THE UNIVERSITY OF WESTERN AUSTRALIA

23 January 2026

Australian Law Reform Commission

Review of Human Tissue Laws: Issues Paper submission

Australian Government

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Submission to the Australian Law Reform Commission - Review of Human Tissue Laws

Dear Commissioner,

I write to you as both a bereaved mother whose child died suddenly and unexpectedly, and as a researcher who has dedicated her life to ensuring that families facing similar circumstances are not left without answers.

Following the sudden and unexplained death of my child, I came to understand both personally and painfully the profound absence of knowledge that exists for families affected by Sudden Infant Death Syndrome (SIDS) and Sudden Unexplained Death in Childhood (SUDC). There is a clear and concerning decline in both the volume and momentum of research in this field, despite the ongoing devastation these deaths cause. The lack of robust, coordinated research left families without explanations and the scientific community without the tools needed to advance understanding or prevention.

This reality led me to return to university as a mature-age student, completing a Bachelor of Biomedical Science at the University of Western Australia, graduating with Honours. I am now undertaking a PhD, the *Sudden Insights Research Study*, which investigates the microbial and immunological origins of SIDS and SUDC. This work is driven by a deep commitment to translating loss into knowledge, and knowledge into prevention.

In navigating the ethical and regulatory processes required to conduct this research, it became clear that there is no consistent, transparent, or sustainable pathway for accessing post-mortem tissue for research purposes. The current legal and procedural landscape is fragmented, unclear, and often prohibitive creating an ethical minefield for researchers and, importantly, a missed opportunity for families who wish to contribute to research in the hope that other children's lives may be saved.

I firmly believe that reigniting SIDS and SUDC research requires the creation of lawful, ethical, and compassionate avenues for sustainable research to occur. Central to this is ensuring that human tissue laws are conducive to allowing parents to donate tissue with clarity, dignity, and ease, particularly in the post-mortem context.

As part of the Sudden Insights Research Study, we have undertaken initial community engagement with bereaved parents to understand their views on consent and the use of tissue for research. I have included a link here to this engagement.

Unanimously, parents expressed that research is vital, that progress cannot be made without tissue donation, and that they would all actively consent to their child's tissue being donated for research, given the opportunity. Many parents articulated a strong desire for reform, expressing that the opportunity to contribute to research offers meaning, purpose, and hope in the midst of profound loss. There is a common misconception that the donation of tissue will retraumatise families, however in my experience this is not the case, it is rather more traumatising for families to know research in the field is not progressing and tissue that could be used to find answers is unattainable in many cases.

I commend the Australian Law Reform Commission for undertaking this important review and respectfully ask that you give careful consideration to the voices of bereaved parents alongside the needs of researchers. Law reform in this area has the potential to enable the safe, ethical, and equitable use of tissue obtained at post-mortem, ensuring that critical fields of research—such as SIDS, SUDC, and other conditions reliant on post-mortem tissue—are no longer impeded by uncertainty or inconsistency.

Thank you for the opportunity to contribute to this review and for your commitment to law reform that is compassionate, evidence-based, and responsive to community need.

Yours sincerely,

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Submission by Melanie Andrew, Sudden Insights Research Study, to the ALRC for Review of the Human Tissue Act

Part A – Issues Paper: Relevance of ALRC Review of Human Tissue Laws to SIDS/SUDC Research

The following questions posed by the Issues Paper's are relevant to this submission;

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

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

3. What are good aims or objectives for laws governing how human tissue is obtained and used?

4. What principles should guide reform of human tissue laws?

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

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

My corresponding answers to relevant questions (1-6) are as follows;

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

My personal experience of how human tissue is obtained and used in Australia is informed by two perspectives: first, as a parent who lost a child suddenly and unexpectedly at the age of 15.5 months, and second, as a researcher working in the field of Sudden Infant Death Syndrome (SIDS) and Sudden Unexplained Death in Childhood (SUDC).

As a bereaved parent, I was not informed that archival tissue from my child was retained following post-mortem examination, nor was I made aware that this tissue could potentially be used for further diagnostic testing or donated for research purposes. At the time, decisions about tissue retention were made without my knowledge or involvement. In hindsight, this represents a missed opportunity both for my family, who may have sought further answers, and for research that could contribute to preventing future deaths.

From a parental perspective, I view the option to donate tissue in a way similar to organ donation. Infants and young children who die from SIDS or SUDC are often not eligible for organ donation, removing a pathway that many families use to find meaning or legacy following a death. The ability to donate tissue for research would have provided an opportunity for legacy and contribution, offering comfort in knowing that my child's death may help prevent future tragedies. Rather than escalating grief or causing additional distress, this opportunity could

have supported the grieving process by allowing parents to exercise agency, purpose, and hope at a time when so much feels out of their control.

This lived experience has highlighted to me that current practices are often driven by fear—fear of causing distress, fear of retraumatising families, and fear of legal or ethical repercussions. While these concerns are understandable, the result is that parents are not always given the opportunity to make informed choices. Many bereaved parents want transparency, agency, and the option to contribute to research. Laws governing human tissue need sufficient flexibility to allow parents to use or donate tissue freely, with appropriate safeguards, rather than having decisions made on their behalf.

From a researcher's perspective, my experience has been one of navigating significant ethical and procedural barriers to accessing post-mortem tissue for research. Conducting ethically approved research in this area has required an exceptional level of dedication and persistence due to unclear processes, inconsistent interpretations of legislation, and a lack of established pathways—this seems particularly onerous for research conducted outside of hospital settings. These barriers result in substantial delays, and in some cases, prevent research projects from proceeding at all and is a likely cause of diminishing research in the field.

While my research focus is SIDS and SUDC, I am deeply concerned that these challenges are not unique to this field. If access to tissue is this difficult for one area of critical public health research, it raises serious questions about how many other vital research projects, regardless of the study scope, across Australia are similarly impeded.

I wish to acknowledge that the Western Australian Coroner's Court has been supportive of my research endeavours. However, coronial services operate within the constraints of current legislation, which does not adequately support or enable research use of tissue, particularly beyond traditional hospital-based frameworks and does not allow for clear, sensitive consenting pathways for families.

Overall, my experience suggests that current human tissue laws and practices can unintentionally limit transparency, parental autonomy, and research progress. Reform is needed to support a system that is ethical, transparent, and responsive—one that respects families' rights to make informed decisions and enables researchers to responsibly advance knowledge in areas where answers are urgently needed.

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

My personal experience of how human tissue laws work in Australia is that, while they are intended to protect individuals and uphold ethical standards, in practice they are often unclear, fragmented, and overly restrictive—particularly in the context of post-mortem tissue and coronial investigations. These limitations affect both bereaved families and researchers and can unintentionally impede transparency, autonomy, and scientific progress.

As a parent, I experienced the operation of human tissue laws as opaque and paternalistic. Decisions regarding the retention, use, and potential future testing or donation of my child's tissue were made without my informed involvement. I was not provided with clear information about what tissue was retained, how long it would be stored, or whether I could consent to its use for further diagnostic purposes or research. The legal framework appeared to prioritise institutional risk management over parental choice, resulting in decisions being made on behalf of families rather than with them.

As a researcher, I have experienced human tissue laws as inconsistent in their interpretation and application across jurisdictions and institutions. Access to post-mortem tissue for ethically approved research is not governed by a clear, standardised process, particularly for research conducted outside of hospital settings. Instead, researchers must navigate a complex and time-consuming system involving multiple approvals, varying legal advice, and differing interpretations of what is permitted under the same legislation. This creates uncertainty, delays, and in some cases, results in research being abandoned altogether.

My experience has shown that the laws lack the flexibility required to support modern, community-informed research practices. Even where there is strong ethical oversight, parental willingness to consent, and demonstrable public benefit, the legal framework can prevent tissue from being accessed or shared. This is particularly problematic in rare and sensitive fields such as SIDS and SUDC, where each case represents a critical opportunity to advance understanding.

Overall, my experience is that Australia's human tissue laws, as they currently operate, are risk-averse rather than facilitative. They do not sufficiently reflect the wishes of many bereaved families, nor do they adequately support researchers working to address significant gaps in knowledge. Reform is needed to provide clarity, consistency, and flexibility—ensuring that human tissue laws protect individuals while also enabling ethical, transparent, and socially valuable research.

3. What are good aims or objectives for laws governing how human tissue is obtained and used?

Laws governing the obtaining and use of human tissue should aim to protect individuals while also enabling ethical, timely, and socially valuable research. Based on my lived experience as a bereaved parent and my professional experience as a researcher, I believe the following objectives are critical.

First, human tissue laws should prioritise informed, transparent, and flexible consent. Consent processes should recognise that many decisions regarding tissue are most appropriately considered as part of the post-mortem process, when information can be provided clearly and compassionately, and when parents can be supported to make informed choices. Laws should facilitate consent that is timely and meaningful, rather than delayed to the point where tissue can no longer be used for diagnostic or research purposes.

Second, laws should support the establishment and operation of national or coordinated biobanks for research, with clear, standardised pathways for access. These biobanks should be designed to facilitate, rather than impede, ethically approved research, and should not be subject to excessive delays, prohibitive costs, or prolonged administrative processes that render research unviable. Efficient access is particularly important for time-sensitive or resource-limited research, including projects led by early-career researchers or those conducted outside major hospital systems.

Third, the legal framework should nurture an environment that actively supports research by providing flexibility in how consent and recruitment are managed. This includes allowing for opt-in strategies, the appropriate use of waivers of consent where ethical criteria are met, and consent processes that are sensitive to individual circumstances while remaining efficient and practical. A rigid, one-size-fits-all approach does not reflect the realities of post-mortem research or the diverse preferences of families.

Finally, laws should be underpinned by consistency, clarity, and proportionality. Researchers, coronial services, and families should be able to understand what is permitted, how decisions are made, and what safeguards are in place. The objective should be to balance protection with progress—ensuring that ethical oversight is strong, while also enabling research that addresses significant gaps in knowledge and delivers meaningful public benefit.

In summary, effective human tissue laws should empower informed consent, support timely access to tissue, enable sustainable research infrastructure, and foster a flexible, ethically robust research environment that responds to both community expectations and scientific need.

4. What principles should guide reform of human tissue laws?

Reform of human tissue laws should be guided by principles that balance protection, transparency, and respect for individuals with the need to enable ethical, timely, and socially valuable research. Based on my experience as both a bereaved parent and a researcher, the following principles are central to effective and compassionate reform.

Respect for autonomy and informed choice
Human tissue laws should recognise the right of individuals and families to make informed decisions about the use of human tissue. Reform should move away from paternalistic models in which decisions are made on behalf of families, and toward frameworks that actively support informed, voluntary choice, including the option to consent to research use where desired.

Transparency and trust
Reform should promote openness about what tissue is retained, how it may be used, and what options are available to families. Transparency is essential to building trust between families, coronial services, health institutions, and researchers. Withholding information out of concern for distress can undermine trust and deny families agency.

Trauma-informed and compassionate practice
Human tissue laws should be implemented in ways that acknowledge grief and vulnerability, without assuming that discussion of tissue use or research participation is inherently harmful. Trauma-informed approaches should focus on sensitivity, clarity, and choice, recognising that many families find meaning and comfort in contributing to research.

Proportionality and flexibility
Legal safeguards should be proportionate to risk and flexible enough to accommodate different research contexts. Reform should allow for varied consent models, including opt-in strategies, staged consent, and ethically approved waivers of consent where appropriate, rather than enforcing rigid, one-size-fits-all requirements.

Facilitation of ethically approved research
A core principle of reform should be that laws do not unnecessarily impede research that has clear ethical approval and public benefit. Human tissue laws should actively enable, rather than obstruct, responsible research, particularly in areas where tissue is scarce and each opportunity is significant.

Consistency and clarity across jurisdictions
Reform should aim to reduce inconsistency in how human tissue laws are interpreted and applied across states, territories, and institutions. Clear, nationally consistent principles would reduce uncertainty for families and researchers and support equitable access to research opportunities.

Equity and public benefit
Finally, reform should recognise the collective benefit of research and ensure equitable access to tissue for legitimate research purposes. Laws should support research that serves the public interest and addresses unmet medical and scientific needs, while maintaining strong ethical oversight.

Taken together, these principles support a human tissue law framework that is ethical, transparent, compassionate, and future-focused—one that respects families, supports researchers, and enables meaningful progress in areas where answers are urgently needed.

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

Yes, I strongly agree that the issues identified in the *'Priority reform areas'* should be a central focus of this Inquiry, particularly the need for consistent, clear, and ethically robust frameworks governing post-mortem and coronial tissue. My experiences as both a bereaved parent and a researcher highlight that current laws and practices vary significantly across jurisdictions, creating substantial barriers for families and research.

Across Australia, there is often **no customised approach to post-mortems**, even for sensitive cases such as SIDS and SUDC. In many instances, pathologists themselves are unaware of what tissue may be retained in archival cases, and families are frequently not informed that

tissue exists. My experience and engagement with other families indicate that many would value the opportunity to have this tissue used in a meaningful way, whether for further testing or research, but only if they are provided with clear information and choice. Families should be informed as part of the post-mortem process about what tissue is retained, how long it will be stored, and the options for future use, in a manner that is sensitive, transparent, and supportive.

Jurisdictional inconsistency further compounds these challenges. Cause-of-death classifications differ between states, making it difficult to obtain accurate rates of SIDS and SUDC across Australia and impeding national research. Similarly, access to post-mortem tissue varies, both in terms of retention practices and the processes for obtaining consent. These inconsistencies result in delays, lost research opportunities, and, in some cases, the inability to conduct ethically approved studies, even when families are willing to participate.

Reform should therefore prioritise:

- **Nationally consistent retention and access protocols** for post-mortem and coronial tissue, including clarity about what tissue may be stored and for how long;
- **Transparent, compassionate consent processes** for parents and next-of-kin, integrated into the post-mortem process, allowing families to make informed choices about the use of tissue;
- **Harmonisation of cause-of-death reporting**, particularly for SIDS and SUDC, to enable accurate national data and research;
- **Ethical, lawful access for research**, ensuring that tissue can be used to answer critical public health and scientific questions without compromising family rights or ethical standards.

Addressing these areas would create a system that is both supportive of families and enabling for researchers. Families would have agency and clarity regarding tissue retention and use, while research that is ethically approved and socially valuable could proceed efficiently and consistently across jurisdictions. Ultimately, reforming these priority areas would ensure that human tissue laws balance protection, transparency, and public benefit, particularly in sensitive and rare cases such as SIDS and SUDC.

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

In addition to the priority reform areas identified by the Commission, I suggest the Inquiry also consider the following issues:

1. **Parental awareness and engagement**
   Many families are not informed that tissue from their child is retained, or that it could be used for further testing or research. Laws and processes should ensure that parents are proactively provided with this information and supported to make informed decisions, in a way that is sensitive to grief and trauma. Clear communication, integrated into the post-mortem process, should be a legal and procedural expectation.

2. **Post-mortem procedures and pathologist guidance**
   Across Australia, there is often no standardised, customised approach to post-mortems for rare or sensitive cases. Pathologists themselves may be unaware of what tissue is retained in archival cases, which leads to inconsistency and missed research opportunities. Reform should include clear guidance and protocols for pathologists and coronial staff regarding tissue retention, consent, and research use.

3. **National data consistency**
   Cause-of-death reporting and classification for SIDS and SUDC varies between states, making it difficult to obtain reliable national data and impeding research. Reform should prioritise harmonised reporting standards to improve consistency, accuracy, and comparability of post-mortem findings across jurisdictions.

4. **Access to tissue for research**
   Current laws and procedures can create lengthy delays, bureaucratic hurdles, and uncertainty about lawful pathways to access tissue, particularly for research conducted outside hospital settings. The Inquiry should explore mechanisms to enable ethically approved research while maintaining robust safeguards, including nationally consistent biobanks, clear consent pathways, and streamlined access procedures.

5. **Support for families and trauma-informed processes**
   Families navigating post-mortem processes are vulnerable and grieving. Law and practice should emphasise trauma-informed approaches, ensuring that consent, communication, and research participation do not exacerbate distress, but rather provide opportunity for legacy and meaning.

6. **Future-proofing for research and innovation**
   Human tissue laws should be adaptable to emerging research technologies, including genomics, microbiome studies, and long-term biobanking. Reform should ensure that tissue retained today can be ethically and lawfully used to answer future research questions, while maintaining parental rights, privacy, and transparency.

Addressing these additional issues alongside the priority reform areas will help create a human tissue law framework that is consistent, compassionate, and research-enabled, while respecting the rights and wishes of families and next-of-kin.

Part B – Discussion Paper: Relevance of ALRC Review of Human Tissue Laws Proposals to SIDS/SUDC Research

My research, the Sudden Insights Research Study, conducted in conjunction with the University of Western Australia and Red Nose Australia, investigates microbial and immunological causes of Sudden Infant Death Syndrome (SIDS) and Sudden Unexplained Death in Childhood (SUDC). The success of this study and the broader advancement of knowledge in this area depends critically on access to post-mortem tissue, parental consent pathways and consistent, transparent and easy to navigate governance. Several ALRC proposals are directly relevant:

1. Proposal 31 – Use of post-mortem tissue for research

Proposal 31 provides that tissue removed during a post-mortem cannot be used for research or other purposes without valid consent. While this principle is essential to ensure ethical research, a strict or rigid interpretation can limit families' ability to participate and impede timely research. In SIDS/SUDC research, families are approached in highly sensitive circumstances, and legislation must be flexible enough to allow trauma-informed consent, staged consent, opt-in or follow-up consent after the initial post-mortem.

In some circumstances, a waiver of consent may also be appropriate—for example, when tissue is de-identified—and legislation should explicitly allow this as a viable option to enable research that would otherwise be blocked.

Challenges and practical considerations:

- Access to next-of-kin information is often restricted, making it difficult for researchers to seek consent or gauge interest in participation, particularly if consent must be obtained prior to the post-mortem in order for tissue to be collected.
- The post-mortem itself is arguably the most convenient, sensitive, and ethically sound time to obtain tissue, especially fresh tissue needed for research. Many post-mortems occur within 24–72 hours after the death of a child, making immediate parental consent in this window highly challenging.

To address this, legislation should allow for additional tissue to be collected and temporarily stored fresh at the time of the post-mortem, while parents are given adequate time to consider consent once the initial post-mortem report is released. Parents could then decide whether the excess tissue may be:

1. Donated for research,
2. Placed in a biobank for future research, or
3. Stored with archival tissue.

This approach reduces the burden on families to make critical decisions in a very short period, allows more thorough consultation, and ensures research can proceed ethically without unnecessary delays.

- Certain studies require fresh tissue, and reliance solely on archival samples can compromise the robustness and validity of the research. A rigid, blanket consent model under the current Proposal 31 framework will continue to impede research and limit the ability of families to meaningfully contribute to understanding rare and devastating conditions such as SIDS/SUDC.

By incorporating flexible, staged, and deferred consent options, legislation can balance ethical safeguards with practical realities of post-mortem research, ensuring both families and researchers are supported.

2. Proposal 36 – Consent by authorised decision-makers

Proposal 36 recognises that an authorised decision-maker, such as a parent or next-of-kin, can provide consent for research use of tissue if the deceased did not provide prior consent. This proposal is critical for SIDS/SUDC research, where all cases involve infants or young children who cannot consent for themselves. It provides a legal pathway for parental consent, enabling research to proceed ethically while respecting the wishes of the family.

Challenges and practical considerations:

- Identifying the appropriate authorised decision-maker can be complex, particularly in multi-jurisdictional or coronial contexts. Clear procedural guidance is essential to ensure parents or guardians understand their role and responsibilities.
- Consent often needs to be obtained within the 24–72 hour post-mortem window to allow tissue collection. This is a period of intense grief, and seeking consent under these conditions can be emotionally overwhelming for families.
- To address this, legislation should allow for staged or deferred consent, where tissue may be temporarily collected and stored fresh at the time of the post-mortem, and parents are given time to make informed decisions once the initial post-mortem report is released. Families could then choose whether the tissue is donated for research, placed in a biobank, retained as archival material or returned. This approach reduces pressure on grieving families while ensuring valuable research can proceed.
- The framework should also be flexible enough to accommodate waivers of consent in circumstances where tissue is de-identified or where minimal risk is involved, further enabling research that might otherwise be blocked.

Importance for research:
Without such flexibility, rigid implementation of Proposal 36 risks delaying or preventing research, particularly in areas like SIDS/SUDC where timely access to fresh tissue is essential. Incorporating deferred consent, staged consent, and parental choice ensures that legislation

supports both ethical rigor and practical feasibility, enabling families to meaningfully contribute to research without undue distress. Clear guidance on coordination with coronial authorities is also essential to avoid delays, ensure ethical oversight, and support families in making informed decisions.

By embedding these flexible mechanisms into Proposal 36, legislation can balance protection of children and family autonomy with the needs of researchers to conduct timely, high-quality studies that may ultimately save lives and prevent future tragedies.

3. Proposal 23 – General consent framework

Proposal 23 establishes a broader framework for consent for the use of human tissue, which is critical for ethically robust SIDS/SUDC research. In practice, consent frameworks must be sensitive, flexible, and trauma-informed, recognising the profound grief families experience when a child dies suddenly and unexpectedly.

Comprehensive consent considerations for SIDS/SUDC research:

- Consent should be opt-in, ensuring that families are fully informed and voluntarily choosing whether to donate tissue for research or biobanking. Families should never feel pressured, coerced, or obligated.
- In certain circumstances, a waiver of consent should also be permitted—for example, where tissue is de-identified or only minimal risk is involved. This allows important research to proceed without placing undue burden on grieving families.
- Consent should be embedded within the coronial and post-mortem process, ideally at the time of the post-mortem or when the interim death report is released, as suggested above. This ensures parents can make informed decisions once they are able, without being repeatedly approached by multiple independent researchers.
- A staged or deferred consent process should be available: tissue may be temporarily collected and stored fresh at post-mortem, giving parents time to decide whether it may be donated for research, placed in a biobank, or retained as archival tissue. This respects families' emotional capacity while preserving tissue viability for high-quality research.
- Consent discussions should be clear, concise, and informative, providing families with the key facts they need to make a decision without overwhelming them. Ethical guidance and support should be provided at all stages to ensure parents feel respected and informed.
- Ethically approved research should be able to follow a clear procedural pathway to apply for tissue access. If consent for research tissue donation is systemically integrated in the coronial process, it reduces the need for researchers to directly contact families and reduces the risk of additional psychological trauma on families. A clear, concise, one point of contact approach is the most viable and efficient option moving forward.

Challenges and practical considerations:
Without a flexible, embedded, and trauma-informed consent framework, research in SIDS/SUDC is significantly impeded. Families may be excluded from contributing due to overly rigid processes, and repeated requests from independent researchers can risk exacerbating the emotional trauma a family is already facing at this devasting time. A lack of standardisation in consent practices also creates legal uncertainty, delays, and inconsistencies in tissue access, which compromises the robustness and timeliness of research.

By embedding consent in the coronial process, allowing opt-in, staged, deferred, and waiver options, and providing clear procedural pathways for ethically approved research, Proposal 23 can ensure that both family autonomy and high-quality research are protected, enabling studies to advance the understanding of rare and devastating conditions such as SIDS and SUDC.

4. Proposals 32–34 – Biobanks, storage, and access

- Proposal 32: National regulation of research biobanks storing human tissue.
- Proposal 33: Defines which collections should be included.
- Proposal 34: Right of individuals or families to access stored tissue.

SIDS/SUDC research relies on archival tissue being retained, accurately catalogued, and accessible across jurisdictions. Currently, many families are unaware that tissue from their child exists or is stored in archives, and there is no standardised approach to retention, cataloguing, or access. To support sustainable and ethical research, tissue should be digitally catalogued, including details of type, quantity, and storage location, and could leverage existing systems such as the National Coronial Information System (NCIS).

It is also essential that legislation clearly defines what constitutes human remains. For example, bioproducts of tissue extraction, such as total nucleic acids, may not currently be classified as human tissue. Clarifying that such bioproducts can be considered within the scope of the Act or explicitly enabling their research use would provide a more accessible avenue for ethically approved studies while removing unnecessary legal barriers.

Challenges and practical considerations:

- Without consistent biobanking, digital cataloguing, and clear definitions, access to tissue is fragmented, research is delayed, and families are denied the opportunity to contribute meaningfully to investigations.
- Separate coronial processes in each state and territory create additional barriers. Researchers often need to navigate multiple Human Research Ethics Committees and governance bodies, many of which lack clear procedures for obtaining tissue. This is time-consuming, resource-intensive, and in some cases results in researchers abandoning studies entirely, limiting progress in understanding conditions like SIDS and SUDC.

- A national biobank with clear, uniform policies for tissue storage, cataloguing, and access would provide a streamlined, transparent pathway for ethically approved research. Embedding consent and access pathways within this framework would reduce duplication, protect families from repeated approaches, and enable sustainable research that could lead to meaningful improvements in the health outcomes of Australian children.

Summary:
Nationally standardised biobanking, digital cataloguing, and clear legislative definitions are essential enablers of SIDS/SUDC research. Together, they ensure tissue is available, ethically managed, and accessible to researchers without unnecessary delays, while allowing families to participate in a meaningful, informed, and trauma-sensitive way.

5. Proposals 42–44 – Data and research governance

These proposals focus on the collection, reporting, and auditing of tissue used for research. For SIDS/SUDC, accurate, consistent national data on cause of death, tissue availability, tissue quantities, tissue types and retention practices is essential to identify patterns, prioritise research, and track outcomes. Harmonised digital records, potentially integrated with systems like the National Coronial Information System (NCIS), would greatly improve transparency, consistency, and research efficiency.

Challenges and practical considerations:

- Without mandatory reporting, clear definitions of tissue, and nationally standardised databases, access to information is fragmented.
- Legal and procedural inconsistencies between states can block ethically approved research, reduce collaboration, and impede progress in understanding rare and devastating conditions such as SIDS/SUDC.
- Standardised, auditable governance systems would enable researchers to identify available tissue quickly, reduce duplication of effort, and ensure families are approached sensitively and only when appropriate.

6. Proposals 45–47 – Implementation, compliance, and urgent reform

These proposals focus on practical mechanisms for implementing legislation, ensuring compliance, and addressing urgent gaps. For rare and time-sensitive research like SIDS/SUDC:

- Delays in reform or inconsistent application across jurisdictions directly result in missed research opportunities.
- Families may be prevented from contributing meaningfully to research due to procedural uncertainty or inconsistent approaches to consent and tissue retention.

- Clear implementation frameworks, supported by national guidance, would streamline ethically approved research, providing consistent pathways for both families and researchers, while maintaining public trust.
- With no clear pathways or procedures for acquisition of tissue for research purposes, researchers are often given no choice but to abandon their studies, leaving SIDS/SUDC research to decline. There needs to be urgent reform that is supportive not inhibitive of research, particularly in paediatric studies where post mortem tissue is required to progress knowledge.

Summary

Collectively, these proposals provide a framework to enable ethical, lawful, and family-centered research in SIDS/SUDC. For this framework to be effective, legislation must:

- Allow flexible, trauma-informed consent, including staged, deferred, or waived consent where appropriate;
- Provide clear guidance and support for parents, next-of-kin, and coronial authorities;
- Harmonise post-mortem tissue retention, cataloguing, and cause-of-death reporting across jurisdictions, utilising digital systems like the NCIS;
- Clearly define human tissue and bioproducts, enabling ethically approved research to proceed without unnecessary legal barriers;
- Ensure ethical, timely, and transparent access to stored tissue;
- Support national governance, reporting, and compliance mechanisms to promote consistency and accountability.

Implementing these measures would allow families to make informed, meaningful decisions regarding tissue donation, while enabling SIDS/SUDC research to be feasible, ethically robust, and impactful, ultimately improving understanding of these devastating conditions and contributing to better health outcomes for Australian children.

Conclusion

I am deeply concerned that research into SIDS and SUDC—the field to which I have devoted my life since the passing of my own daughter, is currently stymied, and that this is not only limiting progress in understanding these devastating conditions but also affecting research into other paediatric conditions that rely on post-mortem tissue. The current legal and procedural barriers are significantly impeding the advancement of health knowledge, and there is an urgent need to establish clear, practical pathways that support rather than inhibit ethically approved research.

I am, of course, fully supportive of protecting the rights and autonomy of families, including ensuring that consent is informed and voluntary, and that any waiver of consent is applied only

through a rigorous assessment pathway. However, it is vital that legislation does not unintentionally block research in fields where discoveries could save lives, uncover causes, or improve outcomes. When laws are so rigid that obtaining post-mortem tissue is excessively difficult, or the manner in which consent must be sough is impractical, the ultimate sufferers are future children who could have benefited from advances in understanding and prevention.

I strongly urge the Commission to ensure that reform in human tissue laws actively supports research, particularly in areas such as SIDS/SUDC, by providing flexible, ethically robust pathways for consent, tissue retention, access, and biobanking. Doing so is not only a matter of research efficiency, it is a matter of justice for children and families, now and in the future, and an essential step toward improving paediatric health outcomes in Australia.