performed as part of a person's clinical care.

To support consistent application, CCI recommends that accompanying guidance clearly articulate the boundary between clinically indicated care and interventions undertaken solely to support donation or research, to minimise uncertainty for clinicians, researchers, and families.

Question 22

CCI considers that a narrowly defined exception may be appropriate for minor, minimal-risk procedures undertaken solely to assess suitability for tissue donation where obtaining prior consent is impracticable, provided strict limits and safeguards apply.

Question 23

We have no additional safeguards to propose beyond valid consent and existing ethics oversight.

Question 24

CCI supports legislation that provides high-level guidance to promote consistent and transparent decision-making where coroners are asked to consent to tissue donation.

Any factors should balance the integrity of coronial investigations with respect for the deceased person's known wishes and the public interest in ethically approved medical research.

Question 25

CCI supports allowing individuals to provide advance consent during their lifetime to a post-mortem examination, as this supports timely and ethically approved medical research.

Question 26

CCI considers that any exception should be tightly limited and permit authorisation only by another authorised decision-maker, where one is available, or otherwise by an independent statutory authority, where reasonable efforts to locate any authorised decision-maker have failed.

Question 27

The Institute supports consent as the default requirement for the use of tissue removed during a post-mortem examination.

CCI considers that any exception should be limited and apply only to small, minimal-risk samples that are de-identified and used for clearly defined medical research purposes, where appropriate ethical oversight is in place.

Any such exception should be tightly circumscribed to maintain public trust and respect for donor autonomy.

Question 28

CCI supports allowing tissue to be removed from adults without decision-making capacity for use in research where the research is ethically approved and cannot reasonably be conducted otherwise.

Any such provision should be subject to clear safeguards, including consent from a legally authorised substitute decision-maker, and respect for the individual's known wishes.

Question 29

We support consent as the foundation for the use of human tissue. However, CCI strongly advocates for reformed secondary use provisions that establish clear and practical pathways for ethically approved research where re-consent is impracticable or would unduly impede important research with clear public benefit is clear.

Current jurisdictional inconsistencies create significant barriers to research, with differing approaches across states and territories.

National reform should enable secondary use through consistent safeguards that protect donors, maintain public trust, and prevent unnecessary delay to critical research.

Question 30

CCI considers that limited exceptions to a consent requirement are appropriate where re-consent is impracticable, and the proposed use has been approved through existing ethics review processes.

Any such exception should be narrowly framed, limited to research of clear public benefit, and implemented in a way that avoids duplication or additional administrative burden.

Question 31

CCI acknowledges that the inclusion of high-level legislative principles governing the storage, access, transfer, and disposal of human tissue used in research biobanks may promote consistency and public trust.

However, any detailed operational requirements should be addressed through guidance aligned with existing ethics and biobanking frameworks, to maintain flexibility and avoid unnecessary administrative burden for researchers.

The above, if adopted, should be developed in consultation with researchers to ensure it is practical and proportionate.

Question 32

CCI considers that national guidance and coordination, rather than new regulatory frameworks, would be beneficial for research biobanks that store and/or distribute human tissue.

For educational collections of human tissue, CCI considers that guidance alone is appropriate, given their differing purposes and generally lower risk profile.

Any national approach should be designed to complement existing oversight and governance arrangements, without creating additional approval bodies or duplicative effort.

Question 33

Refer to the above.

Question 34

We acknowledge the importance of transparency and donor autonomy and consider that any right of access should be clearly defined and proportionate, limited to the individual donor or their authorised decision-maker, and focused on access to information about stored tissue rather than physical possession, without compromising research integrity, privacy, or ethical governance.

Question 35

CCI acknowledges the importance of maintaining consistent ethical standards and public trust in relation to the prohibition on exchanging human tissue for reward, including in cross-border contexts.

If extra-territorial application is pursued, CCI considers that a nationally consistent Commonwealth mechanism would provide greater clarity than state-based approaches.

Question 36

No comment.

Question 37

No comment.

Question 38

No comment.

Question 39

No comment.

Question 40

We acknowledge that the Commonwealth may consider including a mechanism in new human tissue legislation to provide assurance that imported human tissue is ethically sourced and obtained with appropriate consent.

If such a mechanism is included, it should operate at a system level, avoid additional reporting requirements for research institutes, and preserve access to internationally sourced tissue required for medical research, including paediatric cancer.

Question 41

If a prohibition is legislated, it should include a clear exemption mechanism to ensure that critical medical research is not impeded.

In determining whether an exemption is justified, relevant factors should include the health needs of Australians, including children; the presence of a high unmet research need; whether suitable tissue can be reasonably sourced domestically; and the level of ethical risk associated with the source of the tissue.

Exemptions should be applied in a transparent and risk-based manner.

Question 42

There is value in improved, high-level data to better understand the availability of human tissue and identify areas of unmet need that may affect medical research, particularly for paediatric diseases.

Any data collected should be aggregate and system-focused, aimed at informing policy development and future planning.

Question 43

Data collection should be proportionate and designed to minimise additional burden on research institutions.

Where data is collected, it should be voluntary and built on existing systems and processes, rather than introducing new reporting requirements.

Approaches that support system-level coordination are preferable to prescriptive reporting frameworks.

Question 44

We do not consider additional inspection powers to be necessary for the purpose of improving system-level data.

Existing ethics, governance, and regulatory oversight arrangements already provide appropriate safeguards, and introducing further inspection powers would risk unnecessary compliance burden without a clear benefit to patients or research outcomes.

Question 45

CCI operates within a strong framework of existing ethics, governance, and legislative requirements and takes its compliance obligations seriously.

Compliance with new human tissue laws should therefore be supported primarily through an educational approach, with enforcement mechanisms proportionate to risk and severity.

A graduated model that prioritises education and remediation, and reserves stronger enforcement for serious or systemic non-compliance, would support ethical practice while avoiding unnecessary regulatory burden on legitimate research activities.

Question 46

CCI recommends that the implementation of any reforms should be staged and proportionate.

Adequate lead times and transitional arrangements will be important to enable medical research institutes to align with new requirements using existing governance and ethics frameworks, without diverting resources from patient-focused research and care.

Question 47

N/A

Conclusion

CCI supports amendments to human tissue laws that enable timely and appropriate access to human tissue for medical research.

Reform should be developed through continued consultation with the medical research sector, including CCI, and implemented in a staged manner to allow for clear guidance and transition.

Any new framework should adopt a risk-proportionate approach to compliance, building on existing ethics and governance arrangements, and avoid unnecessary regulatory burden that could impede critical medical research.

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

Yours sincerely,

[redacted]

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