Human Tissue Law Discussion Paper Submission

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Chapter 2 — The objects of human tissue laws

Question 1: Do you agree with the objects in Proposal 5?

Response: Yes. The proposed objects provide a coherent, principled foundation that:

- Modernise and harmonise Australia's human tissue laws across jurisdictions.
- Centre respect for people, bodily integrity, autonomy and dignity.
- Improve access while upholding equity, non-exploitation and public trust.
- Embed responsiveness to technology and practice via a flexible legislative framework. [

From a university health-sciences perspective (teaching, research, clinical partnerships), these objects align with ethical guidance (e.g., NHMRC), operational realities in teaching anatomy and tissue-based research, and the community's expectations of transparency and accountability.

Question 2: Should other objects be included?

Response: Add the following clarifications to strengthen the framework:

1. Culturally safe practice and First Nations partnership**.** Make explicit the commitment to culturally safe processes, including recognition of First Nations decision-making and repatriation protocols. This supports both equity and public trust.
2. Data transparency and proportional oversight. Include an object to promote transparent, proportionate regulation and data reporting across the sector (tissue banks, imports/exports, research biobanks). [
3. Research enablement with safeguards. Recognise the societal benefit of ethically conducted research (including fit-for-purpose consent models for stored samples) while protecting privacy and autonomy.

Chapter 3 — Removing barriers and promoting equitable access

Question 3: Do new laws need provisions to remove barriers and promote equitable access?

Response: Yes. While many inequities arise from service delivery rather than statute, legislation can still:

- Require equity impact assessments for codes/standards issued by the Regulator.
- Mandate culturally safe practices and decision-making recognition (e.g., broadened authorised decision-maker hierarchy and disclosure rules that allow families/kin to share donor stories, where consented).
- Compel national reporting on access and outcomes (including First Nations-specific indicators) to steer policy and funding.

Question 4: Which barriers should legislation address?

Response:

- Decision-maker definitions: Replace narrow “senior next of kin” with a culturally inclusive “authorised decision-maker” hierarchy and clarify tie-break rules.
- Information-sharing limits: Reform non-disclosure provisions to permit consented family storytelling and culturally appropriate communication; align privacy with clinical disclosure duties.
- Language accessibility: Require that key public-facing materials (registration, consent information) be available in accessible formats and major community languages.

Chapter 4 — Definition of “tissue”

Question 5: How should “tissue” be defined to be suitably broad?

Response: Adopt a broad, adaptive definition—e.g., “material that consists of, includes, or derives from human cells”, paired with explicit statutory exclusions handled via delegated legislation. This “in-unless-excluded” approach reduces gaps as technologies evolve and allows agile response to novel materials (e.g., organoids, engineered constructs).

Question 6: Replace the word “tissue”?

Response: Support retaining “tissue” or switching to a neutral catch-all (e.g., “substance of human origin”**)** to remove ambiguity between clinical usage (“tissue” vs “organs”). If “tissue” is retained, pair it with separate statutory definitions for cells**,** organs**,** and tissue to reduce interpretive confusion across sectors.

Question 7: Exclusions from the definition

Response:

- Human milk: Exclude from core human tissue law for routine clinical uses (regulated as food/TGA biologicals) but include within consent and anti-trade rules to prevent exploitation. [
- Foetal tissue**:** Do not categorically exclude; regulate with specific safeguards (consent, ethics approval, prohibitions on trade), noting varied current treatment in HTAs.
- Faecal tissue (FMT): Manage primarily under TGA biologicals with human tissue law recognising consent and non-commercialisation boundaries.
- Gametes (posthumous): Include retrieval within human tissue legislation pending comprehensive ART frameworks, to avoid gaps.
- Cell lines: Treat as excluded from trade prohibitions only if fully de-identified and non-reidentifiable but included for consent/ethics when linked to identifiable donors or used in ways that meaningfully implicate the original donors. Use delegated legislation to refine scope.

Chapter 5 — Determination of death

Question 8: If determination-of-death provisions apply for all purposes, are there unintended consequences?

Response: Low risk. A unified, brain-based legal standard (“permanent loss of capacity for consciousness and all brainstem functions”) aligns with contemporary clinical guidelines and clarifies that recirculation technologies (e.g., NRP) do not undermine legal death where brain function remains permanently absent. This supports consistency across health, coronial, criminal, and estates law without altering clinical practice.

Question 9: Best statutory location to maintain national consistency

Response: Prefer a Uniform Death Act enacted as national uniform legislation (mirror/applied model), with an intergovernmental mechanism to keep amendments consistent. If not feasible, place the standard in new human tissue legislation in each jurisdiction plus an intergovernmental agreement to manage future changes. Avoid fragmentation that would erode public trust.

Chapter 6 — Living donation

Question 10: Additional safeguards beyond Proposal 14?

Response: Yes—add:

- Cooling-off and independent assessment calibrated by risk (e.g., 24-hour default for solid organs; flexible for urgent liver cases).
- Independent donor advocate models to screen coercion/conflicts.
- Commercial-use transparency where donated surgical excess may enter commercial pathways.
- Readability standards for consent materials translated as needed.

Question 11: Are the best-interests considerations for children appropriate?

Response: Appropriate and comprehensive. Add explicit reference to cultural identity and community obligations, school/psychosocial supports post-donation, and documented conflict-of-interest safeguards where relatives are potential recipients.

Question 12: Situations where removal from a child should not require Committee approval

Response: Permit Committee-free removal only when all are true: (i) negligible/low risk minor procedures (e.g., cheek swab, small volume blood) within HREC-approved research; (ii) parental consent + child assent (where capable); and (iii) clear right to withdraw from future uses, consistent with the National Statement. All therapeutic/non-negligible-risk donations should remain under Committee oversight.

Question 13: Best-interests factors for adults without capacity (Proposal 22)

Response: Appropriate. Add: (a) prior values/preferences (advance statements) with documented attempts to retrieve them; (b) cultural safety and community expectations; (c) minimisation of procedural burden; and (d) independent ethics advice where conflicts are present.

Question 14: When should donation from adults without capacity proceed without Committee approval?

Response: Only for minimal-risk tissue removal in HREC-approved research (e.g., use of surgical excess already being removed for the person's clinical care), with substitute decision-maker consent and explicit prohibition on non-therapeutic, more-than-minimal-risk removals without Committee approval.

Question 15: Appropriate composition of the Committee

Response: A national panel (with jurisdictional sub-panels for timeliness) comprising:

- Chair (clinical ethicist or senior clinician with ethics expertise).
- Transplant surgeon/physician and anaesthetist/intensivist (as relevant).
- Paediatric specialist for child cases.
- Legal member with health law expertise.
- First Nations representative and cultural safety advisor.

- Social worker/psychologist.
- Independent lay member.
- Ability to co-opt domain experts (e.g., ART, biobanking) as needed.

Decision-making should follow a published framework with rapid-response timelines.

Chapter 7 — Reforms relating to deceased donation

Question 16. Role of the Designated Officer

Response: Support removal. The Designated Officer function duplicates well-established DonateLife workflows, introduces location-based inconsistency (hospital vs non-hospital deaths), and can cause delays that risk tissue viability. Replace with a single, nationally consistent consent **+** documentation **+** audit model led by clinical teams and DonateLife, with after-the-fact compliance checks by the National Regulator (or alternative).

Question 17: Balance in Proposal 23

Response: Broadly appropriate. Centres donor autonomy, enables substitute decision-making aligned to the person's values, adds informed-consent thresholds that improve transparency about commercial uses, harmonises hospital/non-hospital pathways. Risks & mitigations**:** Potential family distress where prior consent exists. Mitigate through best-practice family conversation protocols and an explicit escalation/mediation pathway when circumstances materially differ from those contemplated by the donor.

Question 18: Form of consent to deceased donation

Response: Specify multi-channel consent: (a) written (including digital via the Australian Organ Donor Register), and (b) oral during last illness in the presence of two witnesses, recorded in the clinical record. Require standardised wording and minimum data to ensure an auditable trail.

Question 19: Tailoring the hierarchy of 'authorised decision-maker'

Response Adopt the NT model as the baseline, with tailoring for deceased donation to:

- Give priority to the person named in an advance care directive.
- Recognise culturally appropriate kinship decisionmakers (including Aboriginal community-recognised relatives).
- Clarify "availability" (e.g., reachable and able to decide within defined timeframes).
- Require all decisionmakers to apply substituted judgment anchored in the donor's known beliefs and preferences.

Question 20: Disagreement between equal-status decision-makers

Response: Use a tiered resolution: (1) seek consensus led by a trained donation specialist; (2) if unresolved and the deceased's clear prior consent exists, proceed; otherwise (3) escalate for rapid ethics/clinical governance review; if still unresolved, do not proceed. This preserves trust and respects ambiguity.

Question 21: Definition of 'pre-mortem interventions' (PMIs)

Response: Support a broad, purpose-based definition ("solely for the purpose of donation after death"), accompanied by non-exhaustive examples in guidance and explicit recognition that NRP is post-mortem and therefore outside PMI scope. [

Question 22: Limited exceptions to consent for PMIs

Response: Allow a narrow, low-risk exception where (i) the decision-maker cannot be contacted promptly, (ii) death is imminent, and (iii) the intervention is necessary to avoid thwarting a likely donation (e.g., draw from existing lines for serology, non-contrast imaging). Conditions: contemporaneous documentation, no more-than-minimal harm, no hastening of death, prompt re-contact for consent, and retrospective ethics review.

Question 23: Additional safeguards for PMIs

Responses: Recommended safeguards**:**

- Two clinicians certify death is imminently expected and the intervention will not hasten death.
- Separation of roles (treating vs retrieval teams);
- Proportionality and minimal-risk principle.
- Mandatory PMI log with audit by the National Regulator.
- Clear substituted-judgment standard and explicit respect for any known objection.

Question 24: Factors for coroners when deciding consent

Response: List factors to consider: forensic requirements, risk to evidentiary integrity, the deceased's documented wishes, authorised decision-maker views, cultural considerations (including First Nations customs), the type of tissue/organs sought, feasibility of delayed/limited retrieval, and the public interest in donation. Require written reasons where consent is refused and annual public reporting to improve consistency.

Question 25: Self-consent to non-coronial post-mortem

Response: Yes. Permit consent given while alive (e.g., within an advance care directive) with options to limit scope (such as external exam, imaging-only, or specific organ exclusions) and a right to revoke at any time prior to death.

Question 26: Exception where the authorised decision-maker cannot be located

Response: Provide a very limited exception allowing external examination and post-mortem imaging only, after documented, reasonable steps to locate the decision-maker and absent any evidence of objection. Any invasive procedures should require either located consent or public-health/statutory authority.

Question 27: 'Small samples' exception from post-mortem

Response: Support a narrow**,** uniform exception for histology slides/blocks within accredited pathology collections under HREC-approved governance, strict de-identification, and audit. Explicitly exclude identifiable genetic analyses without consent and exclude First Nations samples unless community-endorsed protocols and repatriation pathways are in place.

Chapter 8 — Tissue donation for research

Question 28: Adults without decision-making capacity donating for research

Response: Support a parallel to the paediatric model with safeguards. HREC approval, negligible/low-risk or direct therapeutic benefit, consent by a legally authorised substitute applying substituted judgment, independent advocacy where conflicts exist, right of the decision-maker to withdraw from future uses, culturally safe provisions, especially for First Nations peoples.

Chapter 9 — Reforms Relating to Donation and Use of Deceased Bodies

Proposal Response: The current Western Australian provisions outlined in Proposals 9.9 and 9.10 are not appropriate from an informed-consent perspective because they allow the State or an executor to authorise anatomical examination in circumstances where the deceased person did not provide clear, voluntary, and affirmative consent. These provisions rely on outdated assumptions—such as verbal objections requiring two witnesses, executor-driven authorisation, and different consent rules depending on place of death—which do not reflect contemporary ethical standards or the nationally accepted principle that decisions about body donation must be made by the individual or their authorised decision-maker. Other Australian states, including Tasmania, apply consistent consent requirements regardless of where the death occurs and ensure that donation proceeds only with explicit consent given in an approved form by the individual or, where appropriate, their next of kin. To align with national practice and modern expectations of autonomy and voluntariness, Western Australia must update these provisions to ensure that anatomical examination is authorised solely through clear, informed, and documented consent.

Chapter 10 — Stored tissue collections

Question 29: Consent for secondary use

Response: Yes, default to consent for uses beyond the original purpose, recognising HREC waivers where criteria are met (impracticability, minimal risk, privacy safeguards, public interest).

Question 30: Exceptions to consent

Response: Permit exceptions where an HREC grants a waiver; for de-identified small samples in defined diagnostic archives; and for mandated public-health surveillance. Require transparency notices where practicable and independent governance for any identifiable linkage.

Question 31: Rules for biobank storage/access/transfer/disposal

Response: Yes, codify minimum standards on custodianship, consent tracking, access committees, security, cross-border transfer, retention limits, disposal, return of results/incidental findings, and audit. Tie to regulator licensing.

Question 32: National regulation and oversight

Response: Yes, for **(**a**)** research biobanks and **(**b**)** educational collections, under the National Regulator (or alternative) with proportionate licensing tiers.

Question 33: What to regulate / what not

Response: Regulate consent governance, provenance and traceability, data protection, access criteria, export/import, pricing/cost-recovery transparency, incident reporting, culturally appropriate repatriation, particularly for First Nations remains. Exclude/Light-touch**:** purely synthetic training models and truly de-identified teaching sets with negligible risk.

Question 34: Right to access one's stored tissue

Response: Yes, create a right to: (i) confirm existence, location, quantity, and current use; (ii) request testing or transfer to another compliant facility; (iii) obtain a copy of associated data. Limits: where exhausted, irreversibly de-identified, or constrained by ongoing studies/public-health orders. Extend a circumscribed right to a deceased person's authorised decisionmaker.

Chapter 11 — Prohibition of trade, advertising, importation & data transparency

Question 35: Extra-territorial effect for prohibition on reward

Response: Yes, best implemented through amendments to the Commonwealth Criminal Code to address transplant tourism and related brokering, complemented by harmonised state/territory provisions.

Question 36: Exceptions & paid plasma

Response: Appropriate; they align with TGA/NBA oversight and public-health needs. Additional exceptions: Explicitly recognise kidney paired exchange as not constituting "reward"; clarify coverage for decellularised or otherwise substantially transformed materials already regulated as biologicals. Paid plasma**:** Do not create a blanket exception. If pursued, use the exemption pathway with stringent safeguards (safety, equity, donor protections, independent price oversight, and transparency), recognising Australia's current reliance on imported remunerated plasma.

Question 37: Factors for exemptions (Proposal 43)

Response: The listed factors are sound; add: (i) transparency and public reporting; (ii) First Nations ethical review where relevant; (iii) demonstrable supply/public-health need; and (iv) controls on marketing to prevent undue inducement.

Question 38: Scope of advertising prohibition (Proposal 45)

Response: Broaden to capture brokering/facilitation and deceptive formats (e.g., "buy a photo, tissue is a free gift"), and to cover online marketplaces and targeted digital advertising. Exempt bona fide public awareness campaigns that do not promote prohibited exchanges.

Question 39: Extra-territorial advertising prohibition

Response: Yes, where communications are accessible in Australia and intended to induce Australians to engage in prohibited exchanges, mirroring other extra-territorial public-policy offences.

Question 40: Ethical sourcing of imported tissue

Response: Prefer a combined model, a baseline prohibition on imports lacking verifiable donor consent or involving reward**,** and a reporting/due-diligence regime for high-volume importers. so the system is both enforceable and transparent.

Question 41: Exempting certain imports

Response: Allow time-limited exemptions where: (i) patient need is compelling; (ii) domestic supply cannot meet need; (iii) rigorous documentation and third-party audit confirm ethical procurement; and (iv) a transition plan to ethical/sustainable sources exists. Publish reasons and conditions for each exemption.

Question 42: Data needed

Response: Utilisation and outcomes by tissue type; donation referral/consent/refusal metrics; coronial approval/refusal and reasons; domestic vs imported volumes and provenance; pricing/cost-recovery schedules; adverse events/recalls; equity metrics (including culturally safe access for First Nations peoples).

Question 43: Reporting approach

Response: Adopt mandatory**,** standardised, regulator-hosted reporting with public dashboards and confidential annexes where needed. Align with TGA traceability and privacy laws, require annual independent assurance.

Question 44: Inspection powers

Response: Yes, grant proportionate inspection/audit powers to the National Regulator (or alternative), including document production, site inspection, and corrective action plans, with civil penalties for non-compliance.

Chapter 13 — Compliance

Question 45: Best compliance mechanisms

Response: Use a graduated toolkit: licensing/accreditation, enforceable undertakings, improvement notices, civil penalties for governance failures, criminal penalties for wilful illegal trade/trafficking, public reporting and targeted education for clinicians, coroners, tissue banks, and schools of anatomy. Embed data-driven risk profiling to focus audits.

Chapter 14 — Timeframe

Question 46: Staging and timelines

Response:

- 0–12 months: Adopt uniform consent/authorised decision-maker provisions, coronial decision factors, PMI safeguards, advertising controls, national data schema.
- 12–24 months: Establish National Regulator (or designate an alternative), issue codes/standards, launch biobank/collection licensing pilots, implement import due-diligence regime.
- 24–36 months: National roll-out of biobank/collection licensing, cost-recovery guidance, public dashboards, evaluate compliance model.
- 36+ months: Consider extra-territorial criminal law amendments, informed by implementation evidence and international cooperation.

Chapter 16 — Other urgent reforms

Question 47: Additional urgent reforms

Response:

- Fund and embed culturally safe donation pathways (e.g., support for NIKTT recommendations) and enable families/kin to share donor stories nationally under clear privacy rules.
- Finalise the unified brain-based death determination and NRP protocols with public engagement to protect trust.
- **Implement a** national, consensus consent form **for body donation to schools of anatomy and research facilities**.
- Create a national “small-samples” policy with tight ethics controls and First Nations governance.
- Clarify the adaptable definition of “tissue” and issue regulator guidelines early to reduce uncertainty for researchers and clinicians.