Submission to the ALRC's Discussion Paper on the Review of Human Tissue Laws

Centre for Law and Genetics
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Introduction

We welcome the opportunity to provide a submission in response to the Proposals put forward and Questions posed in Discussion Paper 90, authored by the Australian Law Reform Commission ('ALRC') as part of its Review of Human Tissue Laws. We congratulate the ALRC team on the Discussion Paper. We find it to be well structured, well written, sensible and comprehensive.

As we already noted in our submission to Issues Paper 51, we are members of the Centre for Law and Genetics (CLG) based at the Faculty of Law, University of Tasmania. Key goals of the CLG's projects are to:

- develop and improve regulatory standards in the field of genetics/genomics;
- facilitate the promise of genetic technology and other emerging technologies; and
- facilitate better healthcare in society.

Our research over many years has been generously supported by the Australian Research Council (ARC), the Medical Research Futures Fund and the National Health and Medical Research Council. We particularly acknowledge the ARC for funding our project Genomic Data Sharing: Issues in Law, Research Ethics and Society (DP180100269) which has informed this submission.

The overriding aim of our research is to promote effective governance of genomic and other new technologies in health care delivery and biomedical research and to facilitate equitable distribution of benefits. The availability of human tissue is fundamental to genomic research because it provides the essential biological material needed to study genetic variation, disease mechanisms, and the development of targeted therapies. Without access to diverse and well characterised tissue samples, the accuracy, applicability, and progress of genomic research would be significantly limited.

In this submission, we focus on aspects of the Discussion Paper that relate to the expertise of members of the CLG and respond specifically to those Proposals and Questions that intersect with our work.

General points

As flagged throughout this inquiry, there are numerous inconsistencies in the legislative and other regulatory arrangements relating to human tissue across Australian jurisdictions. This creates legal uncertainty which hampers national coordination in health and research and provides inconsistent protection for tissue donors. We very much support the view that an important goal for this inquiry should be a harmonised national framework or at least greater

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consistency across the States and Territories. We are pleased to see that Discussion Paper Proposals 1-3 not only echo this call for a national legislative framework but further propose a National Regulator to administer the framework. We strongly support these proposals.

Further, as we noted in our submission relating to Issues Paper 51, although we recognise the importance of regulating human tissue for transplantation purposes, particularly with a view to increasing the availability of donated tissue used for transplantation in Australia, research uses of tissue, including genomic research, should also be a matter of priority for this inquiry. We are pleased to see that the issues associated with research use of human tissue have now been addressed in detail in Chapters 8 and 10 and we broadly support the Proposals therein.

We also noted in our submission to Issues Paper 51 our concern that privacy protection does not currently apply to tissue, only to information derived from tissue. We noted, in this regard, that the ALRC, together with the Australian Health Ethics Committee, in the report of their inquiry into the protection of genetic information (referred to hereafter as Essentially Yours) recommended the extension of privacy protection to genetic samples (i.e. tissue). We see it as unfortunate that this recommendation was not supported by the government of the day in its broader response to the recommendations. This recommendation has become increasingly pertinent as sequencing techniques have advanced, lessening the distinction between tissue samples and data extracted from such samples.

A number of the Proposals included in Discussion Paper 90 create protections akin to those provided for personal information in the *Privacy Act 1988* (Cth) (*Privacy Act*). We strongly support these Proposals, but recommend that close scrutiny should be given to the compatibility of the proposed changes to human tissue legislation with equivalent provisions in the *Privacy Act.*

More generally, we strongly endorse the view that the proposed changes to human tissue legislation should create a regime for human tissue that is compatible with other regulatory regimes that impinge on this area. For example, we support the suggestion that the definition of human tissue is compatible with the definition of biologics in the *Therapeutic Goods Act 1989* (Cth) (TGA).

Specific responses to proposals and questions

Chapter 1

As noted above, we strongly endorse Proposals 1-3 relating to a national regulatory framework and a National Regulator. While uniform Commonwealth legislation would provide the highest level of uniformity, it is perhaps unrealistic to assume that the States and Territories would be willing to cede control over all aspects of human tissue regulation. As such, we suggest that Proposal 1(a) is more likely to find traction and support than Proposal 1(b).

We support Proposal 2 in its current form, and lean towards Proposal 3(b) with regard to the National Regulator. We agree that the UK Human Tissue Authority provides a useful model with regard to the functions of the Regulator. We strongly support the view that duplication of responsibility for areas already regulated should be avoided.

While the referred legislative model in Proposal 4 is probably the cleanest way to achieve a national regulatory framework, the hybrid model adopted for gene technology regulation perhaps provides the most realistic option.

Chapter 2
We support the Proposals in this Chapter for the inclusion of an objects section in the new human tissue legislation. We believe the objects listed in Proposal 5 set the right tone for the legislation. They reflect the aspirations of Australians with regard to our health and welfare, and recognise the particular ethical, social, political and historical context within which use of human issue is situated.

While we agree with the inclusion of each of the objects listed in Proposal 5, we suggest that a further object should be included, to reflect the (presumed) desirability of encouraging the development of health and medical technologies in Australia. We do recognise that trade in human tissue per se is not desirable and support the Proposals relating to this in Chapter 11. However, the Australian public interest is unlikely to be served if national health and medical technology development is not supported, or is disadvantaged relative to foreign equivalents. The Discussion Paper is largely silent on the commercial aspects of usage of human tissue. We suggest that explicit acknowledgement of the value of public-private partnerships and other arrangements to Australia and Australians may allay relevant concerns.

An object in support of this goal might be formulated as such:
h. Facilitate the development of innovative medical and health technologies reliant on human tissue, heeding the objectives enumerated in objects a-g.

Chapter 3
We endorse the suggestions in this Chapter that there is a need to remove barriers and promote equitable access to human tissue. We strongly support the need to focus on the particular concerns of Australian First Nations communities and further suggest that the principles that emerge from the analysis of barriers and lack of equitable access for these communities may, in many cases, be usefully adopted as best practice for all Australians.

Chapter 4
We support the adoption of a broad definition of human tissue and lean towards the adoption of the UK definition, given its breadth and succinctness. We do agree that the language of 'tissue' may be inaccurate, given that cells, tissues, organs and other substances (eg milk) may also be included. While 'biologics', as defined in the TGA, is a useful term, it is not part of the common lexicon. Therefore, on balance we suggest that the safest option may be to retain the language of tissue, but to ensure that there is legislative clarity around the full scope of the definition.

With regard to Question 7, in our view none of the materials listed should be excluded. It is difficult to envisage the types of circumstances that warrant exclusion, because the principles relating to human tissue should be applicable to anything of human origin that is capable of identifying an individual, including , for example, human milk and posthumous gametes.

Chapter 8
We suggest that the current Chapter 10 should flow on directly after Chapter 8, or be sufficiently cross linked to it, to reflect that fact that both address use of tissue for research.
We suggest that it would be useful in both Chapters to define research and clearly distinguish it from quality assurance.

We suggest that the term 'identifiability' be clearly defined, as this is a key concept for a number of the proposed reforms. Further, it should be acknowledged that human tissue is always potentially identifiable because of the DNA it contains. This leads us to recommend that the distinction between identifiability/deidentification should not be used as a mechanism for regulatory decision-making.

We support the notion that consent for research can include other models of consent beyond specific consent to participate in a particular research project, although it is vitally important that donors know what they are consenting to with some level of precision.

While we support Proposal 32, we do take issue with point 3, that ‘valid consent is sufficient legal authority for the removal of the specified tissue for the intended research uses …’ Our concern is that this statement fails to reflect the substance of Proposal 34 (which we support), that the removal of tissue for research purposes must be done in a manner that is consistent with the Australian Code and National Statement, responsibilities that go beyond the confines of consent. In our view there needs to be some reflection on the need to comply with these obligations in point 3.

While we generally support Proposal 33, we suggest that there should be appropriate levels of consultation with the scientific community that collects and stores human tissue for future research use, to ensure that enshrining the right of access and right of withdrawal is feasible and effective.

We support Proposal 35 on removal of tissue from children for research, and suggest this provision should be extended to include adults without decision-making capacity. We do query whether adoption of the Tasmanian provision may be too narrow or too uncertain, specifically with regard to the ‘best interests of the child’. We posit that there may be some instances where research use of tissue derived from one child may have broad paediatric benefit, beyond the individual child. We also understand anecdotally that guardianship tribunals and human research ethics committees may have different views on what constitutes ‘benefit to the child’. We suggest that consultation with paediatric researchers may provide further guidance on the appropriateness of this terminology.

We support Proposals 36 and 37. However, we are aware that there may be some circumstances where it would be beneficial for genetic relatives other than the authorised decision-maker to have a right of access to information about how the tissue is being used and a right to withdraw consent. This may warrant more detailed scrutiny.

With regard to Proposal 37, we suggest that the right of withdrawal should go beyond destruction, recognising that for some communities return of unused tissue may be more ethically defensible.

Chapter 10

We suggest that it may be useful to make a clear distinction in this chapter between stored tissue collections already in existence and prospective collections. This distinction is particularly important in addressing Questions 29 and 30.

In response to Question 29, in light of modern conceptions of consent, it seems hard to justify creating and using new collections for research purposes without explicit consent from the tissue donor for storage for research purposes and for the research itself. Likewise, in response to Question 30, it is hard to imagine the types of circumstances that would justify exceptions to the requirement for consent for research use of new collections. We find it difficult to see how application of the waiver of consent provisions provided in the National Statement (discussed further below) could be justified in the context of new collections (while there might be some justification, in limited circumstances, for their use in the contest of existing collections).

We do note that Question 29 makes reference back to Question 27 in an earlier Chapter. Question 27 asks whether there should be an exception to the need for consent so that ‘small samples’ can be taken during post-mortem examinations and used for scientific, medical, or educational purposes. We see no justification for this exception unless the purpose is for training in post-mortem examination techniques or other forms of quality assurance. It seems to us that the critical distinction is between quality assurance and research.

We stress that, beyond post-mortem examination, it is of broader importance that the new provisions make a clear distinction between research and quality assurance (which might include, for example, NATA accreditation and internal benchmarking) in determining the need for consent for the use of tissue collected for clinical purposes. Arguably, consent many not be required for uses of such tissue that are restricted to quality assurance, provided that privacy is appropriately protected and that other good laboratory practices are followed. The size of the sample (small or otherwise) seems irrelevant.

In contrast to prospective research collections, where, in our view, consent for storage and research use is the sine qua non (irrespective of whether the primary purpose for collecting the tissue is for research or clinical purposes), there are likely to be some existing collections that were created in the absence of consent for research purposes. The legitimacy of research uses of such collections in the absence of consent for research (or reconsent) requires careful balancing of what could be conflicting public interests.

It is relevant at this point to consider the requirements of the National Statement regarding creation and use of tissue collections for research purposes. We have provided a summary of the key elements below. We hope this provides some assistance in determining whether the proposed provisions align with National Statement requirements.

While the National Statement applies to all research involving humans, it does provide that some research may be exempt from ethics review. Specifically, paragraph 5.1.17 provides (inter alia) that use of collections of information or data from which all personal identifiers have been removed may be exempt from ethics review. Notably, this exemption does not extend to uses of collections of human tissue. On this basis, we conclude that, as a general rule, creation of new human tissue collections for research and uses of existing and new collections for research purposes requires ethics review. While some existing collections may have been subjected to ethics review prior to their creation, this is not necessarily the case.

The National Statement designates human research that does not fit within the limited exemptions provided in paragraph 5.1.17 on a continuum from higher risk to lower risk. All higher risk research must be reviewed and approved by a properly constituted Human Research Ethics Committee (HREC) embedded within the institution. Lower risk research can be reviewed through an alternative pathway determined by the institution.

Chapter 3.2 of the National Statement deals specifically with the use of human tissue (or biospecimens, using the National Statement language) in laboratory-based research. Paragraph

3.2.1 makes it clear that in all cases where human tissue (biospecimens) is collected for research purposes (including for biobanking), 'there should be ethics review and approval by an HREC of the proposed consent, collection, processing, storage and distribution or disposal.' However, paragraphs 3.2.2 and 3.2.3 make it clear that, for research using only stored tissue (biospecimens) and involving 'no more than lower risk', alternative institutional pathways for non-HREC levels of review may apply. The National Statement thus makes a distinction between existing and new collection of tissue, seeing use of human tissue hosed in the former types of collections for research as potentially lower risk than use of the latter.

This brings us back to the question of whether stored tissue collections can and should be used in research in the absence of consent to do so. Consent is a feature of all aspects of ethics review under the National Statement, although there is provision for consent requirements to be waived in limited circumstances. Paragraph 2.3.10 allows an HREC (but not any other institutional ethics review body) to waive the consent requirement provided that it is satisfied that a range of conditions are met. In the specific context of use of stored tissue collections for research, the National Statement highlights in paragraph 3.2.14 two particular considerations that should be taken into account:

> (a) whether there is a pathway to identify and re-contact the donor(s) in order to seek their informed consent to the use of their biospecimens in research
>
> (b) whether there is a known or likely reason for thinking that the donor(s) would not have consented if they had been asked.

On this basis, these waiver provisions could be relied on by researchers seeking to use existing tissue collections, particularly when seeking re-consent is practically impossible. Even so, this would require full HREC review.

Limited attention has been paid to the adequacy of existing waiver provisions in the Australian bioethical and sociological literature. However, our recent empirical research suggests that current waiver provisions may not adequately reflect community expectations (L Newett et al, 'Australian Attitudes Towards Waivers of Consent Within the Context of Genomic Data Sharing' (2024) 19 *Journal of Empirical Research on Human Research Ethics* 113-123). In our view, if the ALRC were to endorse waiver of consent for research using existing collections, it would be important to: review the current provisions in the National Statement; identify community concerns and ensure that more attention is paid to them; and improve requirements regarding transparency, accountability and disclosure of waivers.

We note that the Commission plans further consultation on this issue of what exceptions should exist to the requirement of consent; we strongly endorse the stated intention of avoiding unnecessarily hindering scientific research whilst also ensuring respect for research participants and enhancing the public trust on which scientific research depends.

In response to Questions 31, 32 and 33, and based on our experience in this field over many years, we submit that, going beyond the requirements in the National Statement:

- legal rules **are needed** for stored tissue collections (including research biobanks and educational collections);
- national regulation, guidance and oversight **would be beneficial**;
- **all** aspects of collection, storage, use, transfer and disposal should be included; and

- **all** types of collections should be regulated.

We do acknowledge that in some instances, it would be appropriate for this regulation to be ‘light touch’.

We support the notion that individuals should have a right of access to their tissue – in our view this is indisputable. In determining who should be granted this right of access, account will need to be taken of the familial nature of genomic information that can be obtained from tissue.

Concerns specific to Aboriginal and Torres Strait Islander communities should also be accounted for here, including principles of Indigenous Data Sovereignty and implications for members of the Stolen Generations. This has particularly relevance in the context of waiver of consent.

Chapter 11

We support the ongoing prohibition on exchange of human tissue for reward. We support the Proposals in this Chapter. However, we suggest that other conceptions of benefit sharing could be discussed here. Benefits of donating tissue and participating in research include such matters as: return of research results and clinically relevant findings; preferential access to healthcare; other less tangible benefits to the individual which benefit society, including return of results to the biobank, publication of results, development of new healthcare products.

Chapter 12

We note that this Chapter seems to relate primarily to information associated with human tissue transplantation. We think it would be worthwhile to signal in this Chapter the point noted above in relation to Chapter 8 that human tissue itself is inherently identifiable because of the DNA it contains, and to discuss the regulatory issues that this raises.