List of questions. Remember, you only need to answer the questions you want to answer

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

This submission has been prepared by members of the Consortium for Australian Children's Trials in Brain Cancer (CoACT: Brain Cancer). CoACT: Brain Cancer is an alliance of childhood brain cancer specialists from leading Australian cancer research groups, international clinical trial consortium partners, and the nine Australian Children's Cancer Centres. We operate as part of the Australian and New Zealand Children's Haematology and Oncology Group (ANZCHOG) and unite 77 researchers from over 30 institutions specialising in childhood brain cancer clinical trials, preclinical research, diagnosis, survivorship, QoL, neuropsychology, radiation oncology, AYA, consumer advocacy, and bioinformatics. Our common goal is to increase clinical trial participation opportunities for children with brain cancer and to improve patient outcomes

Across Australia, there are numerous biobanks that are in place to facilitate high-quality research aimed at understanding and curing childhood cancers. Obtaining human tissue/cancer specimens from children involves a collaborative approach between clinicians, researchers, and families. Following approval by our local hospital and/or tertiary institution's independent ethics committees, informed consent is obtained from parents or guardian. Clear communication is provided about the purpose of the research, the handling of the tissue samples, how the tissue will be used and how patient privacy is maintained. Samples such as tumour tissue, blood, or cerebrospinal fluid are typically collected during routine clinical procedures, to minimise impost on patients. Alternatively, parents often choose to donate their child's brain after death for research. They are often motivated by a profound desire to create meaning from their loss and to help other families facing the same diagnosis. Donation offers a way to honour their child's life, contribute to finding a cure, and ensure their suffering was not in vain. Many parents find comfort in knowing their child's legacy may advance research and improve outcomes for future children. Upon donation, human tissue specimens are processed and stored in accredited biobanks, which adhere to national standards for biospecimen handling, but also ensures that the dignity and rights of young patients and their families are upheld throughout the research process.

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

We have direct experience navigating Australia's human tissue laws. We are a group of childhood brain cancer researchers and also act as managers of different cancer biobanks. As such, we have prepared multiple human ethics applications involving the use of paediatric cancer specimens, which requires in-depth understanding of national guidelines (e.g., the National Statement on Ethical Conduct in Human Research and the Privacy Act 1988) and state-specific legislation, including the Human Tissue and Transplant Act 1982 (WA), the Human Tissue Act (NSW).

Similar approval processes across different Australian hospitals ensures all research involving childhood brain cancer tissues is supported by valid informed consent, has scientific justification, and meets rigorous standards for governance, privacy, and custodianship. Our roles involve oversight of biospecimen access and facilitating responsible use of donated samples to support research aimed at improving outcomes for children with cancer.

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

- *increasing the amount of tissue available for transplantation and/or other uses;*
- *creating a transparent and easy to navigate tissue donation system;*
- *making sure tissue donation happens safely;*
- *making sure people have a good understanding of what is involved in donating tissue;*
- *making sure people understand how their tissue will be used;*

- *equity, and removing barriers faced by some individuals or groups to human tissue onation or transplantation;*
- *making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

In the context of childhood brain cancers, such as high grade gliomas (including diffuse midline glioma or DMG), and central nervous system (CNS) embryonal tumours (including medulloblastomas and atypical teratoid rhabdoid tumour or ATRT), these aims take on added urgency. These cancers are rare, devastating and under researched. Translational and preclinical research for these rare cancers is essential to ensure only the most promising treatments move forward into clinical trials, providing hope to families and accelerating meaningful clinical progress. Part of this involves the establishment of reliable preclinical models, uniformly reliant on donated tissue specimens, supported by robust ethically approved methodologies, transparent reporting and tested frameworks for evaluating new therapies and treatments.

A nationally unified approach – including our established Consortium for Australian Clinical Trials in Brain Cancer (CoACT:Brain Cancer), a Medical Research Future Fund (MRFF) supported national program – demonstrates how coordinated efforts can streamline access to rare specimens, enhance research impact, and respect the contributions of patients and families.

To ensure new regulations support research while respecting the privacy of families, several key actions should be taken:

1. **Simplify and standardise consent processes**: Introduce nationally consistent, broad consent models that allow parents to authorise future use of their child's tissue for ethically approved research, without needing repeated re-consent.
2. **Clarify governance pathways**: Streamline ethics and governance approval processes across jurisdictions (e.g., through mutual recognition of ethics review) to reduce duplication and delay in accessing samples for research.
3. **Promote public and clinician awareness**: Invest in education for families and hospital care providers about the value of tissue donation, empowering informed decision-making and increasing donation rates.
4. **Embed research into clinical care**: Formalise and support biobanking and research sample collection as part of standard oncology care, with clear ethical and legal safeguards.
5. **Enable responsible data sharing**: Align tissue laws with frameworks that also support access to and storage of linked clinical and genomic data, ensuring researchers can derive maximum insight from each donation.
6. **Engage researchers in policy development**: Include biobank managers, clinician-researchers, and consumer advocates in shaping legislation, ensuring it reflects practical realities and ethical imperatives.

4. When we think about reforming human tissue laws, what principles should guide reform? You might consider principles such as:

- *respect for persons and for the human body;*
- *equity;*
- *the importance of public trust in the framework that governs how human tissue is obtained and used in Australia;*
- *the importance of laws that are well designed and effective.*

Australia's human tissue laws should be guided by principles that both uphold ethical standards and remove unnecessary barriers to research. Regulation must be proportionate to risk, with clearer distinctions between low-risk uses (such as de-identified cell line generation or development of mouse models) and more sensitive applications (such as use of embryonic stem cells). Overregulation of minimal-risk, de-identified research hinders innovation without improving protections.

To support ethically sound and impactful research, reforms should enable broad or tiered consent models, allowing families to contribute to future research without repeated re-consent processes. This is particularly vital in childhood cancer, where tissue is often scarce, and the development of preclinical models is critical to finding cures. Ethically, there is a responsibility to ensure that rare and historically under-researched populations, such as children with high-grade brain tumours, are not excluded from the benefits of scientific progress. These groups risk being left behind as advances in technologies, collaborative networks, and clinical trial infrastructure increasingly rely on donated specimens to drive innovation and translation.

To ensure equitable progress continues, laws must be clear, consistent across states, and embedded within a research-supportive clinical culture. Tissue donation should be encouraged and seen as a routine and valued part of clinical care, not an exceptional activity. Transparent governance, with community involvement and public education, will help build trust and increase willingness to participate.

One of the key challenges in cancer tissue biobanking, particularly for rare diseases like childhood brain cancer, is the difficulty in accessing tissue from patients in rural and remote communities. When a child passes away far from a metropolitan hospital, there are often logistical, financial, and procedural barriers to enabling timely donation of tissue for the development of cell lines or patient-derived xenograft (PDX) models.

Access is limited by the lack of trained personnel authorised to collect and process tissue for research in regional areas, as well as by the prohibitive costs associated with transporting a deceased child to a tertiary facility. While some families are supported through philanthropic funding to make this possible, this is not a sustainable or equitable solution. As a result, valuable opportunities to advance research—particularly in rare paediatric cancers where every sample counts—are being lost. Overcoming these barriers is essential to ensure that all families, regardless of location, can contribute to research if they choose, and that progress towards better treatments is not limited by geography.

Finally, research-enabling governance frameworks are essential. Ethics and approval pathways should be efficient, risk-sensitive, and designed to facilitate timely access to biospecimens and associated data, while maintaining high ethical standards.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

For research to be both ethically responsible and efficient, it is critical to distinguish between original human tissue donations and laboratory-derived, de-identified models of cancer, such as established human cancer cell lines and patient-derived xenograft (PDX) models. Once tissue has been ethically obtained and converted into a validated research model, these derivatives should not be subject to the same level of regulation as primary human tissue donations. Applying human tissue governance to laboratory models in perpetuity creates unnecessary regulatory bottleneck that hinders innovation, delays therapeutic discovery and development, and places a disproportionate burden to researchers and committees without benefit—particularly in rare, urgent and underserved fields like childhood brain cancer.

There are several reasons to consider these as separate:

1. **They are no longer functionally or ethically equivalent to human tissue**
   Once a tumour sample is used to derive a stable, immortalised cell line or PDX model, it undergoes multiple biological changes and expansions, often in non-human hosts (e.g. mice). These models are laboratory constructs, not finite or intact human tissue. As such, they do not carry the same ethical sensitivity as the original biospecimen.
2. **They are de-identified and de-linked**
   In research practice, cell lines and PDX models are **de-identified**, and researchers working with them have no access to identifiable personal or clinical information. Their ongoing use

presents no risk to the donor, which is the central concern of human tissue laws. Regulating these models as if they are still human tissue creates unnecessary administrative burdens without improving protection.

3. **Overregulation delays research with no added benefit**
   Requiring ethics or re-consent processes for every downstream use of de-identified models **slows scientific progress**, especially in cancer research where time and samples are limited. For example, sharing a PDX model between labs or testing a new therapy in vitro should not trigger the same level of regulatory oversight as the original collection of the tumour.
4. **Current interpretation is inconsistent and limits collaboration**
   Inconsistent definitions of what constitutes "human tissue" across jurisdictions hinder national and international collaboration. Clarifying that established, de-identified models are no longer human tissue will reduce red tape and promote open, ethical sharing of research tools essential for translational impact. Delays have fatal consequences!
5. **Ethical oversight is already built into initial consent**
   When consent is obtained at the time of tissue collection for the purpose of generating cell lines or PDX models, patients and families agree to future research use including model development and its use in research. Provided this consent is in place, ongoing oversight through biobank governance and institutional ethics ensures responsible use. Additional regulatory classification adds duplication without improving accountability.

In terms of sharing models of childhood cancer with other researchers, Australian paediatric cancer biobanks do not provide reimbursement to donors or families, and most ethically approved projects prohibit selling donated tissue samples and the derivatives made from them (including data, cell lines or PDX models). However, funding is required to cover the cost of retrieving samples from storage and for shipping, which is most commonly provided by the researcher requesting the sample. Funding for paediatric cancer biobanks is variable across Australia, with most underpinned by philanthropic or family-run organisations; yet, the long-term economic and health benefits that arise from research that utilises donated human tissue are well documented. As such, dedicated and ongoing government funding to support these critical national resources is warranted.

6. What, if any, other issues should we be focusing on in this Inquiry?
You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about:
y if there are issues caused, or likely to be caused, by current or emerging technology that we haven't identified in this Issues Paper; and
y if there is a need to update the HTAs to account for contemporary community values, in ways that we haven't identified elsewhere in this Issues Paper.

It is essential that any reform or practice involving human tissue recognises and respects the cultural beliefs and values of diverse communities, particularly Aboriginal and Torres Strait Islander peoples, who may hold spiritual or cultural views about the body, tissue, and biospecimen use.
For biobanking to proceed in a culturally respectful and inclusive manner—particularly involving samples from Aboriginal and Torres Strait Islander peoples—it is essential that community consultation is undertaken by the right people, in the right way. Engagement with communities should be led by Aboriginal and Torres Strait Islander researchers in a genuine, ongoing, and culturally safe manner, ensuring that consent processes are not only legally valid, but also culturally informed. Where appropriate, specific protocols or governance structures—such as community advisory input or the involvement of Aboriginal health services—should guide the use of samples from these populations. We recommend that a clear set of national guidelines are developed in conjunction with Aboriginal and Torres Strait Islander communities to govern the use of human tissue in medical research.

Incorporating culturally safe practices and governance not only honours Aboriginal and Torres Strait Islander sovereignty and self-determination but also builds trust and improves participation, ensuring that the benefits of cancer research are shared equitably across all communities.

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?

In paediatric brain tumour research, where post-mortem tumour tissue fuels primary cell line culture, patient derived xenograft models, and therapeutic testing, an inconsistency not fully highlighted in the Issues Paper (page 15) is the varying consent requirements for research use of post-mortem tissue across states. South Australia's Transplantation and Anatomy Act 1983 requires specific consent for scientific uses, while Victoria's Human Tissue Act 1982 assumes consent for post-mortem examinations includes research. NSW's Human Tissue Act 1983 and Queensland's Transplantation and Anatomy Act 1979 mandate specific consent but allow exceptions for small samples. Varying rules hinder multi-state research collaborations, risk misaligned expectations, and erode trust in paediatric cases. Harmonising HTAs to create a national, explicit consent framework, covering initial and future research uses, is critical to expedite discoveries, streamline ethical research, support families, and maintain public trust.

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?

The Inquiry should reconsider sidelining emerging technologies such as AI, computational analysis and genetic analysis, which are listed under "Issues we are unlikely to focus on" (p. 19). In our field, tumour and blood donations generate genomic and clinical datasets that AI analyses to identify treatments or personalise care, often shared across jurisdictions or reused over the long term. Genetic analysis may also uncover new information in the future, such as previously unknown hereditary risks affecting a donor's family. Yet, the HTAs, enacted in the late 1970s and early 1980s, provide no guidance on consent, data governance or ethical oversight for these uses. For example, if future discoveries reveal familial risks, who is informed and how? Without clear rules, researchers face legal uncertainty, risking delays in innovation and loss of public trust. Modernising HTAs with national guidelines on consent and data handling covering both initial and future uses of tissue derived data is essential and achievable.