Westmead Biobank
c/o Westmead Institute for Medical Research
[redacted]

23 January 2026

The Secretary
Australian Law Reform Commission
[redacted]

Dear Secretary,

RE: Submission on the ALRC Discussion Paper - Review of Human Tissue Laws (Discussion Paper 90, November 2025)

Thank you for the opportunity to provide a submission to the Australian Law Reform Commission's *Review of Human Tissue Laws Discussion Paper 90* and taking a thoughtful and inclusive approach in launching this national review.

Please find attached a submission from the Scientific Advisory Committee of the Westmead Biobank to the Australian Law Reform Commission's Discussion Paper 90, Review of Human Tissue Laws.

This submission has been prepared from the perspective of a large, hospital-embedded research biobank operating within a complex health and medical research ecosystem. It responds to the Discussion Paper's proposals through a practical, governance- and implementation-focused lens, with particular attention to consent, secondary use, ethical oversight, cost recovery, privacy, and public trust.

To support clarity and navigability, the submission includes an appendix mapping our responses directly to the relevant ALRC proposals.

We appreciate the opportunity to contribute to this important review and would be pleased to provide any further information or clarification if it would be of assistance.

Executive Summary

The Westmead Biobank welcomes the Australian Law Reform Commission's review of Australia's human tissue laws and strongly supports the move toward a nationally harmonised, purpose-based legislative framework. From the perspective of a large, hospital-embedded research biobank operating at the interface of clinical care, research, ethics, and data-driven innovation, updates to the current state-based Human Tissue Acts are welcomed to support progress on several systemic and complex challenges.

Australia's existing legal framework was largely designed for transplantation and therapeutic use and does not adequately reflect contemporary biobanking practice, precision medicine, or data-intensive research. From a research biobanking perspective, biobanks face legal ambiguity that constrains ethically approved research, can create inefficiencies, increases institutional risk aversion, and has the potential to undermine Australia's global research competitiveness.

Biobanks are foundational national infrastructure. They enable longitudinal and secondary use of human biospecimens and associated data to support translational research, clinical trials, genomics, and precision

medicine. They can also bridge research and routine clinical care, supporting equitable participation and public trust through strong governance, ethics oversight, and quality systems aligned with international standards (e.g. ISO 20387). However, biobanks operate at the intersection of multiple regulatory regimes: state Human Tissue Acts, national research ethics frameworks, privacy law, institutional governance, and international collaboration requirements. Misalignment between these frameworks can lead to operational friction and legal uncertainty that reforms have the opportunity to address.

Our submission identifies several systemic issues that arise under existing human tissue legislation:

1. Research is not clearly recognised as a lawful purpose for the retention and use of human tissue in some jurisdictions, creating uncertainty for core biobank activities.
2. Consent frameworks are outdated and inconsistent, with limited statutory recognition of broad, tiered, opt-out, or waiver-based consent models that are already ethically sanctioned under the NHMRC National Statement.
3. Secondary use of clinical remnant and legacy samples is legally ambiguous, despite high public value and low risk when governed appropriately.
4. Governance roles are unclear, particularly the legal standing of Human Research Ethics Committee (HREC) approvals, custodianship versus ownership of tissue, and decision-making for complex or multi-site collections.
5. Definitions of "human tissue" are outdated, failing to clearly encompass derivatives, digital data, emerging biospecimen types, and imported materials.
6. Cost recovery is poorly defined, with confusion between prohibited sale of tissue and legitimate recovery of service costs essential for biobank sustainability.
7. Inter-jurisdictional and international sharing of tissue and data is hindered by inconsistent legal interpretation, limiting collaboration and research impact.

The Westmead Biobank strongly supports national harmonisation of human tissue laws and endorses the Commission's move toward a purpose-based, risk-proportionate framework. To ensure reforms are effective in practice, we humbly recommend that new legislation considers:

1. Explicitly recognising research as a legitimate purpose for the collection, retention, and secondary use of human tissue.
2. Legally codifying contemporary consent models, including broad, dynamic, opt-out, and waiver-of-consent approaches, where approved by HRECs and supported by public interest safeguards.
3. Providing clear statutory authority for secondary use and legacy collections, enabling ethical reuse of valuable samples under defined governance.
4. Recognising HREC approval as a lawful decision-making pathway, aligned with national ethics guidance and avoiding duplicative oversight.
5. Modernising and harmonising definitions of human tissue, including derivatives, digital data, and emerging technologies.
6. Clarifying permissible cost-recovery models, distinguishing legitimate service fees from prohibited commercialisation.
7. Enabling lawful national and international sharing, with clear rules for transfer, export, and data-intensive research.

The reforms proposed in Discussion Paper 90 represent a critical and valuable opportunity to modernise Australia's human tissue laws in a way that strengthens donor protections while enabling high-impact, ethically governed research. From a biobanking and research-infrastructure perspective, success may depend on legal clarity, national consistency, and alignment with established ethics and governance frameworks. We are excited that this reform has the potential to unlock the full public value of donated tissue, support sustainable research infrastructure, and position Australia to lead in precision medicine and data-enabled health innovation.

Background to the Westmead Biobank

The Westmead Biobank is a shared research infrastructure supporting the ethical collection, storage, and use of human tissue for research across the Westmead Research Hub and associated partners. It operates within established ethical, governance, and quality frameworks to support translational medical research, from discovery science through to clinical and precision medicine applications. The Biobank is a Core Facility of the Westmead Research Hub (WRH), one of Australia's largest health and medical research precincts. WRH brings together multiple partner organisations, including the Westmead Institute for Medical Research, the University of Sydney, NSW Health Pathology, Western Sydney Local Health District, the Sydney Children's Hospitals Network, the Children's Medical Research Institute, and CSIRO. Within this integrated environment, clinicians, researchers, and academics work closely to translate research insights into improved patient care.

As a centralised biobanking facility, the Westmead Biobank provides governed access to high-quality biospecimens and associated information to support a wide range of ethically approved research programs, including work in cancer, infectious diseases, genomics, immunology, neuroscience, and rare diseases. Through participation in national research initiatives, clinical trials, and collaborative projects, the Biobank contributes to Australia's broader research ecosystem while remaining embedded in a publicly funded health and research context. Our experience operating within existing legal and regulatory frameworks has highlighted both the importance of strong safeguards and the practical challenges that arise when laws developed in earlier eras are applied to contemporary, large-scale, research-driven biobanking.

The impact of human tissue laws on the biobanking sector

Biobanks play an important role in enabling ethically governed research by providing structured systems for the collection, long-term stewardship, and controlled access to human tissue. Across Australia, biobanks vary significantly in scale, scope, and focus, ranging from small disease-specific collections to large, multi-institutional infrastructure embedded within major health precincts. Despite this diversity, biobanks share a reliance on legal frameworks that provide clarity around consent, retention, secondary use, governance, and collaboration. From a biobanking perspective, variation in human tissue legislation across jurisdictions, combined with the age of some statutory provisions, can create uncertainty when applied to contemporary research practices, particularly those involving long-term storage, secondary research use, and multi-institutional collaboration.

Biobanks operate at the intersection of multiple regulatory and governance domains, including human research ethics frameworks, institutional policies, privacy and health records legislation, and, in some cases, voluntary standards or guidance used to support consistent practice. Navigating this overlapping governance environment is a routine part of biobanking operations, but legal ambiguity at the tissue law level can amplify complexity, increase administrative burden, and contribute to inconsistent interpretation across institutions. From our experience, these challenges do not arise from an absence of ethical oversight, but rather from the difficulty of applying fragmented or historically oriented legislative frameworks to modern, data-integrated, research-focused biobanking models.

Biobanking in the Australian health and research landscape

Biobanks are a critical component of Australia's health and research infrastructure, enabling ethically governed access to high-quality human tissue and data. These repositories do more than simply store samples - they create the foundations for discovery, diagnostics, and the development of new treatments and public health strategies. Modern biobanks serve a distinctive and irreplaceable function in the translational research pipeline and are foundational to Australia's research success. They:

- **Enable high-impact translational research**: From COVID-19 to cancer immunotherapy, many recent scientific breakthroughs have depended on access to well-annotated biospecimens and linked clinical data. Biobanks support longitudinal studies, storing samples across decades and enabling research on disease progression, treatment response, and population-level health patterns.
- **Provide vital rare biospecimen collections critical for medical research**: biobanks are critical for making progress on rare diseases, including rare cancers, where research relies on biospecimens collected over many years and from many sites.
- **Support precision medicine and clinical trials**: Biobanks provide infrastructure for diagnostic validation, biomarker discovery, patient stratification, and therapeutic monitoring - all of which are core to modern precision medicine approaches.
- **Promote equity and participation**: By integrating biospecimen collection into diverse clinical and community settings, biobanks can support research that includes underrepresented populations, helping to close health equity gaps.
- **Enable secondary and tertiary use**, ensuring that once tissue is collected, it can be ethically re-used, with appropriate governance, to extract the maximum scientific and clinical value.
- **Future-proof discovery science**, by preserving samples and associated data for research questions not yet conceived and technologies not yet invented.
- **Bridge research and care**, particularly for integrated hospital-based biobanks, by embedding biospecimen collection within routine clinical workflows to support precision medicine, personalised treatment, and health equity.
- **Foster innovation in data and diagnostics**: With appropriate legal and ethical frameworks, biobanks can be enabled to contribute to downstream innovation in diagnostics that deliver new tools for clinicians and researchers.

Biobanks in NSW and nationally underpin landmark research in areas such as cancer, genomics, rare diseases, and infectious diseases, and are key enablers of national priorities including the Medical Research Future Fund (MRFF), National One Stop Shop (NOSS), Genomics Australia, and the Australian Cancer Plan. Unlike many other parts of the health system, biobanks operate at the intersection of multiple regulatory domains. A single biospecimen may be simultaneously governed by:

- Human research ethics frameworks under the National Statement on Ethical Conduct in Human Research.
- NHMRC biobanking guidelines, which articulate principles for consent, governance, and access.
- Institutional governance and privacy policies, including those of hospitals, universities, and research institutes.
- International and quality standards, such as ISO 20387 (Biobanking), ISO 9001 (Quality Management Systems), and ISO 27001 (Information Security).
- State and territory Human Tissue Acts, which are inconsistently aligned and, in most cases, pre-date the emergence of large-scale, data-integrated, research-driven biobanks.

This overlapping governance architecture is navigated daily by biobank managers and researchers, who must ensure compliance while enabling access and maximising research value.

While biobanks strive for transparency, consistency, and rigour, the current legal landscape introduces significant barriers:

- **Consent ambiguity and fatigue**: Current legislation lacks clarity on how consent for future or unspecified research should be managed. Ethics committees and researchers often interpret the law differently, creating inconsistent practices and repeated re-consent requests that burden participants and delay research.
- **Cost recovery uncertainty**: Biobanks, particularly those embedded in clinical settings, often rely on partial cost recovery from researchers and industry users to remain sustainable. The current lack of

clarity around whether cost recovery constitutes "trading" in tissue under HTA legislation can create operational and legal uncertainty.

- **Data and interoperability limitations**: The absence of harmonised data-sharing protocols across jurisdictions limits biobank participation in national initiatives that require integrated sample and data access, such as federated data platforms and open science collaborations.
- **Imported tissue governance**: Research increasingly involves the exchange of tissue across borders. However, current laws do not adequately address the conditions under which imported human tissue for research can be received, stored, and used, creating compliance risks and blocking international collaborations.

Each of these challenges increases the administrative and ethical complexity of biobanking, placing undue burden on already resource-constrained research teams, and reducing Australia's competitiveness in international biomedical research.

The focus of this submission

Across the proposals set out in the Discussion Paper, the Commission is grappling with the inherent difficulty of designing a single legislative framework capable of governing a wide range of human tissue uses across clinical, research, educational, and other contexts, while maintaining public trust, ethical integrity, and practical workability. Many of the issues raised in the Paper involve longstanding ethical tensions and operational realities that cannot be resolved through legislation alone, but which nonetheless require clearer statutory footing to support consistent and accountable practice.

This submission is intended to contribute a biobanking perspective to that broader task. It reflects the experience of those working within research infrastructure who are responsible for the long-term stewardship of human tissue, and who must operate at the intersection of human tissue law, research ethics frameworks, institutional governance, and public expectations. In offering this perspective, we recognise that biobanking represents only one of many sectors affected by human tissue law reform, and that the Commission must balance diverse and sometimes competing considerations across the system as a whole.

Drawing on frontline experience at the Westmead Biobank, and engagement with national biobanking networks, this submission highlights areas where existing legal ambiguity or inconsistency can create ethical, operational, or compliance challenges for biobanking practice, even where robust ethics approval and governance arrangements are in place. The intent is not to prescribe outcomes, but to identify points where careful legislative design and implementation may be important towards reforms are workable, proportionate, and capable of supporting ethically governed research alongside donor protection.

In that context, the submission focuses on the following thematic areas, which are explored in detail in subsequent sections:

- **Definition and recognition of research as a legitimate use of human tissue:** How research use is framed within human tissue legislation, and the implications this has for the lawful retention and use of tissue in biobanking contexts.
- **Consent frameworks for research and secondary use:** The interaction between statutory consent provisions, contemporary research consent models, and the practical role of ethics committees in managing secondary use, legacy collections, and future unspecified research.
- **Ethics and governance mechanisms:** The relationship between human tissue law, human research ethics oversight, and institutional governance arrangements, including questions of role clarity, accountability, and custodianship in multi-site and long-term collections.

- **Legal definitions and scope of "human tissue":** How statutory definitions align with contemporary research materials and practices, and the implications of definitional clarity or uncertainty for biobanking operations.
- **Opt-out and waiver-based consent models:** The use of opt-out and waiver-of-consent approaches in low-risk research, and the challenges that arise where such models are well established in ethics guidance but lack explicit statutory recognition.
- **Retention periods and legacy samples:** Issues relating to long-term retention of biospecimens and the ethical use of legacy collections where consent may be unclear or incomplete.
- **Cost recovery and sustainable access models:** The boundary between prohibited trade in human tissue and legitimate recovery of costs associated with ethical stewardship, storage, and access, and the operational uncertainty that can arise in the absence of clear guidance.
- **International collaboration and sample transfer:** The governance challenges associated with national and international research collaboration, including cross-border transfer of biospecimens and the maintenance of ethical oversight once tissue leaves its original jurisdiction.

These themes are addressed with the aim of supporting the Commission's broader reform objectives by identifying areas where legislative clarity, guidance, or proportionality may assist biobanks to operate transparently, ethically, and in a manner that maintains public confidence, while recognising the complexity and diversity of the human tissue landscape the ALRC is seeking to reform.

This submission does not seek to pre-empt the Commission's conclusions, but to assist by describing how particular proposals may operate in practice within the biobanking sector.

Thematic analysis of proposals impacting biobanking in NSW

This section examines how the ALRC's proposals address the use of human tissue for research across several key themes, and considers the implications for biobanking practice in NSW in each before outlining sector-facing implementation considerations.

1. Definition and recognition of research as a legitimate purpose

1.1. Relevant ALRC proposals

The ALRC proposals do not establish "research" as a discrete statutory purpose for the collection and use of human tissue. Rather, research is treated as a form of "medical, educational or scientific purpose", with additional and differentiated consent and governance requirements reflecting the particular ethical considerations associated with research use.

As set out in Chapter 8 of the Discussion Paper, the Commission recognises that traditional models of informed consent do not always translate effectively to research contexts, particularly where tissue is stored for future or unspecified use, or where the primary risks are informational rather than physical. The proposed framework therefore addresses research use through tailored consent models, withdrawal rights, and public interest considerations, rather than through purpose-based categorisation alone. In adopting this approach, the ALRC seeks to balance respect for autonomy, transparency, and public trust with the practical realities of contemporary research practice, without privileging research over other lawful uses of human tissue. While this avoids embedding sector-specific priorities in primary legislation, it also highlights an inherent tension between legislative neutrality and the lived operational realities of research-focused biobanking (as one downstream area impacted by the Human Tissue legislation).

1.2. Implications for biobanking in NSW

In practice, research constitutes the primary operational activity of biobanking in NSW. Biobanks are established, governed, and resourced to collect, store, and distribute human tissue specifically for use in ethically approved research, often across extended timeframes and multiple projects. Within the NSW context, biobanks typically operate at the intersection of public hospitals, NSW Health Pathology, universities, and research institutes, and function as shared infrastructure supporting a wide range of translational and population-based research programs. While the ALRC's procedural treatment of research provides important safeguards, the absence of explicit recognition of research as a central operational function may create uncertainty for biobanks in articulating their role, designing governance arrangements, and communicating clearly with donors, researchers, and the public. This is particularly relevant in large, integrated research precincts, where biobanks support collaboration across institutions and jurisdictions and steward collections intended for long-term public benefit.

1.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, clearer articulation of the role of research within the proposed legislative framework would assist with consistent interpretation and implementation, particularly for biobanks whose primary function is the stewardship of tissue for research over time. While the ALRC appropriately addresses research through differentiated consent and governance mechanisms, consideration could be given to more explicitly acknowledging research as an anticipated and legitimate use of human tissue within the objects or guiding principles of new legislation. Such clarification would support alignment between statutory interpretation, ethical governance frameworks, and public-facing communications, without displacing the Commission's proposed safeguards or oversight mechanisms. Explicit recognition of the research function of biobanks may also strengthen public understanding of how donated tissue is managed and used for public benefit within NSW's publicly funded health and research system.

Explicit recognition of research as a legitimate purpose may reduce legal ambiguity, but it also raises difficult questions about the boundaries between research, clinical care, quality improvement, and other uses of human tissue that legislation alone cannot fully resolve. Operationalising such recognition will require careful drafting and guidance to avoid creating new areas of uncertainty at the margins of research practice.

2. Consent frameworks for research and secondary use

2.1. Relevant ALRC proposals

The ALRC proposes a differentiated consent framework for research use of human tissue, recognising that fully specific consent may not always be practicable in research contexts. The Commission acknowledges the widespread use of broad and unspecified consent for research biobanks, and the challenges associated with re-contacting donors for each subsequent use. Through these proposals, the ALRC seeks to balance respect for autonomy and transparency with the realities of long-term tissue storage and secondary research use.

Under the proposed framework, consent for research use may be valid even where all future research purposes are not known at the time of tissue removal, provided that donors are appropriately informed, consent is voluntary, and governance safeguards are in place. The proposals also preserve important participant protections, including rights to withdraw consent for future research uses where tissue remains identifiable or re-identifiable, and the application of additional authorisation or public interest oversight in defined circumstances.

The Commission's proposed consent framework necessarily navigates a difficult balance between respecting individual autonomy and enabling ethically governed research over long timeframes, particularly where future uses cannot be fully anticipated.

2.2. Implications for biobanking in NSW

NSW biobanks rely heavily on broad or unspecified consent models to enable the long-term storage and secondary use of tissue for ethically approved research. This reflects the operational reality of biobanking, where future research questions cannot always be anticipated at the point of collection and samples may be used across multiple projects over time. NSW biobanks also steward legacy collections and pathology-derived samples that were collected under earlier consent frameworks or in clinical contexts where research use was not the primary purpose at the time of removal. Governance of these collections currently relies on ethics review, institutional oversight, and risk-based decision-making to support appropriate use and maintain public trust. While the ALRC's proposed consent framework broadly aligns with these practices, its implementation will have practical implications for how NSW biobanks manage consent documentation, withdrawal requests, public interest assessments, and communication with researchers and donors across complex institutional environments.

We acknowledge that there is no single consent model that can fully accommodate all research contexts, and that any legislative approach will involve trade-offs between autonomy, feasibility, proportionality, and long-term public benefit.

2.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, statutory confirmation of the validity of broad and unspecified consent for research use would support legal clarity and national consistency, while reinforcing existing ethical safeguards. In implementing the proposed framework, consideration could be given to ensuring that requirements relating to withdrawal, identifiability, and public interest assessment are applied proportionately and in a manner that is operationally workable for large-scale biobanks. In particular, clearer guidance on the treatment of legacy samples and pathology-derived collections would assist biobanks in managing existing holdings without unnecessary disruption to ethically approved research. Alignment between statutory consent requirements and established ethical guidance would further support consistent interpretation across jurisdictions and reinforce public confidence in the governance of research using human tissue.

We acknowledge that reasonable views differ on how best to balance flexibility, certainty, and public protection in these areas, and that the Commission must weigh these considerations across sectors with differing risk profiles.

3. Ethics and governance mechanisms

3.1. Relevant ALRC proposals

While research ethics frameworks provide essential guidance for practice, they cannot substitute for clear statutory authority, nor can legislation alone resolve all ethical questions. The ALRC proposes a layered and proportionate governance framework for the use of human tissue, combining consent-based authorisation with additional oversight mechanisms where required to protect public trust and manage ethical risk. The proposals recognise that different uses of human tissue raise varying levels of sensitivity and that governance responses should be calibrated accordingly. In the context of research, the ALRC does not prescribe a single, universally sufficient approval pathway. Instead, the framework relies on a combination of consent, ethics review, and public interest considerations, with additional safeguards applying in defined

circumstances such as where consent is absent, unclear, or impracticable. This approach is intended to preserve flexibility, ensure accountability, and avoid over-reliance on any single decision-making mechanism. Across Proposals 32–39, the ALRC emphasises transparency and public confidence as central objectives of governance arrangements for research use of human tissue. The Commission's emphasis on proportionality appropriately recognises that not all uses of human tissue warrant the same level of oversight, while also raising difficult questions about how consistency and predictability can be maintained across institutions and jurisdictions.

3.2. Implications for biobanking in NSW

In NSW, governance of research biobanking is currently centred on institutional ethics review, supported by Human Research Ethics Committees (HRECs), research governance offices, and established ethical guidance frameworks. These mechanisms play a central role in assessing research risk, overseeing consent models, and maintaining public confidence in the use of human tissue for research. The ALRC's proposed governance approach broadly aligns with the principle of proportionality underpinning current NSW practice. However, its implementation may introduce additional complexity for biobanks operating across multiple institutions and research programs. In particular, uncertainty regarding when ethics review alone is sufficient, and when additional public interest authorisation is required, may lead to duplication or inconsistent interpretation across institutions. For large, shared biobanking infrastructure, governance arrangements that are unclear or fragmented may increase administrative burden and affect the timely access to tissue for ethically approved research.

While strengthened governance arrangements can improve consistency and accountability, neither ethics frameworks nor legislation alone can resolve all questions of responsibility and risk in complex, multi-institution research environments.

3.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, effective implementation of the ALRC's proposed governance framework is likely to depend on clear guidance regarding the interaction between consent, ethics review, and public interest authorisation, and the circumstances in which additional oversight mechanisms are intended to apply. Consideration could be given to recognising robust, appropriately constituted ethics review processes as a primary governance mechanism for low-risk research use of human tissue, particularly where broad consent has been obtained and research is conducted in accordance with established ethical standards. Additional authorisation should be reserved for defined categories of higher-risk or more sensitive use, consistent with the Commission's emphasis on proportionality and public trust. Clear articulation of governance roles, decision-making thresholds, and oversight pathways would assist biobanks in designing governance arrangements that are transparent, consistent, and workable in practice, and would support coherent implementation across institutions and jurisdictions.

4. Legal definitions and scope of "Human Tissue"

4.1. Relevant ALRC proposals

The ALRC proposes reform aimed at increasing national consistency and clarity in the legal definition and scope of "human tissue", recognising that inconsistent and fragmented definitions across jurisdictions create uncertainty for lawful collection, storage, use, and disposal. The Commission is navigating an inherently difficult boundary question here: how to draft a definition that is future-facing and practically workable, without inadvertently expanding human tissue law into neighbouring domains such as data governance and privacy regulation.

The Discussion Paper indicates a preference for definitions that are sufficiently clear to support consistent interpretation, while remaining workable across diverse contexts in which human tissue is handled, including clinical care, donation, transplantation, education, training, and research. At the same time, the Commission's approach reflects a genuine drafting challenge: definitions must be precise enough to provide legal certainty, but not so rigid that they become quickly outdated or fail to accommodate emerging practices in health and research. This tension is particularly acute where "human tissue" intersects with complex categories such as tissue-derived materials, processed samples, and the varied pathways by which tissue may be used for medical or scientific purposes. In setting out this approach, the ALRC is not proposing that all downstream products, information, or activities associated with tissue automatically fall within the same legal category as tissue itself. Rather, the Discussion Paper's focus is on defining the scope of "human tissue" for the purposes of the human tissue legislative framework, recognising that adjacent issues (such as privacy, information governance, and the handling of health information) may be addressed through other legal and regulatory regimes.

4.2. Implications for biobanking in NSW

For biobanks, too narrow a definition risks leaving operational "grey zones" that lead to inconsistent practice and reduced public clarity. However, too broad a definition risks drawing the legislative scheme into areas better governed by privacy and health information frameworks. For NSW biobanks, definitional clarity is operationally significant because it shapes the scope of what is regulated as "human tissue" across the full lifecycle of biobanking activities, including collection (often in clinical settings), long-term storage, processing, distribution, secondary research use, and disposal. In practice, biobanks manage materials that may sit along a continuum from minimally processed samples to derivatives and aliquots prepared for specific research applications. NSW biobanks also operate in complex institutional environments spanning public hospitals, pathology services, universities, and research institutes. In these settings, inconsistent or ambiguous definitions can create uncertainty about governance responsibilities, consent documentation, handling requirements, and the conditions under which materials may be shared with researchers or transferred across institutions and jurisdictions.

A further practical implication is that biobanking is closely connected to information governance. While "human tissue" and "data about tissue" are not legally interchangeable concepts, biobanks routinely handle linked information (for example, donor identifiers, clinical annotations, and research-generated results) that is essential for research value and stewardship. Definitions that are unclear at the tissue boundary can indirectly complicate how biobanks communicate with donors, design operational policies, and maintain trust about what is being collected and how it may be used.

4.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, clear and nationally consistent definitions of "human tissue" would materially support lawful, transparent, and efficient biobanking practice, particularly for biobanks operating across multi-institution and multi-jurisdiction research environments. In implementing a harmonised definition, consideration could be given to ensuring that the legislative framework provides practical clarity regarding the treatment of common biobanking materials and workflows, including:

- processed tissue and derivatives (for example, aliquots or materials prepared for research use), and how these relate to the scope of the human tissue framework;
- tissue held in long-term storage for future research use, including where secondary uses are expected; and
- boundary clarity between tissue governance and information governance, so that the human tissue regime does not inadvertently duplicate, displace, or confuse obligations under privacy, health records, and related legislation.

If the Commission considers that emerging practices (for example, advanced tissue processing or the generation of highly informative derivatives) create definitional uncertainty, an implementation approach that combines clear statutory definitions with supporting guidance may assist. This would allow the core legal concept of "human tissue" to remain stable, while enabling practical clarification over time as biobanking practice evolves.

In making these recommendations, we recognise that there is no "perfect" definition that will eliminate all edge cases. A pragmatic goal is to reduce uncertainty in the most common operational scenarios while preserving the Commission's intent to avoid undue expansion of the scheme beyond the governance of tissue itself.

A key unresolved question for implementation is how best to handle "in-between" categories, where a material is derived from human tissue and retains biological significance for research, but may not intuitively be understood by donors or practitioners as "tissue" in the everyday sense. Clear guidance on these boundary cases will be important to maintain consistent practice and public confidence.

Any attempt to modernise statutory definitions must balance the need for clarity against the risk of unintentionally constraining future scientific developments that cannot yet be anticipated.

5. Lack of clear legal provisions for opt-out or waiver-based models

5.1. Relevant ALRC proposals

The Commission is confronting a difficult policy question here: how to accommodate research that cannot feasibly rely on individual consent, while avoiding legal models that might be perceived as diluting respect for individual choice or transparency. The ALRC Discussion Paper does not propose a general opt-out or waiver-based consent model for the use of human tissue in research. Instead, the proposed framework remains grounded in consent as the primary authorisation mechanism, with additional pathways available where consent is absent, unclear, or impracticable, and where use may be justified through public interest considerations and appropriate oversight. In considering research use, the Commission acknowledges circumstances in which seeking individual consent may be impracticable or impossible, particularly for large-scale, retrospective, or population-based research. However, rather than endorsing opt-out models as a default, the proposals emphasise case-by-case assessment, ethical review, and proportionate safeguards to determine whether use without explicit consent is justified. This approach reflects the ALRC's caution in an area that directly engages questions of autonomy, trust, and legitimacy, and its intention to avoid creating broadly framed authorisations that could undermine public confidence in the governance of human tissue.

5.2. Implications for biobanking in NSW

In NSW, biobanks operate within ethical and governance frameworks that, in limited and carefully defined circumstances, permit research use of tissue without explicit individual consent. This includes the use of waiver-based approvals for low-risk research, legacy collections, and certain pathology-derived samples, subject to ethics review and institutional oversight. These models are typically applied where re-contacting donors is impracticable, where risks to participants are minimal, and where the proposed research is judged to have sufficient public value. In practice, such approvals are tightly constrained and rely on professional judgement exercised by ethics committees within established ethical guidance.

For NSW biobanks, waiver-based models can be essential for enabling certain categories of ethically approved research, yet they remain among the most sensitive and easily misunderstood aspects of tissue governance. The absence of explicit statutory recognition of opt-out or waiver-based models may create uncertainty for biobanks operating under these arrangements, particularly where governance expectations differ across institutions or jurisdictions. At the same time, overly broad legal recognition of such models

could raise concerns about erosion of consent norms and public trust, especially in the absence of clear safeguards.

5.3. Implementation considerations and sector recommendations

An ongoing challenge for implementation will be determining how to articulate waiver-based pathways in law in a manner that provides sufficient clarity for institutions and researchers, while remaining intelligible and acceptable to donors and the broader public. From a biobanking sector perspective, clearer statutory guidance on the circumstances in which research use of human tissue may proceed without explicit individual consent would assist with consistent interpretation and application across institutions, while maintaining appropriate ethical safeguards. Rather than establishing a general opt-out model, consideration could be given to articulating more clearly the conditions under which waiver-based approvals may be relied upon, including the role of ethics review, assessment of risk, impracticability of consent, and public interest considerations. Such clarification would support transparency and consistency without diminishing the primacy of consent as the default authorisation mechanism. Any legislative or regulatory recognition of waiver-based pathways should be carefully framed to avoid normalising non-consensual use of tissue, and should emphasise that these mechanisms are exceptional, tightly governed, and justified only in limited circumstances. Clear communication of these boundaries would be critical to maintaining public trust in biobanking and research governance.

At the same time, expanding statutory recognition of opt-out or waiver-based models raises legitimate concerns about transparency, community expectations, and the conditions under which public trust may be sustained.

6. Retention periods and legacy samples

6.1. Relevant ALRC proposals

The ALRC is responding to a complex question with regards to how to respect evolving ethical standards and community expectations without imposing retrospective requirements that would be impracticable, disruptive, or disproportionate for existing collections. The ALRC Discussion Paper recognises that human tissue may be retained for varying periods depending on its purpose, context of collection, and intended use, and that rigid or uniform retention requirements are unlikely to be workable across all settings. Rather than prescribing fixed retention periods, the Commission's proposals emphasise governance mechanisms, consent conditions, and proportional oversight to guide decisions about storage, ongoing use, and disposal.

The Commission's approach reflects an understanding that legacy samples are both ethically sensitive and scientifically valuable, and that any legal framework must navigate this tension without undermining public trust or unnecessarily foreclosing research opportunities. It is acknowledged that there are particular challenges associated with tissue collected under historical legal, ethical, or institutional frameworks that differ from contemporary expectations. The Discussion Paper does not propose retrospective application of new consent standards to all existing collections. Instead, it signals a need for careful consideration of how such materials may continue to be used lawfully and ethically, particularly for research conducted in the public interest.

6.2. Implications for biobanking in NSW

For biobanks, long-term retention of tissue is both a scientific necessity and an ethical responsibility, requiring careful stewardship to balance respect for donors with the potential public benefit of future research. In NSW, biobanks commonly retain human tissue for extended periods to support longitudinal, retrospective, and secondary research. Long-term retention is often fundamental to the scientific value of

biobanked collections, particularly where research depends on historical samples, rare conditions, or the ability to re-analyse material as technologies evolve. NSW biobanks also steward substantial legacy collections, including pathology-derived samples and materials collected under earlier consent models or governance frameworks. These collections are typically managed through ethics review, institutional oversight, and risk-based governance processes that assess the appropriateness of ongoing storage and use, rather than through fixed retention limits. Uncertainty around how new legislative frameworks will treat long-held samples, or whether retention expectations may shift over time, has practical implications for biobanks' storage planning, consent management, donor communication, and long-term sustainability. At the same time, imposing overly prescriptive retention or re-consent requirements could compromise the viability of ethically approved research programs that rely on historical collections.

6.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, legislative frameworks that allow flexibility in retention periods, guided by consent, ethical oversight, and public interest considerations, are essential for the responsible stewardship of human tissue over time. In implementing the ALRC's proposals, consideration could be given to providing clearer guidance on how legacy samples may continue to be retained and used, particularly where original consent is broad, limited, or silent on future research. Such guidance would assist biobanks in applying consistent governance approaches while avoiding the unintended consequence of rendering large, valuable collections unusable due to retrospective uncertainty. Implementing any new statutory approach to legacy samples will also carry significant administrative and resource implications for biobanks, many of which are managing large collections accumulated over decades under differing consent and governance regimes.

More broadly, an approach that emphasises ongoing governance, transparency, and accountability, rather than fixed retention limits, might better support proportionate decision-making as scientific practices, community expectations, and ethical standards evolve. This may include encouraging biobanks to periodically review retention and use practices, rather than requiring wholesale re-consenting or disposal of legacy materials. A continuing challenge for implementation will be determining how to communicate clearly with donors and the public about long-term retention and future use of tissue, particularly where legacy collections were established in periods with different norms of consent and disclosure.

7. Cost recovery and sustainable access models

7.1. Relevant ALRC proposals

The Commission is grappling with a difficult boundary issue in terms of how to maintain a clear prohibition on trade in human tissue while acknowledging that sustainable systems for tissue stewardship cannot operate without some form of cost recovery. The ALRC Discussion Paper does not propose a comprehensive framework governing cost recovery, charging practices, or sustainability models for the use of human tissue. Nor does it seek to redefine the boundary between permissible use of tissue and prohibited trade. Instead, the Commission reiterates the longstanding principle that human tissue should not be the subject of trade, while recognising that lawful handling, storage, and use of tissue inevitably incur costs.

It acknowledges that a range of activities associated with human tissue, including collection, processing, storage, governance, and distribution, may legitimately involve cost recovery, provided that such arrangements do not amount to the sale of tissue itself or undermine ethical principles of voluntariness and public trust. However, the ALRC stops short of prescribing specific cost recovery models, leaving considerable discretion to institutions and existing regulatory frameworks. This restraint reflects the Commission's recognition that cost recovery sits at the intersection of ethical principle, operational

necessity, and public perception, and that overly prescriptive legislative approaches risk unintended consequences across diverse contexts of tissue use.

7.2. Implication for biobanking in NSW

For biobanks, cost recovery is essential to sustainability, yet it must be carefully structured to avoid perceptions that human tissue, rather than the services surrounding its stewardship, is being commodified. In NSW, biobanks operate within publicly funded health and research systems and rely on cost recovery mechanisms to support the infrastructure required for ethical stewardship of tissue. These costs commonly relate to sample processing, quality assurance, storage, data management, governance, and compliance, rather than the tissue itself.

Access to biobanked tissue for research is typically governed through transparent application processes and ethics approval, with cost recovery applied to support sustainability and equitable access rather than profit generation. Nevertheless, the absence of clear statutory guidance distinguishing acceptable cost recovery from impermissible trade can create uncertainty, particularly where practices vary across institutions or where collaborations involve interstate or international partners.

There is also a practical tension for NSW biobanks between maintaining affordability for publicly funded or early-stage research and ensuring that infrastructure remains viable over time. Without sustainable access models, biobanks risk becoming dependent on short-term funding or cross-subsidisation, which may itself undermine equity, transparency, and long-term public benefit.

7.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, clearer articulation of permissible cost recovery practices within the human tissue framework would support consistent, transparent, and ethically grounded access models, particularly for publicly funded biobanks operating at scale. Rather than introducing prescriptive charging regimes, consideration could be given to clarifying the distinction between prohibited trade in human tissue and legitimate recovery of costs associated with its ethical stewardship, including governance, quality management, and long-term storage. Such clarification would assist institutions in designing access policies that are defensible, equitable, and aligned with community expectations.

Any approach to cost recovery should emphasise transparency, proportionality, and accountability, and avoid normalising arrangements that could be perceived as commercial exploitation of donated tissue. Clear communication with donors and the public about how costs are recovered, and how this supports public benefit research, will be critical to maintaining trust.

A continuing challenge for implementation will be determining how cost recovery models can be articulated in law and practice in a way that is both operationally workable and publicly intelligible, particularly in an environment where perceptions of commercialisation can erode confidence even where ethical safeguards are in place.

Clarifying the boundary between prohibited trade and permissible cost recovery is particularly challenging, as even well-governed cost-recovery models may be perceived by donors or the public as commercialisation if not carefully framed and communicated.

8. Handling of international collaboration and sample transfer

8.1. Relevant ALRC proposals

This area represents a particularly complex policy challenge in terms of how to accommodate the realities of global research collaboration while ensuring that Australian community expectations, ethical standards, and governance protections are not diluted once tissue crosses national borders. The ALRC Discussion Paper recognises that contemporary health and medical research frequently involve international collaboration, including the transfer of human tissue across jurisdictional boundaries. At the same time, the Commission approaches this area with caution, given the heightened ethical, legal, and trust considerations associated with cross-border use of human tissue.

The proposals do not establish a general entitlement to export human tissue for international research, nor do they seek to harmonise Australian law with international regimes. Instead, the ALRC emphasises the continued importance of consent, ethics review, and appropriate governance in determining whether international transfer or collaboration is lawful and justified in particular circumstances. The Discussion Paper also highlights that international transfer raises additional considerations beyond those applicable to domestic research, including differing regulatory standards, variability in oversight mechanisms, and the potential loss of control over tissue once it leaves Australia. The Commission's approach therefore prioritises safeguards, accountability, and public trust over facilitation of cross-border research per se.

8.2. Implications for biobanking in NSW

For NSW biobanks, international collaboration presents a clear tension between the scientific value of global research partnerships and the ethical responsibility to ensure that donated tissue remains subject to appropriate oversight and stewardship, regardless of where research is conducted. NSW biobanks are embedded in research ecosystems that increasingly operate at an international scale, including participation in multinational studies, disease registries, and collaborative research networks. In some cases, international collaboration may involve physical transfer of tissue samples; in others, collaboration may be enabled through shared analysis, data linkage, or coordinated research protocols.

From an operational perspective, international collaboration can be essential for advancing research in areas such as rare diseases, genomics, and population health, where sufficient scale cannot be achieved within a single jurisdiction. However, international sample transfer also introduces heightened governance complexity for biobanks, including managing consent expectations, ensuring ethics approvals are appropriately scoped, and negotiating material transfer agreements that reflect Australian ethical and legal standards. Uncertainty regarding how proposed legislative reforms will apply to international transfers may affect biobanks' willingness to participate in global collaborations, particularly where governance requirements are unclear or perceived as inconsistent across jurisdictions. Conversely, insufficient clarity around safeguards may undermine public confidence in how donated tissue is protected once used beyond Australia.

Developing nationally consistent approaches to international collaboration is especially complex, as Australian safeguards must operate within legal, ethical, and regulatory environments over which domestic legislation has limited control.

8.3. Implementation considerations and sector recommendations

From a biobanking sector perspective, clearer guidance on the governance of international collaboration and sample transfer would support consistent and responsible participation in global research, while maintaining public trust and ethical integrity. Rather than adopting a permissive or restrictive default position, consideration could be given to articulating the conditions under which international transfer of

human tissue may be appropriate, including requirements relating to consent scope, ethics review, governance equivalence, and ongoing accountability. Such guidance would assist biobanks in assessing international collaborations on a case-by-case basis, without assuming that all overseas partners operate under comparable regulatory standards.

Transparency with donors and the public regarding the possibility of international collaboration, and the safeguards that apply to such arrangements, will be critical. Clear articulation of expectations around stewardship, permitted use, and oversight following transfer may help maintain confidence while enabling ethically justified research partnerships. A continuing challenge for implementation will be determining how Australian institutions can meaningfully assure ongoing ethical governance of tissue once it is transferred internationally, particularly in research environments where legal, cultural, and regulatory norms differ substantially.

General support for non-biobanking-specific proposals

The breadth of the Discussion Paper highlights the inherent challenge of designing a coherent legislative framework capable of addressing diverse and sometimes competing uses of human tissue within a single statutory scheme. This ALRC Discussion Paper addresses a wide range of matters that extend beyond the specific context of research biobanking, including proposals relating to donation, transplantation, clinical practice, education and training, decision-making capacity, authorisation pathways, and enforcement mechanisms. These proposals reflect the Commission's broader objective of modernising and harmonising human tissue laws across jurisdictions, while strengthening ethical safeguards and public confidence.

While these matters are not directed specifically at biobanking, they provide important context for the regulatory environment in which NSW biobanks operate. Greater clarity and consistency across the human tissue framework, particularly in relation to consent, authorisation, and oversight, supports public understanding and trust in the governance of human tissue more broadly. At the same time, many of these proposals engage ethical, clinical, and operational considerations that differ materially from those encountered in research biobanking, and sit outside the primary expertise of this submission. Accordingly, this submission does not seek to advance detailed commentary on proposals that do not materially affect biobanking practice, and instead offers general support for the direction of reform in these areas. The breadth of the Discussion Paper also highlights the inherent difficulty of designing a single legislative framework capable of governing diverse uses of human tissue, each with distinct ethical and social dimensions. Ongoing consultation during implementation will therefore be important to ensure that reforms remain coherent, workable, and trusted across the full range of contexts to which they apply.

Conclusion

The ALRC Discussion Paper reflects the considerable complexity involved in modernising human tissue laws in a way that is ethically robust, legally coherent, and capable of operating across a wide range of contemporary contexts. The Commission is seeking to reconcile diverse and sometimes competing considerations, including respect for autonomy, public trust, scientific advancement, and practical workability, within a single legislative framework that must serve many sectors with differing responsibilities and expectations.

This submission has been provided to assist the Commission by offering the perspective of the research biobanking sector in NSW, recognising that biobanking represents only one part of the broader human tissue system addressed by the proposed reforms. The issues raised here are intended to highlight areas where the proposals intersect with biobanking practice, and where careful implementation will be important to ensure that ethical safeguards and public confidence are maintained alongside the responsible use of tissue for research.

We acknowledge that no legislative framework can fully resolve all of the ethical and operational tensions inherent in the governance of human tissue, particularly in an environment of evolving scientific practice and community expectations. The challenges identified in this submission are therefore not presented as deficiencies in the Commission's approach, but as areas where continued dialogue, guidance, and consultation will be essential as reform progresses.

We thank the Australian Law Reform Commission for the opportunity to contribute to this important consultation, and for the care with which it has engaged with the diverse sectors affected by human tissue law reform. We welcome the opportunity for ongoing engagement as these proposals are further developed and implemented.

Yours sincerely,

Westmead Biobank Scientific Advisory Committee (members listed below)

Name	Title	Location
Christine Clarke	Emeritus Professor	The University of Sydney
Jane Carpenter	Biobanking Advisor	Westmead Institute of Medical Research
James Curnow	Head of Operations	Children's Medical Research Institute
Anna DeFazio	Sydney West Chair in Translational Cancer Research	Westmead Institute of Medical Research
Fran Evesson	Senior Lecturer, and Group Leader within Kids Neuroscience Centre,	Children's Hospital at Westmead
Kim Fung	Principal Research Scientist and Team Leader	Molecular Diagnostics Solutions, CSIRO
Jonathan Iredell	Director, Centre for Infectious Disease and Microbiology,	Westmead Institute of Medical Research
Sean Lal	Associate Professor, and Chair, FMH Biobank Best Practice Working Group	The University of Sydney
Carina Lauter	Biobanking Coordinator, Phage Australia	Westmead Institute of Medical Research
Wieland Meyer	Director, Westerdijk Fungal Biodiversity Institute of KNAW	The Netherlands
Elizabeth Salisbury	Clinical Director, NSW Health Pathology	ICPMR Westmead
Smadar Kahana-Edwin	Academic Advisor, The Children's Hospital at Westmead Tumour Bank	Kids Research, The Children's Hospital at Westmead
Rebecca Sedicol	Marketing and Communications Manager	Westmead Research Hub
Leia Tria	Communications and Admin Officer	Westmead Research Hub
Maggie Wang	Director, Scientific Operations	Westmead Institute of Medical Research
Ya Wang	Advanced Biobank Specialist / Westmead Biobank Manager	Westmead Institute of Medical Research
Roshni Sharma	Project Manager, PrecisionGO / Westmead Biobank Secretariat	Westmead Institute of Medical Research

Appendix: Mapping This Submission with ALRC Discussion Paper 90's Proposals

The below tables map the proposals in Discussion Paper 90 that are directly relevant to research biobanking and biospecimen stewardship. Proposals relating primarily to transplantation, coronial processes, or non-research uses of human tissue are outside the scope of this submission.

The body of this submission is structured around eight thematic sections that examine how the proposals in Discussion Paper 90 intersect with the operational, ethical, and governance realities of research biobanking. These sections are deliberately thematic rather than proposal-by-proposal, reflecting the fact that many of the issues raised by the Discussion Paper cut across multiple chapters and proposals and cannot be meaningfully analysed in isolation. This structure is intended to support clarity and transparency for readers, while avoiding artificial or misleading alignment between complex, interconnected governance issues and individual proposals.

The Appendix tables that follow serve a complementary purpose. They map the specific proposals in Discussion Paper 90 that are materially relevant to research biobanking to the corresponding sections of this submission. The tables are intended as a navigational aid, demonstrating where and how particular proposals are addressed, rather than as a comprehensive response to every proposal or consultation question in the Discussion Paper.

Not all thematic sections of the submission appear as standalone entries in the Appendix tables. In particular, sections addressing legal definitions and scope and opt-out or waiver-based consent models are cross-cutting in nature. These sections analyse issues that arise across multiple proposals and chapters of the Discussion Paper, rather than responding to a single discrete proposal. As such, they inform and underpin the analysis in several sections of the submission and are reflected across multiple entries in the tables, rather than being mapped one-to-one.

Chapter 2: A nationally consistent framework for human tissue regulation

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
1	Nationally consistent human tissue regulation	Primary	Sections 1, 2	Support	Inconsistent human tissue laws create uncertainty for biobanks operating across institutions and jurisdictions. Greater consistency would support lawful, predictable stewardship of biospecimens in multi-site research.
2	Legislative principles and objects	Primary	Sections 1, 2	Support	Clear legislative objects provide an important interpretive framework for ethical use of human tissue, including research and biobanking.
3	National governance arrangements	Secondary	Sections 2, 3	Support with implementation considerations	National governance may assist consistency, provided it complements existing research ethics and health governance systems and avoids duplicative approval pathways.

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
4	Intergovernmental agreement	Secondary	Section 2	Support	Intergovernmental coordination is important to ensure reforms are implemented consistently for biobanks managing tissue collected under different state regimes.

Chapter 8: Research use of human tissue

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
32	Consent for removal of human tissue for research	Primary	Section 2	Support	Statutory recognition of consent for research use supports lawful collection and long-term stewardship of biospecimens within ethics-approved biobanking.
33	Broad consent, information provision, and withdrawal	Primary	Section 2	Support with implementation considerations	Broad consent is widely used in biobanking. Withdrawal and information rights will require proportionate application for long-term collections.
34	Interaction with the National Statement on Ethical Conduct in Human Research	Primary	Sections 2, 3	Support	Alignment with established research ethics frameworks supports consistent interpretation and reduces unnecessary duplication in biobanking governance.
35	Research involving children	Primary	Sections 2, 3	Support	Clear legislative pathways for ethically approved paediatric research are important for biobanks supporting child health research.

Chapter 9: Research use of human tissue after death and body donation

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
36	Consent for research use of human tissue after death	Primary	Sections 2, 6	Support	Statutory clarity regarding post-mortem research consent supports ethical stewardship of legacy and post-mortem collections.
37	Information provision and withdrawal after post-mortem consent	Primary	Section 2	Support with implementation considerations	Application of withdrawal and information rights requires careful calibration where tissue is de-identified or used in downstream research.
38	Whole-body donation for research and education	Contextual	Not substantively addressed	Support in principle	Clear consent pathways support public understanding and confidence in donation systems.
39	Research involving the recently deceased	Primary	Sections 2, 6	Support	Legislative recognition of ethically approved research involving the recently deceased supports scientific inquiry while maintaining safeguards.

Chapter 10: Trade, cost recovery, and sustainability

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
40	Prohibition on trade in human tissue	Primary	Section 7	Support	A clear prohibition on trade is essential to protect donors and public trust, provided it is distinguished from legitimate cost recovery.
41	Void agreements involving prohibited trade	Primary	Section 7	Support	Unenforceability of unlawful agreements provides clarity for institutions entering research and collaboration arrangements.

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
42	Exceptions to the prohibition on trade	Primary	Section 7	Support	Carefully defined exceptions accommodate regulated medical and research activities without undermining safeguards.
43	Exemptions framework	Primary	Section 7	Support with implementation considerations	Transparent exemption mechanisms may assist lawful operation while maintaining donor protections.

Chapter 7: Respect, dignity, and authorisation (contextual)

Proposal	Proposal (DP90 language)	Relevance to biobanking	Where addressed in submission	Position	Biobanking perspective
28	Respectful and dignified treatment of human bodies	Contextual	Not substantively addressed	Support in principle	Public trust in research depends on dignity and respect throughout the tissue lifecycle.
29	Authorisation to remove human tissue	Contextual	Not substantively addressed	Support in principle	Clear authorisation supports lawful tissue collection entering biobank systems.
30	Consent for non-coronial post-mortem examination	Contextual	Not substantively addressed	Support in principle	Lawful post-mortem consent underpins ethical provenance of tissue later used for research.
31	Restrictions on secondary use of post-mortem tissue	Secondary	Section 6	Support with implementation considerations	Clear secondary-use rules help prevent unnecessary loss of valuable samples while maintaining safeguards.