Submission to the ALRC's Issues Paper on the Review of Human Tissue Laws from the Centre for Law and Genetics

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Introduction

We welcome the opportunity to provide a submission in response to the questions posed in the current inquiry by the Australian Law Reform Commission ('ALRC') into human tissue laws. We have read with interest the ALRC's *Review of Human Tissues Laws: Issues Paper 51* ('Issues Paper 51').[6]

The authors 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, 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) to which much of the research mentioned in this submission relates.

The overriding aim of our research is to promote effective governance of genetic 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 will focus on aspects of Issues Paper 51 that are relevant to the goals of the CLG and will respond to those questions that interact with our work.

Context

We note that the focus of Issues Paper 51 is mainly on donated tissue used for transplantation purposes. Whilst we recognise the importance of this, particularly with a view to increasing the availability of donated tissue used for transplantation in Australia, we are of the view that research uses of tissue, including genomic research, should also be a matter of priority for this inquiry.

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Essentially Yours: The Protection of Human Genetic Information in Australia (2003) Report 96.

The original Human Tissue Acts (HTAs) predate the genomic era and do not adequately address genomic research and secondary use of tissues. Substantial government funding is committed to such research. The impacts for individuals from whom the tissue was derived can be significant – for example, discovering how their cell lines have been used. With increasing globalisation and commercialisation, genomic research is becoming more ethically and legally contentious, which calls for greater clarity and guidance. Attention should not just be focused on future donations of human tissue, but also on the large and diverse stored collections that are currently in existence across Australia. Proper documentation does even not exist for many of these. Yet they are an important source of tissue for research purposes. Related to this, we recommend that attention also be given to required consent for use of tissue samples for research purposes, including national consistency in this area.

As noted above, in light of our particular expertise relating to the regulation of genomic and other health-related research, our submission primarily focuses on regulation of uses of human tissue in research, and the potential for human tissue legislation to play a greater role in this area. We submit that there is some urgency in addressing regulatory lacunae in this space. The increased availability of whole genome sequencing and medical profiling, and the new era of personalised medicine necessitate ongoing assessment of the adequacy of existing regulation of research and the capacity of the law to respond. There is a close intersection between the regulation of clinical healthcare products and services and the regulation of biomedical research in this area, and the boundaries are becoming blurred.[7] With the development of biobanks in Australia and other countries,[8] and growing acceptance of a broad consent model to facilitate participation in future, as yet unspecified research, there is a heightened need to ensure adequate protection of donors of human tissue that is used in research, and good research governance more generally.

Some of us provided detailed submissions to the ALRC Inquiry into the Protection of Human Genetic Information in Australia jointly undertaken with the National Health and Medical Research Council inquiry into the protection of genetic information (referred to hereafter as Essentially Yours). Many of the issues raised in that inquiry, over 20 years ago, are still relevant today. Together with other collaborators, we canvassed these issues in a report on the national regulatory landscape within which collection and use of health-related genomic information is situated (which we referred to as 'Essentially Ours').[9] That report was commissioned by the federal Health Department. Of particular relevance to this inquiry, we noted in that report that:

> Genomics research involves the movement of tissue samples and associated data from participants and patients to researchers, clinicians and beyond. Mechanisms for the control of samples and data include: ownership rights, ethical frameworks, intellectual property rights, custodianship sovereignty models, and provenance records. People have intuitive assumptions about rights of ownership or control over their samples and data. However, the legal position is more complicated and frequently does not provide the control that may be assumed.

On this basis, we submit that there remain serious gaps in the regulation of the use of human tissue samples for research that this inquiry has the potential to explore and address more fully.

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[7] Rebekah McWhirter, Lisa Eckstein, Don Chalmers, Jane Kaye, Jane Nielsen, Margaret Otlowski, Megan Prictor, Mark Taylor and Dianne Nicol, *Essentially Ours: Assessing the Regulation of the Collection and Use of Genomic Information* (Hobart: Centre for Law and Genetics Occasional Paper No 11, 2022), https://www.utas.edu.au/law-and-genetics/publications/occasional-papers

[8] See, for example, the newly established Australian Health Biobank located within CSIRO: https://www.csiro.au/en/work-with-us/industries/health/australian-health-biobank

[9] Above, n7.

As flagged in the Terms of Reference for the inquiry, there are inconsistencies in legislative arrangements across Australian jurisdictions. This creates legal uncertainty which hampers national coordination in health and research. We very much support the view that an important goal for this inquiry should be a harmonised national framework or at least greater consistency across states and territories.

Aims of HTAs

Question 3 of Issues Paper 51 asks about what should be the aims and objectives of HTAs. It includes a list of possible aims, all of which we support.

Principles to guide HTAs

Question 4 of Issues Paper 51 considers what might be the appropriate principles for reforming HTAs. We support all of the proposed principles that Issues Paper 51 puts forward.

Regarding the third dot point – 'The importance of public trust in the framework that governs how human tissue is obtained and used in Australia' we suggest amending to: 'The importance of public trust in *and trustworthiness of* the framework that governs how human tissue is obtained and used in Australia'.

With respect to the fourth dot point – 'The importance of laws that are well designed and effective' – we believe this intersects with the call for greater consistency across HTAs in Australia.

We note at page 7 of Issues Paper 51 under the heading 'Reform should support increased use of human tissue in Australia' there is mention in paragraph 31 of the importance of access to tissue for research purposes. However, this is not followed through in the rest of that section, particularly regarding paragraph 35 which outlines possible reforms to promote increased access to human tissue which is focused solely on use of tissue for donation. In our view it is essential that the inquiry give appropriate attention to the use of human tissue in research and how this can be better regulated under the HTAs. To this end, we suggest inclusion in the principles guiding reform the promotion of access to tissue for human research.

Priority reform areas

What should be included in the definition of tissue?

The definition of tissue needs to be broad enough to encompass emerging technologies. We suggest a risk-based definition: if tissue contains human genomic material, it should be 'tissue' for the purposes of the HTAs. This would facilitate a coherent and risk-focused approach that aligns with community expectations, and will contribute to addressing many of the gaps that exist under the current approach.

What legal protections are needed for adult living donors?

More attention needs to be given to the protections for donors of tissue used for research. Privacy protection does not currently apply to tissue, only to information derived from tissue. We note in this regard, the recommendations made in the Essentially Yours Report for the extension of privacy protection to samples but which were not supported by Government in its response to the recommendations; we elaborate on this below under the heading – 'The relationship between laws relating to human tissue and laws relating to data derived from that tissue.'

Increasing commercialisation of cell-based products raises the urgency of resolving ownership issues relating to human tissue-derived products which we elaborate on below under the heading 'Ownership' as part of our submission on additional issues that the inquiry should address.

What tissue should be used in research?

Para 57 notes that 'After tissue has been removed from a living purpose for a valid clinical purposes such as in surgery, most of the HTAs allow it to be used for an additional purpose. The HTAs do not generally require consent to the additional purpose from the donor or impose rules for how the removed tissue case be used.'

We support the inquiry addressing this gap and potential concerns regarding the use of tissue initially removed for a clinical purpose, subsequently used in research, transferred overseas and or used for genetic testing without the donors' knowledge. Even where there is consent for research use, it may be inadequate consent and not legally valid.

We note that human research ethics committees (HRECs) have an important role to play with regard to the regulation of genomic research but are often not well equipped to do so; more guidance for HRECs is needed either through the HTAs or through guidelines authorised under the Acts. The UK Confidentiality Advisory Group (CAG) – an independent body which provides expert advice on the use of personal information, could be a useful model to consider: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/

Who should be able to authorise tissue donation when a person dies?

In addition to considering issues relating to tissue donation, it would be of considerable value to address the issue of taking unconsented genetic samples from deceased people, as well as genetic testing of samples from deceased individuals without consent.[10] This is currently not regulated or clear, and this is an area where this type of activity may result in harms to living genetic relatives and/or communities. Providing guidance on what the process for this should be, as well as permissible uses, would assist in clarifying the responsibilities of clinical repositories and better mitigate potential risks.

What, if any, other issues should be focused on in this Inquiry

In response to this question, we submit that the following issues may warrant further consideration.

Stored collections of tissue

As flagged above, we are of the view that this inquiry should include coverage of stored collections of tissue. There are many and diverse stored collections of tissue in Australia, some of which are quite old and could now come within cultural heritage laws. We note that Essentially Yours devoted an entire chapter to this issue (Chapter 19). There remains, in our view, unfinished business as there is currently insufficient information and guidance available regarding stored tissue collections and related consent requirements. We recommend that provision be made for a set of guidelines to be authorised under the HTAs (e.g. by the NHMRC) to help provide guidance regarding these collections and permissible uses and also to cover repatriation of remains, including but not limited to Indigenous remains. We note that

[10] See e.g. Rebekah McWhirter and Margaret Otlowski, 'Regulation of Non-consensual Genetic Testing in Australia: Use of Samples from Deceased Persons' , (2016) 24(1) *Journal of Law and Medicine* 150.

included under issues that the inquiry is unlikely to focus on is First Nations ancestral remains to the extent that they are dealt with under cultural heritage laws; even if that is the case, it is still necessary to ensure that there is clarity of regulation up to that point, and to ensure that there is relative consistency between groups and over time.

Consent

As already flagged earlier in this submission, we are of the view that there are a number of aspects relating to consent in connection with the use of human tissue samples that warrant consideration as part of this inquiry. We have indicated above our support for the inquiry to address the gap in regulation where tissue initially removed for a clinical purpose is later used in research without the donors' knowledge. We have also recommended above that guidance be provided regarding stored tissue collections and related consent requirements.

Additional areas requiring attention include: to what extent is broad consent for future use acceptable for human tissue samples, and what additional legal protections may be warranted for the use of banked human tissue? Considerable interest has developed in the use of dynamic consent platforms to allow research participants to update their consent preferences over time. This may warrant dedicated attention in the context of the future use of human tissue. Where tissue has been collected for a clinical purpose and authorisation is sought for its use in research, HRECs are entrusted with assessing the acceptability of a waiver of the requirement for consent. This is an ethically and legally challenging task, and attention by the inquiry on the extent to which HRECs are equipped to perform such a role would be welcome.

Ownership

Ownership of human tissue is an ongoing and intractable issue that warrants consideration. Currently governed by common law principles, case law has confirmed that human tissue is capable of being 'owned' in some cases once it has been removed from the human body. Nevertheless, there has been limited judicial consideration of the issue outside very specific contexts (primarily return of human gametes for reproductive purposes) and there remains considerable uncertainty in other contexts.[11] It may be that legislative clarification of the position in relation to ownership is required to provide guidance, although few jurisdictions have gone down the legislative route in relation to ownership of tissue. Ownership is a threshold question for trade in products which is to be covered in the inquiry so the question of ownership of human tissue must be contemplated in order to address this further question. The relationship between ownership and control over tissue samples is also important, and feeds into the adequacy of the laws on privacy and consent (noting that we discuss the issues relating to privacy more fully below).[12] The issue of ownership of genetic/genomic data derived from tissue samples presents even greater difficulties,[13] and as we point out below, increasingly it is becoming more difficult to separate human tissue and genomic data.

[11] Essentially Ours, n7 above, chapter 9.
[12] Ibid.
[13] See e.g., Jane Nielsen and Carolyn Johnston, 'Ownership of Genomic Data' (2005) 55(2) *Internal Medicine Journal* 329; Jane Nielsen and Dianne Nicol, 'Data ownership in genomic research consortia' (2024) 11(2) *Journal of Law and the Biosciences* https://doi.org/10.1093/jlb/lsae024

Lack of protection of genetic samples (addressing unfinished business from the Essentially Yours Report.)

We would particularly recommend that consideration be given to some form of complaints/redress mechanism through an oversight body, possibly through an expansion of the role of the Organ Transplant Authority. Currently, there are few options open to individuals or communities who have been harmed by unauthorised use or misuse of their genetic samples, and it may be productive to examine what options exist in other jurisdictions; for example, we note the broad remit of the Human Tissue Authority in the UK: https://www.hta.gov.uk/

The relationship between laws relating to human tissue and laws relating to data derived from that tissue

At present there is disparity between the laws governing collection, storage, use and disposal of human tissue, and genetic/genomic data respectively. One of the recommendations included in Essentially Yours that we were particularly in favour of was the inclusion of genetic samples within the definition of personal information in the *Privacy Act 1988* (Cth). In our view, defining samples in terms of personal information would bring them into an existing and workable regulatory scheme.[14] At that time, there was already some academic support for the view that genetic samples are information, or, more accurately, that they are records containing information. We noted that technologies such as bioinformatics were already establishing the linkage between computer technology and genetic technology and that it was likely that human tissue samples would, over time, be seen increasingly as living databases of information. We extended this idea further in 2016, introducing the concept of the 'walking biobank'.[15] We elaborated further that:

> The basis of this idea rests in substituting the collection and long-term storage of tissue for the ongoing engagement of the participant in genomic research. On this model the research participants themselves serve as the storage units of their genomic material…

The basis for our support of the inclusion of genetic samples in the definition of personal information in privacy legislation was to ensure that all of the people who come into possession of genetic samples are bound by privacy obligations, irrespective of whether or not they, themselves, extract genetic information. This change, we argued, would improve the capacity to keep track of the use and transfer of genetic samples from the source to the end user of genetic information. We recognised that research conducted using genetic samples must be in accordance with the NHMRC National Statement on the Ethical Condict of Research involving Humans (the National Statement), as well as the privacy principles if it involves the collection or use of personal information. However, the section 95 and 95A provisions in the *Privacy Act 1988* and the waiver of consent provisions in the National Statement do allow for use without consent in certain circumstances. We argued that the inclusion of genetic samples in the *Privacy Act 1988* would provide an additional layer of protection to sample providers.

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[14] Margaret Otlowski and Dianne Nicol, 'The Regulatory Framework for the Protection of Genetic Privacy in Australia' in Terry S-H Kaan and Calvin W-L Ho (eds.) *Genetic Privacy: An Evaluation of the Ethical and Legal Landscape* (Imperial College Press; 2013) 283.

[15] Don Chalmers, Dianne Nicol, Jane Kaye, Jessica Bell, Alastair V Campbell, Calvin W L Ho, Kazuto Kato, Jusaku Minari, Chih-hsing Ho, Colin Mitchell, Fruzsina Molnár-Gábor, Margaret Otlowski, Daniel Thiel, Stephanie M Fullerton and Tess Whitton, 'Has the Biobank Bubble Burst? Withstanding the Challenges for Sustainable Biobanking in the Digital Era' (2016) 17 *BMC Medical Ethics* 39.

We submitted that it was appropriate that the sample collector should be under an obligation to explain the purpose of collection, primary and related secondary uses, the persons to whom the samples are usually transferred, access rights etc at the time of collection of the sample. This is consistent with the obligations of researchers to explain future uses of genomic information when conducting human genomic research. We were of the view that if these matters were properly explained to sample providers, growing concerns about the use of samples may well be alleviated. Moreover, the perceived need for samples to be accorded property status in order to protect the rights of sample providers (which, we submitted, was highly problematic) may be rendered unnecessary. In many respects the protection afforded by the privacy principles is precisely the type of protection sought by advocates of property rights.

In our view, these requirements would not have imposed an unreasonable burden on sample collectors. In the climate at the time of Essentially Yours (a climate which, we submit, continues to this day), with increasing concerns about personal privacy and increasing capacity to extract personal information from genetic samples, it made good sense that sample providers should be told about what happens to their samples after removal. In many instances, all that may be required is for the sample provider to be notified that their sample will be stored for a particular period and then destroyed.

We argued that the proposed mechanism for providing privacy protection for samples would be relatively simple to establish. All that would be required is some minor amendments to the definitions in the *Privacy Act 1988* and to the privacy principles. In contrast, the creation of a regime for the protection of samples based on property notions would have been much more complex, and, if left to the vicissitudes of the common law, may never emerge. We did suggest at the time that it may be possible to establish an equivalent regime, either through sui generis legislation or through amendments to the human tissue legislation in the states and territories. We encourage this analysis to be undertaken as part of the current ALRC inquiry.

In our view at the time, the one major drawback of the proposed change to the privacy regime was that enforcement powers are relatively weak when compared with common law actions. The privacy regime is complaints-driven and conciliation-based and that orders of the Privacy Commissioner (now the Australian Information Commissioner) can only be enforced by court action. However, we did recognise in our submission that there are many advantages of conciliation over litigation.

We did see one major disadvantage, however. Even if the inclusion of genetic samples within the definition of personal information had been accepted by the government and implemented, it would most likely not have had retrospective force, and therefore, there would still have been gaps in the protection afforded to providers of samples already in existence. As such, although we accepted that proposed amendments to the *Privacy Act 1988* appeared to provide a reasonable solution to the problems associated with collection and use of future genetic samples, it would still have been necessary to consider other avenues for oversight of the use of existing genetic samples, particularly when stored in databases or collections linked to other identifying information.

In our view, many of the issues we raised in 2003 relating to our support for the inclusion of genetic samples in the definition of personal information in the *Privacy Act 1988* could be used to support the inclusion of equivalent provisions in human tissue legislation. We urge consideration of this issue.