Submission in response to ALRC Issues Paper 51

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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').

The authors are working together on a national research project funded by the Medical Research Future Fund, in which our work is focused on the legal and ethical issues that arise from the possible expansion of newborn screening ('NBS') to include genomic sequencing. This submission is made by the authors in their personal academic capacities.

NBS is national population health screening delivered through five programs and available to all babies born in Australia. NBS is aimed at early identification of serious, treatable, childhood-onset medical conditions. Our work considering legal and ethical issues in the expansion of NBS is relevant to the current inquiry to the extent that the bloodspot samples taken and stored in the Australia's NBS programs are retained and may be (with processes and approvals varying by state or territory jurisdiction) made available for secondary uses, including research purposes.

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The key issues we will address in this submission relate to tissue collected within the NBS programs for the purpose of identifying relevant medical conditions.

In this submission, we will respond to those questions from Issues Paper 51 that interact with our current work.

Context

The focus of Issues Paper 51 is largely on donated tissue. Our work is focused not on donated tissue per se, but on tissue collected for screening and retained primarily for verifying results or related aspects such as quality control or auditing. A relevant consideration is that tissue is retained for different periods across the five NBS programs operating in Australia, and that different consent arrangements are in place across the programs including in respect of any secondary use of the tissue samples. While such consent processes exist, these are not currently regulated by human tissue laws even though they extend to secondary use of human tissue.

In all the NBS programs, consent is sought from the parent(s) of the newborn. That consent is primarily for the collection and analysis of the sample. Consent is also sought for retention of the sample and its use for quality assurance purposes and potential research use. In two of the five programs, consent is written with the two distinct uses—screening and research—separately dealt with. In the remaining programs, consent is verbal. We submit that the current consent processes in place in Australia—whether verbal or written—give rise to legal questions about the extent to which parents, at the time of their child's birth, are fully aware of the nature of the consents they are being asked to give on behalf of their child.[1] In none of the programs is the tissue collection referred to in terms of donation.

As such, it is relevant to address, in this submission, the current limited scope of human tissue laws in Australia and their silence about NBS tissue samples.

While all states and territories have legislation covering human organ and tissue removal and use, these laws mainly focus on transplant of donated tissue rather than management of tissue obtained during screening, including clinical testing, storage, research or other third-party use. For example, human tissue laws deal with the situation of tissue taken from a child – with parental consent – for transplant or transfusion to a family member.[2] However, the legislation lacks guidance on consent for blood taken for screening NBS, or for its secondary use for purposes like research.

One exception is the *Human Tissue Act 1983* (NSW), section 20 of which allows parental consent for taking blood from a child under 16 years—other than for clinical purposes for the

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1 Jean-Louis Dhondt, 'Expanded newborn screening: Social and ethical issues' (2010) 33(Supp 2) *Journal of Inherited Metabolic Disease* S211, S215; Andrea Akkad et al, 'Patients' perceptions of written consent: Questionnaire study' (2006) 333(7567) *BMJ* 528.

2 See, for example, *Human Tissue and Transplant Act 1982* (WA) s 13.

child[3]—but only if the child agrees to the removal, and a doctor advises the health risk to the child is minimal. Section 20A provides another route involving parental consent when the child is unable to agree, but this can only be used when the blood is used to treat the child's parent or sibling.[4] These provisions suggest that newborns, unable to agree, cannot have their samples legally used for research. This raises serious questions about the validity of the current NBS consent practices in NSW in respect of consent for research use.

Quite appropriately, the legislative regulation of human tissue use in Australia imposes fairly strict conditions around the use of tissue obtained from children. While the long titles of the various statutes often include 'and for other purposes', they do not generally expressly deal with the situation of retention and secondary use of blood taken for screening or clinical analysis. Most state and territory laws do have provisions dealing with 'donations from children', limiting use to family transplants with both parental consent and the 'child's agreement' and provisions dealing with blood collection for transfusion or 'other therapeutic or for medical or other scientific purposes' with both parental consent and the child's agreement (or an alternative approval mechanism).[5] The NT Act is silent on tissue donations from children and deals only with blood donations from people aged 16 years and over.[6]

Access for medical research purposes to the biobank of bloodspot cards retained by each program is governed by human research ethics frameworks and specific policy and regulation in certain Australian states. These purposes are, however, generally limited. For example, the *Human Tissue Act 1983* (NSW) states, in section 34(1), that the Act does not prohibit certain things. These include:

> (b2) the retention of tissue lawfully removed from the body of a person … in prescribed circumstances for such period as the regulations authorise for the purpose of obtaining an authority under this Act to use the tissue for therapeutic, medical or scientific purposes,
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> (b3) the use of small samples of any tissue that is lawfully removed from the body … for the purpose of carrying out analyses or tests –
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> (i) that are part of a program (including any quality assurance program, quality control program, audit or evaluation) to ensure, or improve, the quality of

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3 Consent to take a child's blood for clinical purposes resides with the parents or guardians of the child under common law.

4 *Human Tissue Act 1983* (NSW) s 20A: specifies that this can only occur where the child is certified as unable to 'understand the nature and effect of the removal' and 'any risk to the child's health … is minimal'. While some NBS results may be relevant for a family member's health, this is not the primary purpose of screening.

5 *Transplantation and Anatomy Act 1978* (ACT) ('TAA ACT') Pt 2 Div 2.3 & Div 2.5 s 21; *Human Tissue Act 1983* (NSW) ('HTA NSW') Pt 2 Div 3 & Pt 3 s 20; *Transplantation and Anatomy Act 1979* (Qld) ('TAA Qld') Pt 2 Div 2A & Div 4 s 18; *Transplantation and Anatomy Act 1983* (SA) ('TAA SA') Pt 2 Div 3 & Div 5 s 19; *Human Tissue Act 1985* (Tas) ('HTA Tas') Pt II Div 3 & Div 5 s 19; *Human Tissue Act 1982* (Vic) ('HTA Vic') Pt II Div 3 & Pt III s 22 s 42; *Human Tissue and Transplant Act 1982* (WA) ('HTTA WA') Pt 2 Div 3 & Div 5 s 19.

6 *Transplantation and Anatomy Act 1979* (NT) ('TAA NT') Pt 2 Div 1 & Div 4 s 14.

> services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products, or
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> (ii) that are necessary for the delivery of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products or for the accreditation under any Act of a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products,

Section 34(1)(b2) does contemplate use for 'scientific purposes', suggesting research use. The *Human Tissue Regulation 2020* (NSW) does include a provision—clause 8—dealing with section 34(1)(b2) but this is limited to 'tissue removed … during medical, dental or surgical treatment performed as a matter of urgency in order to save the life of the person or to prevent serious damage to the health of the person'. As such this provision does not provide an exception to prohibition of research use of NBS tissue samples.

The extent to which section 34(1)(b3) covers biomedical research is not readily apparent, with the clear focus being on research to ensure the validity and integrity of testing processes. A further complication is that these do not expressly deal with research conducted by commercial entities to develop new treatments that can be commercialised. The requirements for access for such purposes would be governed by health research ethics committee ('HREC') requirements under the *National Statement on Ethical Conduct in Human Research* ('*National Statement*').[7] It is notable, however, that such access, and access by university research teams is not expressly permitted by human tissue legislation with the language of these provisions being quite restrictive. For example, paragraph (b3)(ii) permits where the 'analyses or tests … are necessary'. Of all the jurisdictions, the NSW legislation provides the clearest detail of permitted use.

The clearest guidance from the *National Statement* is found in Figure 2, which is a 'Guide to how participation of children and young people in research is authorised based on levels of maturity, requirements of consent and assent, and other provisions'. The first category in that figure is 'Infants who are unable to take part in discussions', being the group from whom NBS tissue samples are taken. The guidance provided is that participation in research requires 'valid parent/guardian consent'.[8] Chapter 2.2 of the *National Statement* sets outs the 'general requirements for consent' and makes it clear that 'consent … should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.'[9] This suggests that, in the absence of clear legislative permission, a person (in this case, a parent) giving broad consent for secondary use (as is obtained under

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7 National Health and Medical Research Council, Australian Research Council and Universities Australia, *National Statement on Ethical Conduct in Human Research* (2025, Canberra: National Health and Medical Research Council),

8 Ibid 80.

9 Ibid 17.

the written or verbal consent processes in NBS) would not satisfy the requirements of the *National Statement*.

In all Australian human tissue legislation, it is a miscellaneous provision that does all the heavy lifting in respect of secondary use of NBS tissue samples. Most of the jurisdictions have a provision in a Part dealing with miscellaneous matters that permits consensual removal of tissue in the course of a procedure or operation carried out, in the interests of the health of the person and the 'use of tissue so removed'.[10] The NSW legislation provides a little more detail,[11] effectively permitting the use and retention of removed tissue for specified purposes, including medical treatment,[12] 'therapeutic, medical or scientific purposes',[13] quality assurance processes and service delivery,[14] and assisted reproductive technology.[15]

The desire of researchers to access bloodspot cards for medical research purposes could be heightened because of the potential to explore the feasibility of using genomic sequencing in NBS. Under the NSW legislation, such research use would not be permitted unless it could be shown that it was 'necessary for the delivery of services … or for the accreditation … of a hospital, etc', or 'part of a program … to ensure, or improve the quality of services …'[16] Unless the various regimes in Australia are brought into harmony, there will be different access potentials across the country giving rise to inequities, for example, with regard to the diversity of reference genetic datasets.

Aims and objectives of human tissue laws

Question 3 of Issues Paper 51 asks about what the aims and objectives of human tissue laws should be. It includes a list of possible aims, all of which are, in our view, sound. These aims do not, however, encompass the situation of tissue obtained for screening or clinical purposes being accessed and used for secondary purposes, as is the case with NBS tissue samples.

As such, we recommend that human tissue laws specifically include the following aim:

- creating a transparent and easy to navigate system for dealing ethically and legally with secondary uses, with appropriate consent, of tissue obtained through any and all screening or clinical processes.

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10 TAA ACT (n 87) Pt 9 s 46; TAA NT (n 88) Pt 7 s 26; TAA Qld (n 87) Pt 9 's 47; TAA SA (n 87) Pt 8 s 37; HTA Tas (n 87) Pt V s 28; HTA Vic (n 87) Pt X s 42; HTTA WA (n 87) Pt 7 s 32

11 HTA NSW (n 87) Pt 8 s 34.

12 HTA NSW (n 87) Pt 8 s 34(1)(b).

13 HTA NSW (n 87) Pt 8 s 34(b1) limited to tissue retained in the form of a 'tissue slide or tissue block which enables microscopic examination of the tissue. As such, this would not extend to NBS bloodspot card use.

14 HTA NSW (n 87) Pt 8 s 34(1)(b3).

15 HTA NSW (n 87) Pt 8 s 34(1)(b4).

16 Ibid.

While our particular focus is on NBS tissue samples, including this aim will benefit human tissue laws through ensuring public trust in medical procedures is maintained irrespective of whether the tissues are obtained through donation or screening or clinical processes. It will specifically assist in ensuring the existing high level of public trust in public health screening programs like the NBS programs in Australia is maintained and even enhanced.

More broadly, we suggest that the review consider including an aim around public reporting of public health benefits of research using donated tissue and tissue made available for secondary uses.

Principles to guide human tissue laws

Question 4 of Issues Paper 51 considers what principles for should guide reform of human tissue laws. In addition to the proposed principles, all of which we support, we consider it important that reform also be guided by:

- the principle of recognition of the evolving capacity of children to understand and give informed consent;
- the right of children to an open future;[17]
- the importance of fully informed and verifiable consent, particularly where consent is given by a person other than the person whose tissue is being obtained; and
- where samples are retained over time, a requirement for re-consent or refreshing consent for continued retention and possible secondary use beyond 16 years of age.[18]

Priority reform areas

One aspect of human tissue laws that is not expressly identified in Issues Paper 51 is the situation of tissue obtained other than through donation. As noted above, in the Context section, Australia's human tissue laws are effectively silent on consent to obtain samples for screening or clinical purposes and as such silent on consent in respect of any secondary use of such samples.

Secondary use of retained NBS samples for research is generally understood to require approval by bodies such as a state health department (eg, under a relevant policy directive) and a human research ethics committee, but it is not clear that there is any legal basis for this.

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17 Joel Feinberg, 'The Child's Right to an Open Future', in Daniel Engster and Tamara Metz (eds), *Justice, politics, and the family* (2014, Taylor & Francis) 145–58. Feinberg describes the 'right to an open future' as protection of what he refers to as 'rights-in-trust', being autonomy rights that a child cannot yet exercise but which should reasonably be held in trust for them to exercise once they are old enough. These rights may be violated during childhood through actions taken by others and such violations remove the possibility of the child exercising them when they reach capacity.

18 Mark J Taylor et al, 'When can the child speak for herself? The limits of parental consent in data protection law for health research' (2018) 26(3) *Medical Law Review* 369.

The issues identified in this section of Issues Paper 51 all relate to donated tissue. Given the tissue we are focused on in this submission is not donated tissue per se, but rather tissue samples obtained in the course of a national screening program, we have addressed the questions in this section on the basis that such samples need also to be expressly addressed in human tissue laws.

Issues relating to tissue obtained from living persons

What tissues should be used in research?

Issues Paper 51 identifies that the '[human tissue laws] do not generally require consent to the additional purpose' where 'tissue has been removed from a living purpose for a valid clinical purpose'. This is not because the human tissue laws expressly address this situation, but rather that they are silent on it. This is problematic as it creates a situation that is highly likely to undermine public trust not only in tissue donation systems, but in clinical treatment systems themselves.

In our view, human tissue laws should deal with this situation expressly as a vital element of ensuring public trust is maintained in the health system.

What protections are needed for children?

As well as being inconsistent in how donation of tissues from children is regulated, human tissue laws are silent about tissue obtained from children through screening or clinical processes. It is important for human tissue laws to be guided by recognition of the evolving capacity of children consistent with international human rights law, the right to bodily integrity and privacy. Of particular relevance to the issue of evolving capacity of children are Articles 5 and Article 12(1) of the *Convention on the Rights of the Child*[19] ('CRC') and the 'Statement of the Committee on the Rights of the Child on article 5 of the Convention on the Rights of the Child'.[20] Of particular relevant to the issue of bodily integrity is Article 7 of the *International Covenant on Civil and Political Rights*[21] ('ICCPR'). Of particular relevance to the issue of privacy is Article 16 of the CRC and Article 17 of the ICCPR.

The appropriate implementation of such guidance in legislation is relevant to the issue of maintaining both parental and public confidence in the NBS, and to ensure that the child's 'rights-in-trust' are not ignored or inadvertently breached.[22] It is also relevant to ensuring that

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19 *Convention on the Rights of the Child*, opened for signature 20 November 1989, 1577 UNTS 3, Australian Treaty Series 1991 No 4 (entered into force 2 September 1990, entered into force for Australia 16 January 1991) ('CRC').

20 Committee on the Rights of the Child, 'Statement of the Committee on the Rights of the Child on article 5 of the Convention on the Rights of the Child' (11 October 2023, United Nations Human Rights Treaty Bodies).

21 *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, GA Res 2200A (XXI), 999 UNTS 171; Australian Treaty Series 1980 No 23, UN Doc A6316 (1966) (entered into force 23 March 1976, entered into force for Australia 13 November 1980, except article 41 which entered into force on 28 January 1993) ('ICCPR').

22 Feinberg (n17).

parents do understand the potential impact of the consent they give to NBS, whether written or verbal,[23] and that governments can be confident that such consent is freely given.

Other uses of tissue and how it should be regulated

As already identified, it is important that human tissue laws expressly regulate use of tissue for both quality assurance and research purposes.

Question 5, 6 and 7

Our responses to these questions are dealt with above.

[23] See, Dhont (n 1); Akkad (n 1). See also, Julia Pinel et al, 'Information and parental consent for French neonatal screening: A qualitative study on parental opinion' (2023) 9(2) *International Journal of Neonatal Screening* 26; Erin Rothwell et al, 'An assessment of a shortened consent form for the storage and research use of residual newborn screening blood spots' (2017) 12(5) *Journal of Empirical Research on Human Research Ethics* 335.