
Newborn screening in Victoria: A case study of tissue banking regulation

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The regulation of human tissue collections is increasingly important in maintaining public trust (and legitimacy) for critical practices and resources directed to public health programs and research. This article examines the governance arrangements applying to VCGS Ltd (under its various incarnations as “Genetic Health Services Victoria”, “VCGS Pathology”, and so on) and the existing collection of population-wide blood samples maintained on newborn screening cards (or Guthrie cards) in Victoria. The analyses reveal a complex web of regulations (and possibly even no regulation) and the limited role of significant statutory schemes that are generally assumed to apply to human tissue collections and the data and information derived from those materials. The article argues that, without a clear regulatory framework (and in particular meaningful consent), there is likely to be a decline in public trust (and legitimacy) with a consequent decreased participation in what is a public health program with immediate and quantifiable benefits and a valuable research resource for the future.

INTRODUCTION

The prospect of genetic technologies advancing public health programs, reducing suffering and hopefully curing diseases is considerable. The newborn screening programs directed to phenylketonuria, cystic fibrosis, congenital hypothyroidism and other rare metabolic conditions are an example of applying the potential of these technologies in a public health program with immediate and quantifiable benefits,¹ and the formation of a valuable research resource.² The contentions arise, however, in respect of the secondary uses of the artefacts of the newborn screening programs in the context of regulating human tissue collections (or bio-banks).³ These artefacts are blood samples

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¹ The program results in the early detection and treatment of approximately 54 babies each year: see Department of Human Services, *Guidelines for Newborn Screening* (Department of Human Services, 2001) p 3; Genetic Health Services Victoria, *Newborn Screening Program for Your Baby: Parent Information* (Victorian Clinical Genetics Services Ltd, 2004) pp 1-2. This is approximately 1 in every 1,000 babies tested (0.1%): Centre for Genetics Education, *Newborn Screening for Genetic Conditions*, Fact Sheet 20 (Centre for Genetics Education, 2007) p 1.

² The Murdoch Children’s Research Institute Ltd reports access to “its” collection (the collection also being claimed by its wholly owned subsidiary Victorian Clinical Genetics Services Ltd (VCGS Ltd) as: “Access has been approved in the following circumstances: 1. Quality assurance – to set up new improved tests (10) – using de-identified blood spot only. 2. Diagnosis – retrospective diagnosis (8) or interstate diagnosis with consent (14). 3. Forensic identification at the request of the Coroner’s Court (30) and by court order for identification of deceased persons (3 – Vic, 2 – NSW). 4. Ethics committee approved research project (CP) with parental consent (225). 5. Ethics committee approved de-identified research into deafness gene frequency (500)”: Murdoch Children’s Research Institute, “Newborn Screening for Serious Disorders”, *Media Release* (26 June 2003), <http://www.mcric.edu.au/pages/news-events/media/media-release.asp?rid=31&y=2003> viewed 24 October 2008. See also Victorian Newborn Screening Committee, *Final Report for the Minister for Health* (Rural and Regional Health and Aged Care Services Division, 2006) p 26.

³ There has been an ongoing controversy about the appropriate regulation of human tissue collection: see eg Annas G, “Privacy Rules for DNA Databanks” (1993) 270 JAMA 2346; McEwen J and Reilly P, “Stored Guthrie Cards or DNA ‘Banks’” (1994) 55 *American Journal of Human Genetics* 196; Skene L, “Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots” (1997) 5 JLM 137; Lawson C and Smith R, “Protecting Genetic Materials and Genetic Information: A Case Study of

collected at the time of the newborn screening (also called Guthrie cards)⁴ and then stored in some instances indefinitely, and sometimes outside the realm of comprehensive governmental regulation in the private sector.

The need for public trust (and legitimacy) to maintain these public health programs was starkly illustrated by the decreased participation in Western Australia after the police obtained blood samples from newborn screening cards without the parents' consent in conducting their investigations.⁵ Without assurances about the possible secondary uses of these newborn screening cards, and in particular the blood on those cards, public trust (and legitimacy) will be undermined to the detriment of a proven public health program.⁶ Credible regulation provides a means of assuring existing and potential participants that their personal information and blood samples (containing their DNA and other valuable personal data and information) are adequately protected against misuse and misappropriation.⁷

This article details the existing governance arrangements for the Victorian newborn screening program conducted by Victorian Clinical Genetics Services Ltd (VCGS Ltd, a wholly owned subsidiary of the Murdoch Children's Research Institute Ltd) on behalf of the Victorian Government's Department of Human Services. The newborn screening program is a central public health program implemented by the Victorian Government's Department of Human Services.⁸ The custody of newborn screening cards was transferred to VCGS Ltd in 1988 and it has been amassing a collection of these newborn screening cards since then under a series of contracts of service with the Department of Human Services as part of genetic screening for preventable illnesses.⁹ The VCGS Ltd holds approximately two million cards with approximately 65,000 new cards added each year.¹⁰ The governance arrangements of these collections in Victoria are therefore a case study of the need to maintain public trust (and legitimacy) through appropriate regulatory frameworks by ensuring proper transparency and accountability for the secondary uses of these blood samples. This is highlighted in the arrangements between the Victorian Government's Department of Human Services and VCGS Ltd

Guthrie Cards in Victoria" (2001) 9 JLM 215. For a recent review of "Australian best practice" see Chalmers D and Nicol D, "Human Genetic Research Databases and Biobanks: Towards Uniform Terminology and Australian Best Practice" (2008) 15 JLM 538.

⁴ "In hospitals around Australia, blood has been taken from newborns, and the sample identified and stored, for the last 30 years. Between two and five days after birth, virtually all children are screened for a variety of conditions. A small sample of blood is taken and placed on a piece of blotting paper [the 'Guthrie card']. The child's name, date of birth, hospital of birth and birth weight, and the mother's name and date of birth, are also recorded on the card": Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia*, Report 96 (Southwood Press, 2003) p 501.

⁵ See Australian Law Reform Commission, n 4, p 506. See also Pennells S, "Baby Test Cards Seized", *The West Australian* (24 May 1997); Pennells S, "Police Test Worry: AMA", *The West Australian* (2 August 1997); Western Australia, Legislative Council, *Parliamentary Debates* (14 March 2000) pp 4645-4646 (Peter Foss, Attorney-General representing the Minister for Health). A similar concern has been expressed in Victoria: see Victorian Parliament Law Reform Committee, *Forensic Sampling and DNA Databases in Criminal Investigations* (Parliament of Victoria, 2004) pp 128-129. Other concerns have also been addressed in the media: see eg Ryan K, Kelly J and Hodgson S, "Alarm Over DNA Secrets", *The Australian* (27 June 2003); Noble T, "Bad Blood over DNA Samples", *The Age* (10 July 2004); Noble T, "How Your DNA is Falling into Private Hands", *The Age* (5 July 2004). See generally Chalmers D and Nicol D, "Commercialisation of Biotechnology: Public Trust and Research" (2004) 6 *International Journal of Biotechnology* 116.

⁶ For an early articulation of the public trust (and legitimacy) discourse in Australia in the context of regulating tissue banks see Commonwealth Parliament, Senate, *Parliamentary Debates* (11 March 1998) p 839 (Natasha Stott Despoja).

⁷ The significant advance in the economics of information asymmetry was the recognition that the information available to "consumers" in a market for goods and services about those goods and services was important in maintaining the quality of those goods and services and the ongoing viability of the market, with governmental intervention in the market being desirable (in the form of regulation) to increase the welfare of all parties in the market through providing some form of quality assurance to potential "consumers": see eg Akerlof G, "The Market for 'Lemons': Quality, Uncertainty and the Market Mechanism" (1970) 84 *Quarterly Journal of Economics* 488.

⁸ See Department of Human Services, *Annual Report 2006-2007* (Department of Human Services, 2007) p 130; Department of Human Services, *Annual Report 2005-2006* (Department of Human Services, 2006) p 130.

⁹ See Department of Human Services, n 8 (2007), p 130; Department of Human Services, n 8 (2006), p 130; Victorian Newborn Screening Committee, n 2, p 5. See also Lawson and Smith, n 3 at 220-222.

¹⁰ Victorian Newborn Screening Committee, n 2, p 5.

because these arrangements are outside the usual accountability and transparency frameworks of government, and instead rely on contractual terms and conditions, self-regulation and re-assurance provided by the Victorian Government and the VCGS Ltd (and its various other incarnations) about the quality of regulatory protections in place. So, eg, a press release from the Murdoch Children's Research Institute Limited asserted:

"To say the newborn screening cards are privately owned is misleading – Genetic Health [Services Victoria] is a not-for-profit State funded service providing genetic healthcare to the Victorian community," ... [the] ... Director of Genetic Health Services Victoria, said today.

"Regulation of access to the newborn screening cards is the important issue, not ownership, and as health care providers, we believe we are appropriate custodians of the cards,"

"The newborn screening samples are covered by the *Health Records Act* and very strict Federal and State guidelines on storage and access, by which we abide," she said.¹¹

This article demonstrates that the existing overlay of contractual terms and conditions, fragmented (self-)regulation and the uncertain arrangements for the custody and control of the existing collection (and the collection to which future contributions are to be made) probably does not provide the kinds of assurances necessary to maintain public trust (and legitimacy) or even to sustain the assurances (such as those set out above) provided by the Victorian Government and the VCGS Ltd (and its various other incarnations).¹² Most importantly, however, the analysis demonstrates the limited role of significant statutory schemes (such as the *Privacy Act 1988* (Cth), *Health Records Act 2001* (Vic), *Human Tissue Act 1982* (Vic), *Public Records Act 1973* (Vic), and the *Information Privacy Act 2000* (Vic)) that are generally assumed to apply to human tissue collections (and the data and information derived from the materials in these collections). The article is structured as follows: the next part reviews the existing contractual terms and conditions and provides an overview of the fragmented (self-)regulatory arrangements; the following parts review recent governmental inquiries addressing newborn screening cards (by the Australian Law Reform Commission and the Australian Health Ethics Committee (together the ALRC/AHEC) and the Victorian Newborn Screening Committee); and finally, a discussion and conclusion address the unresolved issues of "ownership" and "possession" of the newborn screening cards and blood samples, and the need for clear regulation addressing consent so as to promote public trust (and legitimacy) and avoid undermining a demonstrably desirable and beneficial public health program and research resource.

THE VCGS LTD CONTRACT

VCGS Ltd is a corporation under the *Corporations Act 2001* (Cth)¹³ and also a wholly owned subsidiary of the Murdoch Children's Research Institute Ltd that is itself a corporation under the *Corporations Act 2001* (Cth).¹⁴ VCGS Ltd provides genetic screening and diagnostic services primarily under the names "Genetic Health Services Victoria" and "VCGS Pathology".¹⁵ "Genetic Health Services Victoria" is a registered business name in Victoria under the *Business Names Act 1962* (Vic).¹⁶ Unfortunately, the public documents about newborn screening in Victoria do not consistently identify the legal entity collecting, using or storing the cards, confusingly and variously using the names "Murdoch Children's Research Institute", "Victorian Clinical Genetics Services", "Genetic Health Services Victoria", "VCGS Pathology", "VCGS Laboratories", and so on. The name "Genetic

¹¹ Murdoch Children's Research Institute, "Newborn Screening Cards Safe, Says Genetic Service", *Media Release* (5 July 2004), <http://www.mcric.edu.au/pages/news-events/media/media-release.asp?rid=47&y=2004> viewed 24 October 2008.

¹² See eg Skene L and Bankier A, "Retention of Guthrie Cards: Reassuring Parents" (2004) 5 *Medicine Today* 68.

¹³ The Australian Securities and Investments Commission records "Victorian Clinical Genetics Services Ltd" as an Australian Public Company limited by guarantee, "ACN 007 032 760" and "ABN 51 007 032 760" registered on 14 July 1988 with a "Registered Office" at "Parkville VIC 3052".

¹⁴ See Victorian Clinical Genetics Services Ltd, *Victorian Clinical Genetics: A Year in Review 2006/2007* (Victorian Clinical Genetics Services Ltd, 2007) p 2.

¹⁵ Murdoch Children's Research Institute, *Annual Report 2005* (Murdoch Children's Research Institute, 2006) p 56.

¹⁶ Consumer Affairs Victoria records "Genetic Health Services Victoria" as a Registered Business Name, "B1567310E" registered on 11 April 2001 trading in "Parkville 3052".

Health Services Victoria” suggests a governmental institution with the adornments of governmentality. However, it is a business name for a private sector corporation conducting a commercial venture.

The VCGS Ltd conducts the newborn screening under a contract with the Victorian Government’s Department of Human Services. A copy of the contract (and variations) was obtained under the *Freedom of Information Act 1982* (Vic) and records the contract (Agreement No 17876) made on 10 July 2006 between the “Secretary of the Department of Human Services” and “Victorian Clinical Genetic Services Limited”. The contract is described by the parties as a “Service Agreement: Non-Governmental Organisation” for the period 1 July 2006 until 30 June 2009. The document was signed by a representative of the Secretary of the Department of Human Services and an authorised director of VCGS Ltd. This contract was subsequently varied according to separate agreements on 9 January 2007, 8 May 2007 and 2 October 2007 between the “Secretary of the Department of Human Services” and “Victorian Clinical Genetic Services Limited” to increase the amount paid for the services. Most importantly, however, the contract was “qualified” with a “Special Conditions Agreement” signed by a representative of the Secretary of the Department of Human Services and an authorised director of VCGS Ltd on 2 October 2007 and 26 September 2007 respectively.

The effect of the contract and variations is that:

- VCGS Ltd “will provide Services” including “Genetic Screening” for an “indicative” payment for the period 1 July 2006 to 30 June 2007 identified as “\$2,660,568.10”.
- VCGS Ltd “agrees to: (a) exercise due care, skill and judgment and at all times act in accordance with applicable professional ethics, principles and standards”.
- VCGS Ltd “agrees to: (c) comply with (i) the agreed service standards ... and any [Secretary of the Department of Human Services and the Director of Housing] Policy ...; (ii) the agreed performance targets”. The agreed service standards are described as “NATA Accreditation Standards” and “NHMRC Ethical Aspects of Genetic Testing – An information paper 2000”. The agreed data collection requirements are described as “Victorian Genetic Services Data Collection”. The agreed performance targets are described as “Genetic Screening” (\$2,660,568.10) with the “performance measures” or “key output measure” being “number of tests: target 208,100.00” with a “unit” recorded as “tests” for the period 1 July 2007 to 30 June 2008.
- VCGS Ltd “agrees to: (c) comply with ... (iii) all Applicable Departmental Policies”. These policies are not identified, although the term “Applicable Departmental Policies” is defined to “include all policies, guidelines and principles of the [Department of Human Services, Victoria, including the Office of Housing] as amended from time to time and as notified to the [VCGS Ltd], and includes but is not limited to the following: (i) Human Services Capital Development Guidelines; (ii) VMIA Insurance Manual for Community Service Organisations; (iii) Departmental Incident Reporting System; (iv) Pre-employment/Pre-placement Safety Screening (Police Checks); (v) [The Secretary of the Department of Human Services and the Director of Housing] Policy and Funding plan(s); (vi) [The Secretary of the Department of Human Services and the Director of Housing] Information Privacy Policy; and (vii) Service Agreement Information Kit for Funded organisations”.
- VCGS Ltd “agrees to: (c) comply with ... (iv) all State and federal laws applicable to the Services including, without limitation, those relating to fire protection, health, and general safety which apply to any premises from which [VCGS Ltd] operates”.
- The Department of Human Services¹⁷ “agrees to act reasonably and in good faith and to provide relevant information, policies and service standards that the [VCGS Ltd] requires for the provision of services”.

The key “special conditions” that “qualified” the contract are:

- An additional recital providing:

The Department is relying on [VCGS Ltd] to meet some of its statutory responsibilities, including the management of information collected by [VCGS Ltd] for newborn screening for the early detection and treatment of medical conditions in newborn babies.

¹⁷ The agreement refers to “Department” that is defined to mean “the Department of Human Services, Victoria, including the Office of Housing”.

- An additional interpretative requirement (additional words in italics) that:
Unless the context requires otherwise ... a reference to a statute, ordinance, code or other law includes subordinate legislation, consolidations, amendments, re-enactments, and replacements or it *or any advice, guidelines, standards or directions issued by the Public Record Office Victoria pursuant to the Public Records Act 1973.*
- An additional provision dealing with record-keeping:

[VCGS Ltd] acknowledges that [the Department of Human Services, Victoria, including the Office of Housing] is a Public Office and the Records received by [VCGS Ltd] in performing the Services are public records pursuant to the *Public Records Act 1973* [(Vic)] and ownership of the Records is held by the State ... [VCGS Ltd] must:

- (a) Maintain the Records for Services conducted under the Agreement, including but not limited to Newborn Screening Records, in formats that support preservation and accessibility.
 - (b) Manage the Records in accordance with the standards and associated specifications issued by the Public Record Office Victoria and pursuant to the *Public Records Act 1973* [(Vic)], as though [VCGS Ltd] were a Public Office.
 - (c) Manage the Records in accordance with any requirements and directions of [the Department of Human Services, Victoria, including the Office of Housing].
 - (d) Maintain a register of and index of the Records and provide this to [the Department of Human Services, Victoria, including the Office of Housing] when requested.
 - (e) Retain the Records for a period as required by the Public Record Office Victoria and agree to consult with [the Department of Human Services, Victoria, including the Office of Housing] regarding any Records not covered, to agree to a disposal schedule.
 - (f) When requested by [the Department of Human Services, Victoria, including the Office of Housing] advise [the Department of Human Services, Victoria, including the Office of Housing] as to the system that [VCGS Ltd] has implemented for the management, storage and retrieval of Records.
 - (g) When requested by [the Department of Human Services, Victoria, including the Office of Housing] provide access to the Records for as long as the Records are required to be in existence.
- An additional provision dealing with record storage:
[The Department of Human Services, Victoria, including the Office of Housing] consents to [VCGS Ltd] sub-contracting the management, retention and storage of Records to an organisation that is approved by the Public Record Office Victoria.
 - An addition provision setting out definitions:

“Newborn Screening Records” means a class of Records (class 3.2.1) defined by the Public Record Office Victoria in Public Record Office Standards PROS 99/04, Variation 2, Issued on 30 July 2004, pursuant to section 12 of the *Public Records Act 1973* [(Vic)].

“Public Office” means public office as defined by section 2 of the *Public Records Act 1973* [(Vic)]. [That is, “(a) any department branch or office of the Government of Victoria; (b) any public statutory body corporate or unincorporate; (ba) a State owned enterprise within the meaning of the *State Owned Enterprises Act 1992* [(Vic)]; (c) any municipal council; and (d) any other local governing body corporate or unincorporate”].

“Public Record[] Office Victoria” is an office established pursuant to section 3 of the *Public Records Act 1973* [(Vic)] for the better preservation, management and utilization of the Public Records of the State of Victoria.

“Record” means any document or data however held, stored or recorded, drawings, plans, specifications, calculations, reports, models, concepts, source codes, files, computerised data, photographic recordings, audio or audio visual recordings.

The significance of the definition of “Newborn Screening Records” reflects a variation to the Public Record Office Victoria’s management of public records standard, the variation specifically dealing with the retention of newborn screening cards:

A new class, 3.2.1, is included. Class 3.2.1 pertains to newborn screening records – cards containing blood samples collected from newborn babies born in Victoria. The disposal sentence is “TEMPORARY. Records shall be either: – retained by the screening laboratory or – other than in exceptional circumstances and subject to a written and signed release, transferred to the custody of the

parent/s or guardian/s of the child or to the child upon reaching 18 years of age. Whether to transfer a card is at the discretion of the Chief Executive Officer of the screening laboratory. Examples of the class include Newborn Screening Cards (also known as Guthrie cards).”¹⁸

The following part places the contract within the existing regulatory framework applying to newborn screening cards in Victoria.

THE APPLICABLE REGULATORY FRAMEWORKS

Under the existing contractual arrangements between the Department of Human Services and VCGS Ltd, the newborn screening cards are supplied by VCGS Ltd to collectors (in public and private hospitals and home-birthing midwives) and then returned to the offices of VCGS Ltd.¹⁹ The cards are retained for two years (in “locked filing cabinets in the screening laboratory”) before being transferred to “an offsite secure storage facility” (in “a locked concrete vault in a locked storage facility”) where they are presently retained indefinitely.²⁰ The newborn screening card itself collects data and information about the hospital’s name and ward, doctor’s name and initials, infant’s full name, date of birth, date of sample, gestation, weight, whether breast fed, sex, blood collector’s name and “relevant family history” (presumably including the mother’s name).²¹ Each screening card is given a unique identifier (mother’s name, hospital and date of delivery) recorded in a computer database in the screening laboratory that is password-protected and the screening results are recorded and encoded in the same database.²² The regulatory framework applying to VCGS Ltd in respect of the newborn screening cards is set out in the following sections.

Consent (and the Human Tissue Act 1982 (Vic))

In Victoria, consent is required to collect a blood sample from a child before the blood is placed on the card.²³ The elements of consent are directed *only* to the physical collection of the blood sample and the risks attendant on that procedure – generally a heel prick.²⁴ Presumably obtaining this consent will address the purposes of the medical procedure,²⁵ although this is not necessarily a requirement as it is

¹⁸ Public Record Office Victoria, *General Retention & Disposal Authority for Public Health Services Patient Information Records*, Standard PROS 99/04 Variations 1, 2 and 3 (Public Record Office Victoria, 2007) p 3.

¹⁹ This is, perhaps, an oversimplification, as “Genetic Health Services Victoria” provides testing, counselling and support for genetic conditions, the laboratory testing being conducted through “VCGS Pathology” in five separate laboratories, the main VCGS Pathology diagnostic laboratories located on the 9th and 10th floors of The Royal Children’s Hospital in Parkville, Melbourne: see Murdoch Children’s Research Institute, n 15, p 56; Victorian Clinical Genetics Services Ltd, n 14, pp 3-4.

²⁰ See Victorian Newborn Screening Committee, n 2, p 9; Public Record Office Victoria, n 18, p 3.

²¹ See Genetic Health Services Victoria, *Newborn Screening*, <http://www.geneticealthvic.net.au/pages/diagnosis/newbornscreen.html> viewed 2 December 2007. See also Victorian Newborn Screening Committee, n 2, pp 9 and 29-36 setting out VCGS Laboratories, *Newborn Screening Card Access*, Version 5 06.01.05 (VCGS Laboratories, 2005).

²² Victorian Newborn Screening Committee, n 2, p 9.

²³ See *Rogers v Whitaker* (1992) 175 CLR 479 at 689-490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ), at 493-494 (Gaudron J). See also *Human Tissue Act 1982* (Vic), ss 22 and 41(1)(ab).

²⁴ See *Rogers v Whitaker* (1992) 175 CLR 479 at 689-490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ); at 493-494 (Gaudron J). See also *Human Tissue Act 1982* (Vic), ss 22 and 41(1)(ab). In other circumstances consent may not always be required to collect a blood sample: see eg *Crimes Act 1958* (Vic), s 464SA.

²⁵ In Australia this appears to have been addressed primarily by informing parents about “the general nature of the proposed tests if they ask and they may refuse the test ... two to three families a year refuse permission for blood to be taken for testing in Victoria”: Skene, n 3 at 138. In more recent times greater care has been taken to inform parents, with guidance materials suggesting consent be obtained before the collection with documentation of this consent to be made on the mother’s/baby’s medical records, and where parents refuse there should be referral to a counsellor, a signed written statement showing that they understand the potential risk to the healthy development of their baby and submission of a newborn screening card to “Genetic Health Services Victoria” with the refusal recorded on the card: see Department of Human Services, n 1, p 3. See also McBride T, Hider K and Naksook C, *Informed Parental Consent for Newborn Screening in Victoria* (Health Issues Centre, 2005); Lang A, “What is the Body? Exploring the Law, Philosophy and Ethics of Commerce in Human Tissue” (1999) 7 JLM 53 at 58-59.

consent to the heel prick (the possible battery and potential negligence) that must be obtained.²⁶ Consent is *not* required for the primary use of the blood in the screening program or any secondary uses of the artefact materials,²⁷ albeit consent may be required to collect personal information associated with the blood,²⁸ and that some information and materials may be provided about likely secondary uses.²⁹ Significantly, the newborn screening card will be a record about that sample (and its information content) owned by the collector,³⁰ and any subsequent records made about that record (such as the screening results) remains the property of the person or entity making the record, subject to a contrary agreement.³¹

Under VCGS Ltd's contract, the question of consent to collect, use and store the blood sample is governed by the common law, with the operation of the *Human Tissue Act 1982* (Vic) expressly excluded from collecting blood samples for newborn screening after 30 August 2006 where there is express or implied consent.³² While consent may not be necessary for a public health program, an attempt at express or implied consent appears to be a part of the VCGS Ltd practices so as to take advantage of the *Human Tissue Act 1982* (Vic) exception.³³ Further, the Department of Human Services in 2001 issued guidelines detailing the requirements of "informed consent" that VCGS Ltd would presumably be bound to comply with under the contract.³⁴ The guidelines provide:

Before the newborn screening test is performed, staff must ensure that parents or guardians are properly informed about the test and its importance. This information is summarised in the pamphlet "Newborn

²⁶ See eg Brown S and Then S-N, "Commercialisation of Regenerative Human Tissue: Regulation and Reform in Australia and England, Wales and Northern Ireland" (2007) 14 JLM 339 at 343; Magnusson R, "Specific Consent, Fiduciary Standards and the Use of Human Tissue for Sensitive Diagnostic Tests and in Research" (1995) 2 JLM 206 at 218-223. See also Hider K and Naksook C, "Identifying Fundamental Problems with the Victorian Newborn Screening Program" (2007) 90 *Health Issues* 36.

²⁷ See Alston B, "Blood Rights: The Body and Information Privacy" (2005) 12 JLM 426 at 428. Notably, consent is, however, a requirement of "ethical research": National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee, *National Statement on Ethical Conduct in Human Research* (NHMRC Publications, 2007) pp 19-21.

²⁸ See *Health Records Act 2001* (Vic), s 21(1) (HPP 1) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 1 and NPP 10).

²⁹ In Victoria a brochure made available to some parents provides: "Storage of newborn screening card: The National Pathology Accreditation Advisory Council of Australia recommends that newborn screening cards be stored for 25 years. In Victoria the cards are stored indefinitely in a secure off-site facility. Information regarding individuals tested and the test results are held at Genetic Health Services in accordance with the Victorian *Health Records Act* and the *Information Privacy Act*": Genetic Health Services Victoria, *Newborn Screening Program for Your Baby* (Victorian Clinical Genetic Services Ltd, 2007) p 1. See also Genetic Health Services Victoria, *Newborn Screening Program: Parent Information* (Victorian Clinical Genetic Services Ltd, 2003).

³⁰ See *Breen v Williams* (1996) 186 CLR 71 at 80 (Brennan CJ), at 88 (Dawson and Toohey JJ), at 100-101 (Gaudron and McHugh JJ), at 126 (Gummow J); *Health Services for Men Pty Ltd v D'Souza* (2000) 48 NSWLR 448 at 449 (Mason P), at 450 (Priestley JA), at 458-460 (Sheller JA). See also Skene, n 3 at 140; Australian Medical Association, *AMA Guidelines for Doctors on Providing Patient Access to Medical Records* (Australian Medical Association, 2002).

³¹ See Lawson and Smith, n 3 at 223; Skene, n 3 at 140. See also Australian Law Reform Commission, n 4, pp 526-529; Australian Law Reform Commission, *Protection of Human Genetic Information*, Discussion Paper 66 (Southwood Press, 2001) pp 451-456 and the references therein.

³² *Human Tissue Act 1982* (Vic), s 42(1)(ab); *Coroners and Human Tissue Acts (Amendment) Act 2006* (Vic), s 13(1). Before the *Coroners and Human Tissue Acts (Amendment) Act 2006* (Vic) amendment took effect on 30 August 2006, the *Human Tissue Act 1982* (Vic), s 42(1)(a)(i) as amended by *Medical Practice Act 1994* (Vic), s 118 (Sch 1 item 27.19) from 1 July 1994 probably applied also requiring "consent, express or implied" to exclude its operation, and from 4 April 1983 until that date the *Human Tissue Act 1982* (Vic), s 42(1) also required consent to exclude its operation, and before 4 April 1983 the *Human Tissue Act 1982* (Vic) did not apply. To take advantage of the s 42(1)(ab) exemption "a health service provider" must obtain express or implied consent, and presumably this will address the "nature and effect of the removal from the body" and that this does not expressly require the purposes to which the tissue will be used to be disclosed (s 15(1)). There are no penalties for misuse of collected human tissues under this legislative scheme: see Goold I, "Tissue Donation: Ethical Guidance and Legal Enforceability" (2004) 11 JLM 331 at 336.

³³ Whether consent is properly obtained remains unclear: see Hider and Naksook, n 26. The Victorian Newborn Screening Committee reported that existing practices might contravene the *Human Tissue Act 1982* (Vic) because the procedure was conducted by a nurse and that this might be resolved by a nurse conducting the procedure supervised by a registered medical practitioner: Victorian Newborn Screening Committee, n 2, pp 16 and 31.

³⁴ Department of Human Services, n 1.

Screening Program” and staff should discuss this with parents before the test is performed. The pamphlets should be given to all mothers prior to delivery and the pamphlet also needs to be available for review after their baby’s birth. Pamphlets are supplied to maternity units by the newborn screening laboratory [that is, the “Newborn Screening Laboratory of Genetic Health Services Victoria”] and are available in community languages ...

Staff need to obtain verbal consent from parents or guardians before performing the [newborn screening] test. There should be documentation on the mother’s/baby’s file stating that there has been discussion about the newborn screening test. The file should also show a record of completion of the test.³⁵

Perhaps significantly, the “Newborn Screening Program” pamphlet does not address the risks associated with a heel prick.³⁶

Public Records Act 1973 (Vic)

The *Public Records Act 1973* (Vic) is expressly invoked by the contract as varied, and applies to “Newborn Screening Records” that are described by reference to a standard that almost certainly includes the newborn screening cards dealt with by VCGS Ltd under the contract – “cards containing blood samples collected from newborn babies born in Victoria”.³⁷ The *Public Records Act 1973* (Vic) establishes the requirement for VCGS Ltd to comply with standards for the creation, maintenance, security, preservation and disposal of these public records.³⁸ The standard applying from 2 October 2007 (the date the authorised representative of the Secretary of the Department of Human Services signed the “Special Conditions Agreement”) requires that the newborn screening cards be

retained by the screening laboratory or – other than in exceptional circumstances and subject to a written and signed release, transferred [at the discretion of the Chief Executive Officer of the screening laboratory] to the custody of the parent/s or guardian/s of the child or to the child upon reaching 18 years of age.³⁹

For newborn screening cards collected before this date, the *Public Records Act 1973* (Vic) could apply only to those cards collected in public hospitals and public health services after 17 April 1973 (the date the *Public Records Act 1973* (Vic) commenced).⁴⁰ For newborn screening cards collected before this date, and between 17 April 1973 and 2 October 2007 outside public hospitals and public health services, the *Public Records Act 1973* (Vic) does not apply.⁴¹ Where the *Public Records Act 1973* (Vic) does apply, it provides that it is an offence to “damage” or “destroy” a “public record”,⁴² although “destruction” or “disposal” is lawful when conducted according to prescribed standards of

³⁵ Department of Human Services, n 1, p 3.

³⁶ See Genetic Health Services Victoria, n 1, pp 1-2.

³⁷ See Public Record Office Victoria, n 18, p 3. It is not certain whether the *Public Records Act 1973* (Vic) would necessarily apply without this provision as it is possible that the collection of the newborn screening cards might be characterised as being collected in public (and private) hospitals on behalf of Victorian Clinical Genetics Services Ltd, in which case the *Public Records Act 1973* (Vic) may not apply because it is “a record which is beneficially owned by a person or body other than the Crown or a public office”: *Public Records Act 1973* (Vic), s 2 (“public record”). For a possibly contrary view see Victorian Newborn Screening Committee, n 2, p 15.

³⁸ *Public Records Act 1973* (Vic), s 12. See Public Record Office Victoria, n 18. The term “public record” means “any record made or received by a public officer in the course of his duties” where “record” means “any document within the meaning of the *Evidence Act 1958* (Vic)” that defines “document” to mean, among other things, “anything whatsoever on which is marked any words figures letters or symbols which are capable of carrying a definite meaning to persons conversant with them”: *Public Records Act 1973* (Vic), s 2 (“public record” and “record”); *Evidence Act 1958* (Vic), s 3 (“document”).

³⁹ Public Record Office Victoria, n 18, p 3.

⁴⁰ See Victorian Newborn Screening Committee, n 2, p 15. The ownership of these newborn screening cards is far from certain and is complicated by the circumstances of their collection, the contractual arrangements applying at the time of the collections and the transfer of cards between corporations asserting custody and control: see Lawson and Smith, n 3 at 220-221 and 226-227.

⁴¹ See *Public Records Act 1973* (Vic), s 2 (“public record”).

⁴² *Public Records Act 1973* (Vic), s 19(1).

management.⁴³ Excising a blood core from a newborn screening card does not impair the information maintained on the card, but it undoubtedly “damages” the card by creating a hole in the card and removing that part of the card.⁴⁴

Health Records Act 2001 (Vic) (and Privacy Act 1988 (Cth))

The *Health Records Act 2001* (Vic) applies to VCGS Ltd under the contract as a “health service provider” for any “health information”.⁴⁵ The newborn screening cards may be, or may contain, “health information” because they could include information about “the physical, mental or psychological health (at any time) of an individual” and “personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or of any of his or her descendants”.⁴⁶

In respect of the information on the newborn screening card, the *Health Records Act 2001* (Vic) (and the *Privacy Act 1988* (Cth)) potentially impose obligations on the collection,⁴⁷ use or disclosure⁴⁸ and storage⁴⁹ that will include the blood sample while it remains connected to the information.⁵⁰ The blood sample by itself is not protected information,⁵¹ and will only obliquely be subject to the *Health Records Act 2001* (Vic) (and the *Privacy Act 1988* (Cth)) when connected with the personal information (the child’s name, date of birth, place of birth, birth weight, and so on) recorded on the same card.⁵² Further, there is *only* a statutory entitlement under the *Health Records Act 2001* (Vic) (and the *Privacy Act 1988* (Cth)) to access the information,⁵³ and there is *no* entitlement to the record on which the blood sample and information is stored.⁵⁴

The *Privacy Act 1988* (Cth) probably does not apply to the collection, use or disclosure and storage of information by VCGS Ltd in the performance of its contract with the Secretary of the Department of Human Services because the newborn screening cards are dealt with by VCGS Ltd

⁴³ *Public Records Act 1973* (Vic), ss 12 and 19(2). The current standard is Public Record Office Victoria, n 18.

⁴⁴ Recalling that the screening program requires that blood cores (comprising some of the blood placed on the card together with the supporting absorbent paper) be excised from the card and then subjected to laboratory testing: see eg Australian Law Reform Commission, n 4, p 501. A similar approach may also be applied for the secondary uses of the blood: see eg Barnes G, Srivastava A, Carlin J and Francis I, “Delta-F508 CF Mutation is Not Linked to Intussusception: Implications for Rotavirus Vaccine” (2003) 39 *Journal of Paediatrics and Child Health* 516 at 516 (reporting “3 mm discs punched from the dried blood spots”).

⁴⁵ *Health Records Act 2001* (Vic), s 3 (“health service provider” and “health service”). Notably, this is complicated by the possibility that the contract between Victorian Clinical Genetics Services Ltd and the Secretary of the Department of Human Services might be characterised as an outsourcing contract with the effect of limiting the operation of the *Health Records Act 2001* (Vic) in some circumstances: *Health Records Act 2001* (Vic), ss 12(2) and 92(1).

⁴⁶ *Health Records Act 2001* (Vic), s 3 (“health information” and “personal information”).

⁴⁷ *Health Records Act 2001* (Vic), s 21 (HPP 1) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 1 and NPP 10).

⁴⁸ *Health Records Act 2001* (Vic), s 21 (HPP 2) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 2).

⁴⁹ *Health Records Act 2001* (Vic), s 21 (HPP 4) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 4).

⁵⁰ Australian Law Reform Commission, n 4, pp 266-267. Some obligations under the *Health Records Act 2001* (Vic) also apply to accessing personal health information (ss 25-44) and may not apply to collections before 1 July 2002 (ss 2 and 20(1)).

⁵¹ *Health Records Act 2001* (Vic), ss 3 (“health information” and “personal information”) and 21(1) (HPP 1) and *Privacy Act 1988* (Cth), ss 6(1) (“personal information”, “health information” and “sensitive information”) and 16A(2) (NPP 1). See also Australian Law Reform Commission, n 4, pp 266.

⁵² See *Health Records Act 2001* (Vic), ss 3 (“health information” and “personal information”) and 21(1) (HPP 1 and HPP 2) and *Privacy Act 1988* (Cth), ss 6(1) (“personal information”, “health information”, “sensitive information” and “record”) and 16A(2) (NPP 1 and NPP 10). See also Australian Law Reform Commission, n 4, pp 262-267; Australian Law Reform Commission, n 31, pp 229-231; Australian Law Reform Commission, *Protection of Human Genetic Information*, Issues Paper 26 (Australian Law Reform Commission, 2001) pp 128-157.

⁵³ See *Health Records Act 2001* (Vic), s 21 (HPP 6) (but only as an absolute entitlement after 21 March 2002: ss 20(3) and 25) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 6) (but only as an absolute entitlement after 21 December 2001: s 16C(3)).

⁵⁴ See *Health Records Act 2001* (Vic), s 21 (HPP 6) and *Privacy Act 1988* (Cth), s 16A(2) (NPP 6). See also Australian Law Reform Commission, n 4, pp 263; Australian Law Reform Commission, n 31, pp 229-231; Australian Law Reform Commission, n 52, pp 128-157.

under a contract of service with the Secretary of the Department of Human Services.⁵⁵ Significantly, this means that the *Privacy Act 1988* (Cth) “guidelines” dealing with health information and medical research will not necessarily apply.⁵⁶ However, the *Privacy Act 1988* (Cth) could apply to the collection, use or disclosure and storage of information outside that contractual arrangement.⁵⁷

Information Privacy Act 2000 (Vic)

The *Information Privacy Act 2000* (Vic) applies to the collection, storage, use and disclosure of “personal information” that is not “health information” for the purposes of the *Health Records Act 2001* (Vic).⁵⁸ The newborn screening cards may be, or may contain, “personal information” because they could include “information or an opinion (including information or an opinion forming part of a database), that is recorded in any form and whether true or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion, but does not include information of a kind to which the *Health Records Act 2001* (Vic) applies”.⁵⁹ Thus, the *Information Privacy Act 2000* (Vic) imposes obligations on VCGS Ltd for any “personal information” that is collections, uses or disclosures and stores according to the Information Privacy Principles⁶⁰ that is not covered by the *Health Records Act 2001* (Vic).

“Ownership” of the blood samples

The question of “ownership” of the blood samples is governed by the common law, with the operation of the *Human Tissue Act 1982* (Vic) expressly excluded for blood samples collected as part of the newborn screening programs where there is express or implied consent.⁶¹ For the blood samples collected by VCGS Ltd and then stored after the primary tests have been conducted, there is essentially very little regulation directly dealing with the blood samples on the newborn screening cards other than that *adopted* (self-regulation) by VCGS Ltd itself, and the regulation of the cards to which the blood is affixed forming a document or record to which the *Privacy Act 1988* (Cth), the *Public Records Act 1973* (Vic), the *Health Records Act 2001* (Vic) and the *Information Privacy Act 2000* (Vic) may apply.

Other regulations

In addition to this formal regulation, there is a mass of non-legal rules, codes, guidelines, circulars, practice notes, fact sheets, international Conventions and ethical standards that can apply to various aspects of collecting, storing and using and disclosing blood samples. Immediate examples that have some relevance in Victoria include certain ethical guidelines,⁶² practice guidelines,⁶³ research

⁵⁵ See *Privacy Act 1988* (Cth), s 7B(5). The Secretary of the Department of Human Services is a body corporate under the *Health Act 1958* (Vic), s 6.

⁵⁶ See *Privacy Act 1988* (Cth), ss 95 and 95A. These guidelines might apply in some circumstances as a consequence of VCGS Ltd (through the Murdoch Children’s Research Institute) receiving the benefits from National Health and Medical Research Council funding for research conducted by VCGS Ltd: see eg Murdoch Children’s Research Institute Ltd, *Annual Report 2006* (Murdoch Children’s Research Institute Ltd, 2006) p 58.

⁵⁷ See also Victorian Newborn Screening Committee, n 2, p 16. The regulatory framework is principally governed by guidelines under the *Privacy Act 1988* (Cth), s 95AA to allow the Privacy Commissioner to approve guidelines issued by the National Health and Medical Research Council addressing the *National Privacy Principles* (the NPPs). See also Commonwealth Parliament, House of Representatives, *Parliamentary Debates* (22 June 2006) p 3 (Phillip Ruddock, Attorney-General).

⁵⁸ *Information Privacy Act 2000* (Vic), ss 3 (“personal information”) and 6(1).

⁵⁹ *Information Privacy Act 2000* (Vic), s 3 (“personal information”).

⁶⁰ *Information Privacy Act 2000* (Vic), ss 14-17.

⁶¹ *Human Tissue Act 1982* (Vic), s 42(1)(ab).

⁶² See eg National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (NHMRC Publications, 2002); Human Genetics Society of Australasia, *Policy Statement on Newborn Screening* (Human Genetics Society of Australasia, 2004).

⁶³ See eg National Pathology Accreditation Advisory Council, *Requirements for the Retention of Laboratory Records and Diagnostic Material* (4th ed, National Pathology Accreditation Advisory Council, 2007); National Pathology Accreditation Advisory Council, *Laboratory Accredited Standards and Guidelines for Nucleic Acid Detection Techniques* (National Pathology

guidelines,⁶⁴ and so on. Of particular effect are the (non-binding) self-regulation guidelines issued by “VCGS Laboratories” addressing access to VCGS Ltd’s (or possibly Murdoch Children’s Research Institute Ltd’s)⁶⁵ stored newborn screening cards.⁶⁶ These guidelines address the “handling of requests for access to newborn screening cards” within their laboratories (presumably within “VCGS Pathology” that conducts the diagnostic tests and retains the cards for two years).⁶⁷ The guidelines prescribe the form of access by the coroner, police, researchers, medical practitioners and private individuals (the parent or individual providing the blood).⁶⁸ The guidelines also identify the level of approval required within the organisation and the procedure to be followed in providing access to an identified card.⁶⁹ The guidelines assert that “[t]he card is under the guardianship of Genetic Health Services Victoria (GHVS) and can only be accessed according to specific and approved guidelines”, and provide no avenue for access decisions to be reviewed or challenged.⁷⁰

THE ALRC/AHEC REPORT

The Australian Law Reform Commission and the Australian Health Ethics Committee (collectively the ALRC/AHEC) conducted a broad-ranging inquiry into whether a regulatory framework was required “to protect the privacy of human genetic samples and information” including newborn screening cards.⁷¹ The likely secondary uses of these artefacts were identified to be quality assurance and laboratory auditing purposes, retrospective diagnosis, carrier testing of family members, to devise and trial new screening tests, medical research, forensic and law enforcement, and parentage and kinship testing.⁷² In addressing these artefacts in the context of “human tissue collections”, the ALRC/AHEC recommended:

Recommendation 19–1

The Australian Health Ministers’ Advisory Council (AHMAC), in consultation with the Human Genetics Commission of Australia (HGCA), the National Health and Medical Research Council (NHMRC) and key professional bodies, should develop nationally consistent rules in relation to the collection, storage, use and disclosure of, and access to, newborn screening cards. In particular, and in consultation with State and Territory Attorney-General’s Departments and police services, AHMAC should develop nationally consistent rules governing disclosure of newborn screening cards for law enforcement purposes. These rules should provide for disclosure only: (a) with the consent of the person sampled or a person authorised to consent on his or her behalf; or (b) pursuant to a court order.

Accreditation Advisory Council, 2006); National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material* (NHMRC Publications, 1999); Human Genetics Society of Australasia, *Policy Statement on Retention, Storage and Use of Sample Cards from Newborn Screening Programs* (Human Genetics Society of Australasia, 2000).

⁶⁴ See eg National Health and Medical Research Council, *Australian Code for the Responsible Conduct of Research* (NHMRC Publications, 2007).

⁶⁵ See Lawson and Smith, n 3 at 227.

⁶⁶ See Victorian Newborn Screening Committee, n 2, pp 29-36.

⁶⁷ Victorian Newborn Screening Committee, n 2, pp 29-36 setting out VCGS Laboratories, *Newborn Screening Card Access*, Version 5 06.01.05 (VCGS Laboratories, 2005) guidelines that are stated to apply to “Genetic Health Services Victoria staff for the handling of requests for access to newborn screening cards” (p 29).

⁶⁸ Victorian Newborn Screening Committee, n 2, pp 33-36 setting out VCGS Laboratories, *Newborn Screening Card Access*, Version 5 06.01.05 (VCGS Laboratories, 2005).

⁶⁹ Victorian Newborn Screening Committee, n 2, pp 33-36.

⁷⁰ Victorian Newborn Screening Committee, n 2, pp 30.

⁷¹ Australian Law Reform Commission, n 4, p 13.

⁷² Australian Law Reform Commission, n 4, pp 502 and 503.

Recommendation 19–2

AHMAC, in consultation with the HGCA, the NHMRC and key professional bodies, should review the need for nationally consistent rules in relation to the collection, storage, use and disclosure of, and access to, other human tissue collections – including collections of pathology samples and banked tissue.⁷³

The Australian Government’s formal response to the ALRC/AHEC’s inquiry was:

The Government supports the development of nationally consistent legislation and/or policies and practices governing the collection, storage, use and disclosure of, and access to, genetic information and samples on Guthrie cards.

The proposed National Health Privacy Code provides for the disclosure of personal health information to law enforcement bodies only under certain conditions, for example, in order to avoid an immediate threat to a person’s safety or under order such as a warrant. The proposed regulatory regime needs to be sufficiently rigorous in order to encourage compliance.

The AHMAC Advisory Group on Human Gene Patents and Genetic Testing is investigating these issues with a view to developing a nationally consistent approach. Where these rules relate to disclosure of newborn screening cards for law enforcement purposes, the advisory group will consult with Commonwealth, State and Territory Attorneys-General and police services.⁷⁴

In the context of the operation of privacy laws under the *Privacy Act 1988* (Cth), the ALRC/AHEC considered unidentified “human genetic samples” did not constitute “information”, “personal information” or a “record”, and that these types of samples could be collected, stored and transferred with little or no regulation.⁷⁵ However, for identified “human genetic samples” the ALRC/AHEC recommended that the *Privacy Act 1988* (Cth) definition of “personal information” should be amended to include bodily samples from an individual whose identity was apparent or could reasonably be ascertained from the sample, and that the definition of a “record” should be amended to include a bodily sample.⁷⁶ The ALRC/AHEC also recommended that for such samples an individual should have a right of access to their own bodily samples through a nominated medical practitioner and for the purpose of medical testing, diagnosis or treatment,⁷⁷ and that a first-degree genetic relative, again through a nominated medical practitioner and with appropriate consent, should have access where such access was necessary to lessen or prevent a serious threat to her or his life, health or safety.⁷⁸ The Australian Government has rejected each of these recommendations.⁷⁹ However, the Australian Government did accept that “concerns raised about the use and handling of genetic samples could be addressed in the *Human Tissues Acts* ... by revision of relevant ethical research guidelines”.⁸⁰ Further, the Australian Government has established the Human Genetics Advisory Committee as a principal committee of the National Health and Medical Research Council.⁸¹ This

⁷³ Australian Law Reform Commission, n 4, p 524.

⁷⁴ Attorney-General’s Department, *Government Response to Recommendations: ALRC’s Essentially Yours: The Protection of Human Genetic Information in Australia* (Attorney-General’s Department, 2005) pp 22-23.

⁷⁵ Australian Law Reform Commission, n 4, pp 262-267. See also Australian Law Reform Commission, *Review of Australian Privacy Law*, Discussion Paper 72 (Australian Law Reform Commission, 2007) p 333.

⁷⁶ Australian Law Reform Commission, n 4, pp 262-267 and 286. See also Australian Law Reform Commission, n 75 (2007), p 333. The Australian Government amended the *Privacy Act 1988* (Cth) to include the issuing of guidelines specifically directed to the handling of genetic information: *Privacy Legislation Amendment Act 2006* (Cth), Sch 2 (item 4). Perhaps significantly, this appears to be the extent of any further consideration of regulating “genetic samples”, as the recent ALRC inquiry into the *Privacy Act 1988* (Cth) expressly excluded such an assessment: see Australian Law Reform Commission, n 75 (2007), pp 333-334.

⁷⁷ Australian Law Reform Commission, n 4, pp 262-267 and 287. See also Australian Law Reform Commission, n 75 (2007), p 333.

⁷⁸ Australian Law Reform Commission, n 4, pp 262-267 and 287. See also Australian Law Reform Commission, n 75 (2007), p 334.

⁷⁹ Attorney-General’s Department, n 74, pp 8-10.

⁸⁰ Attorney-General’s Department, n 74, p 9.

⁸¹ See National Health and Medical Research Council, *Annual Report 2005* (NHMRC, 2006) p 17.

committee has met and discussed various aspects of newborn screening cards and their regulation, although there have been no determinative announcements so far.⁸² The Australian Government has also amended the *Privacy Act 1988* (Cth) to include the issuing of guidelines specifically directed to the handling of genetic information.⁸³ This appears to be the extent of regulating “genetic samples”, the recent ALRC inquiry into the *Privacy Act 1988* (Cth) expressly excluding any further assessment.⁸⁴

THE VICTORIAN NEWBORN SCREENING COMMITTEE

Following “much discussion in the media concerning the issue of newborn screening for genetic conditions”, a meeting of “key stakeholders” was convened by the Health Services Review Council that recommended establishing a “review committee” to report to the Minister for Health with “an options paper”.⁸⁵ The review committee’s terms of reference identified collection, storage, access and the legal status of the newborn screening cards as issues that needed to be addressed.⁸⁶ In addressing collection, the review committee considered that a “more structured consent process with detailed retention options could alleviate many of the concerns associated with long-term storage of the newborn screening cards”.⁸⁷ In particular, the review committee recommended that “the consent for the program and the consent for access for secondary uses be separated into two processes”, that the consent be written and obtained *before* the blood sample was collected.⁸⁸ The review committee recommended that storage continue under the existing arrangements with parents being informed of indefinite retention (unless otherwise requested).⁸⁹ In addressing access, the review committee recommended that access be strictly controlled and limited to diagnosis of the individual, research (subject to research ethics committee approval), transfer to the parents or individual, and law enforcement agencies.⁹⁰ The review committee also identified a number of uncertain legal issues about the application to newborn screening cards of the *Public Records Act 1973* (Vic) collected outside public institutions,⁹¹ the *Health Records Act 2001* (Vic) to the data and information on the screening cards,⁹² the application of the *Human Tissues Act 1982* (Vic) to the blood samples,⁹³ and that blood removed from the cards escapes both the *Public Records Act 1973* (Vic) and the *Health Records Act 2001* (Vic).⁹⁴ Importantly, the review committee appears to have accepted that the blood on the card

⁸² See Human Genetics Advisory Committee, *Communiqué – 3 November 2006* (NHMRC, 2006); Human Genetics Advisory Committee, *Communiqué – 11 August 2006* (NHMRC, 2006); Human Genetics Advisory Committee, *Communiqué – 9 June 2006* (NHMRC, 2006); and so on.

⁸³ The *Privacy Legislation Amendment Act 2006* (Cth) inserted a new s 95AA in the *Privacy Act 1998* (Cth).

⁸⁴ See Australian Law Reform Commission, n 75 (2007), pp 333-334.

⁸⁵ Victorian Newborn Screening Committee, n 2, p 3.

⁸⁶ Victorian Newborn Screening Committee, n 2, p 4.

⁸⁷ Victorian Newborn Screening Committee, n 2, p 8.

⁸⁸ Victorian Newborn Screening Committee, n 2, p 8.

⁸⁹ Victorian Newborn Screening Committee, n 2, p 10.

⁹⁰ Victorian Newborn Screening Committee, n 2, pp 11-14.

⁹¹ The review committee accepted advice from the Victorian Solicitor General that such cards were not “public records” for the purposes of the *Public Records Act 1973* (Vic), although this might be resolved by a resolution of the Governor in Council: Victorian Newborn Screening Committee, n 2, p 15.

⁹² The review committee accepted advice from the Victorian Solicitor General that such cards were “health information” for the purposes of the *Health Records Act 2001* (Vic), although this might not apply to cards collected before 1 July 2002: Victorian Newborn Screening Committee, n 2, p 15.

⁹³ The review committee accepted advice from the Victorian Solicitor General that such blood samples collected by nurses were prohibited for the purposes of the *Human Tissues Act 1982* (Vic), although this might be resolved by nurses extracting blood and laboratory technicians conducting blood tests under the supervision of a registered medical practitioner: Victorian Newborn Screening Committee, n 2, p 16.

⁹⁴ The Review Committee accepted advice from the Victorian Solicitor General that such blood samples removed from the cards was no longer a “public record” for the purposes of the *Public Records Act 1973* (Vic) or “health information” for the purposes of the *Health Records Act 2001* (Vic): Victorian Newborn Screening Committee, n 2, p 16.

itself could not be “owned” and that the legal status of these blood samples remained unresolved.⁹⁵ The outcome of the review committee report was to suggest options for the Minister: a reference to the Victorian Law Reform Commissioner to examine the issues more comprehensively, legislation specifically addressing newborn screening cards, or amendment of existing legislation to address some of the identified concerns.⁹⁶

Perhaps the most interesting aspect of the review committee’s report was the supplementary report provided by the Victorian Privacy Commissioner recommending “purpose-built newborn screening legislation”.⁹⁷ While supporting the review committee’s final report as “temporary”,⁹⁸ the Privacy Commissioner considered that “existing elements of Victorian law and administrative practice applying to the collection are not adequate to meet the current and foreseeable challenges of managing the archive and the ongoing program”.⁹⁹

THE UNRESOLVED ISSUES

Some of the remaining unresolved issues are:

- the storage and access to cards (and blood) forming part of the existing collection;¹⁰⁰
- what diagnostic tests can be conducted on the collected blood;¹⁰¹
- ownership of the cards, blood samples and the results from using the cards and/or blood samples;¹⁰² and
- the limitations in existing laws directed to “public records” in the *Public Records Act 1973* (Vic) and “health information” in the *Health Records Act 2001* (Vic).¹⁰³

However, each of these issues might be addressed within the existing law and resolved for the future through the threshold questions about meaningful consent. The following parts address the “ownership” of the newborn screening cards, the “possession” of the blood samples, and the “possession” of the results from using the cards and/or blood samples, to show that prior meaningful consent will almost certainly obviate the need to formally resolve these issues. However, other solutions will be required to address the existing collection of newborn screening cards.

“Ownership” of the cards

The newborn screening cards are supplied by VCGS Ltd and returned to VCGS Ltd with data and information inscribed onto the card together with blood spots.¹⁰⁴ The cards are maintained in the VCGS Ltd laboratory for two years and then placed into long-term storage,¹⁰⁵ with VCGS Ltd supervising (and funding) their custody and control until their destruction or provision to others (such

⁹⁵ Victorian Newborn Screening Committee, n 2, p 17. See also Australian Law Reform Commission, n 4, pp 527-529 identifying authority for the proposition that lawful authority to use the sample together with applying some work or skill in the preservation of the sample may be enough for the sample to be the property of the user.

⁹⁶ Victorian Newborn Screening Committee, n 2, p 17.

⁹⁷ Victorian Newborn Screening Committee, n 2, p 40.

⁹⁸ Victorian Newborn Screening Committee, n 2, p 38.

⁹⁹ Victorian Newborn Screening Committee, n 2, p 40.

¹⁰⁰ Victorian Newborn Screening Committee, n 2, p 41.

¹⁰¹ Victorian Newborn Screening Committee, n 2, pp 41-42. This issue is particularly important as, with improving technology and efficiency, conducting a standard array of tests may become the standard, and the exceptional circumstance will arise when a particular test or tests are not required.

¹⁰² Victorian Newborn Screening Committee, n 2, pp 52-54.

¹⁰³ Victorian Newborn Screening Committee, n 2, pp 54-57.

¹⁰⁴ The significance of this practice is to suggest that those taking the blood sample and placing the blood sample on the cards are acting as agents for VCGS Ltd: see *Leicestershire County Council v Michael Faraday & Partners Ltd* [1941] 2 KB 205 at 216; *Breen v Williams* (1996) 186 CLR 71 at 88 (Dawson and Toohey JJ).

¹⁰⁵ See Victorian Newborn Screening Committee, n 2, p 9; Public Record Office Victoria, n 18, p 3.

as the court).¹⁰⁶ There seems little controversy that these newborn screening cards will be owned by VCGS Ltd, subject to a contrary agreement.¹⁰⁷ The contract between the Department of Human Services and VCGS Ltd is likely to be such a contrary agreement. The question of “ownership” will depend therefore on the contract in place at the time the newborn screening card was made (the data, identifying information and blood were placed onto the card).

According to the “special conditions” that “qualified” the contract, the ownership of the cards is probably resolved after 2 October 2007 (the date the varied contract was finally signed) awarding ownership of the newborn screening cards to the State of Victoria. The relevant contractual provision provides:

[VCGS Ltd] acknowledges that [the Department of Human Services, Victoria, including the Office of Housing] is a Public Office and the Records received by [VCGS Ltd] in performing the Services are public records pursuant to the *Public Records Act 1973* [(Vic)] and ownership of the Records is held by the State ...

The term “Newborn Screening Records” is defined to mean a “class of Records” according to the Public Record Office Victoria standard for the purposes of the *Public Records Act 1973* (Vic) so that the term “Records” will include the newborn screening cards collected *after* 2 October 2007 and held by VCGS Ltd.

For the newborn screening cards collected *before* 2 October 2007, they will almost certainly *not* be owned by the State of Victoria.¹⁰⁸ This will include the newborn screening cards collected and donated to VCGS Ltd in 1988 and the subsequent collections where ownership has not been addressed in the contract, or the contract has terminated and the cards have effectively been donated to VCGS Ltd (and probably then to Murdoch Children’s Research Institute Ltd).¹⁰⁹ Perhaps significantly, the “special conditions” “qualified” the contract so that VCGS Ltd “agree[d] to consult with [the Department of Human Services, Victoria, including the Office of Housing] regarding any Records not covered, to agree to a disposal schedule”. This term of the contract probably confirms that the existing newborn screening cards are already owned, but not by the State of Victoria.¹¹⁰

An unresolved question is whether a contractual provision deeming ownership of the newborn screening cards by the State of Victoria would survive the termination of the contract, or other conduct that might be characterised as passing ownership to another. The existing contract is for a defined period from 1 July 2006 to 30 June 2009 and there are no provisions extending the operation of parts of the contract after 30 June 2009. Presumably this means that any obligations imposed on VCGS Ltd by the contract also cease at that time. This is significant as VCGS Ltd is maintaining the newborn screening cards in their laboratory for two years after collection and then placing them in a secure facility according to the Public Record Office Victoria standard for the purposes of the *Public Records Act 1973* (Vic). However, this is according to the direction and control of VCGS Ltd, and in particular

¹⁰⁶ See Victorian Newborn Screening Committee, n 2, pp 5 and 30.

¹⁰⁷ *Breen v Williams* (1996) 186 CLR 71 at 80 (Brennan CJ), at 88 (Dawson and Toohey JJ), at 100-101 (Gaudron and McHugh JJ), at 126 (Gummow J) establishes that a doctor owns the medical records (as chattels) that he or she created. *Health Services for Men Pty Ltd v D’Souza* (2000) 48 NSWLR 448 at 449 (Mason P), at 450 (Priestley JA), at 458-460 (Sheller JA) establishes that an incorporated entity owned the medical records of a medical practice that was run and serviced by an incorporated entity. Patients do not have a right of access to those medical records unless the denial of access would prejudice the health of the patient or “the request for disclosure is reasonable having regard to all the circumstances”: *Breen v Williams* (1996) 186 CLR 71 at 78-79 (Brennan CJ), at 97 (Dawson and Toohey JJ). However, where the records (such as x-ray photographs, pathology reports, and so on) have been paid for by the patient, there may be a valid claim by the patient: *Breen v Williams* (1996) 186 CLR 71 at 88-89 (Dawson and Toohey JJ). See also Skene, n 3 at 140.

¹⁰⁸ The likely effect of earlier contracts is uncertain, although some analysis of earlier contracts suggests that the common law has not been upset: see Lawson and Smith, n 3 at 224-227.

¹⁰⁹ Lawson and Smith, n 3 at 226-227.

¹¹⁰ Perhaps significantly, VCGS Ltd has asserted in publicly available documents that “[t]here is no consensus on the ownership of the blood spot. The card is under the guardianship of Genetic Health Services Victoria (GHSV) and can only be accessed according to specific and approved guidelines” (Victorian Newborn Screening Committee, n 2, p 30), and in internal documents that “[t]his [newborn screening] card is the property of Genetic Health Services Victoria ... [The company] owns the card” (Noble, n 5).

paying for the storage, and assessing and deciding whether a card might be released. These are significant factors in speculating that ownership (and most certainly some of the bundle of rights that is “ownership”) of the newborn screening cards has passed to VCGS Ltd, or alternatively, the bundle of rights reflected in “ownership” is limited in favour of VCGS Ltd having various of those rights (such as “possession”, “control”, “use”, “commercially exploit”, and so on).

This analysis shows that the question of “ownership” remains uncertain and most probably is very difficult to resolve. If the question of “ownership” had been addressed at the time the newborn screening card was made (the data, identifying information and blood were placed onto the card), the content of the consent will almost certainly be resolved as between VCGS Ltd, the Department of Human Services *and* the blood donor. This does not, however, resolve the “ownership” of the existing collection of cards.

“Possession” of the blood sample

While the blood sample remains connected with the newborn screening card, it will be subject to the same rules that apply to the card. When blood is removed from the cards, it ceases to be obliquely “health information” for the purposes of the *Health Records Act 2001* (Vic) (unless the identity of the person from whom the blood was taken can be established) and is no longer a “public record” for the purposes of the *Public Records Act 1973* (Vic).¹¹¹ The “ownership” of the separated blood sample, however, remains contentious.¹¹² Over centuries of considering the ownership of human tissue samples, there is some authority for the proposition that there can be no “property” in human tissues.¹¹³ However, the situation would appear to be much clearer in the case of the “possession” of blood samples held for the purposes of diagnostic tests, and where “possession” then entitles the possessor to control of access and use. In these circumstances, the question of “ownership” may not need to be resolved in considering the present regulator arrangements because “possession” establishes sufficient control of access and use (thus “possession is nine tenths of the law”).¹¹⁴

In *Doodeward v Spence* (1908) 6 CLR 406 a still-born two-headed fetus was taken away by a medical attendant at birth (presumably lawfully), preserved in spirit in a container, and then kept as a curiosity before being sold for valuable consideration to the plaintiff’s father (at 410-411). The fetus was displayed in a container as a curiosity by the plaintiff (presumably to continue its display for monetary gain) whereupon it was seized by a police officer (the defendant) placing the fetus in the “University museum” and returning only the container to the plaintiff (at 417). The plaintiff wanted the fetus returned (presumably to continue its display for monetary gain) and sued in detinue to recover the fetus from the police officer (at 417). The New South Wales Supreme Court in *Doodeward v Spence* (1907) 7 SR (NSW) 727 considered that there could be no property in dead humans (at 278 (Simpson J), at 729 (Cohen J) and at 729 (Pring J)), and no property in a severed body part (at 729 (Pring J)). On appeal to the High Court, Griffith CJ (with whom Barton J “entirely” agreed; at 417)¹¹⁵

¹¹¹ See Victorian Newborn Screening Committee, n 2, p 16.

¹¹² Victorian Clinical Genetic Services Ltd asserts “guardianship” and then prescribed the rules for accessing the blood samples: see eg Victorian Newborn Screening Committee, n 2, p 30.

¹¹³ See Brown and Then, n 26 at 340-342; Goold, n 32 at 334-335; Skene L, “Proprietary Rights in Human Bodies, Body Parts and Tissue: Regulatory Contexts and Proposals for New Laws” (2002) 22 *Legal Studies* 102 at 105-115; Taylor R, “Human Property: Threat or Saviour?” (2002) 9 *Murdoch University Electronic Journal of Law* at [5]-[38]; Mortimer D, “Proprietary Rights in Body Parts: The Relevance of Moore’s Case in Australia” (1993) 19 *Mon LR* 217 at 235-248; Magnusson R, “The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions” (1992) 18 *MULR* 601 at 616-620; Lynch M, “Property in Human Gametic Material and the New Reproductive Technologies” (1999) 6 *JLM* 348 at 349-352; Griggs L, “The Ownership of Excised Body Parts: Does an Individual Have the Right to Sell?” (1994) 1 *JLM* 223 at 225-227. See also Australian Law Reform Commission, n 4, pp 527-528; Victorian Newborn Screening Committee, n 2, p 16. English law has in the past recognised ownership over slaves and parts of slaves: see eg *Gregson v Gilbert* (1783) 99 ER 629.

¹¹⁴ Albeit that there are compelling cases and commentary showing that there can be ownership of human tissues in certain circumstances: see eg Brown and Then, n 26 at 340-342 (and the cases there cited); Goold, n 32 at 334-335 (and the cases there cited). See also Magnusson, n 113.

¹¹⁵ Although Barton J also said (at 417): “I do not wish it to be supposed that I cast the slightest doubt upon the general rule that an unburied corpse is not the subject of property.”

considered that previous authority was not binding, that the matter should be resolved applying general principles of law,¹¹⁶ and that as a general matter “possession is not unlawful if the body possesses attributes of such a nature that its preservation may afford valuable or interesting information or instruction” (at 412).¹¹⁷ Griffith CJ then stated (at 414):

If ... there can, under some circumstances, be a continued rightful possession of a human body unburied, I think ... that the law will protect that rightful possession by appropriate remedies. I do not know of any definition of property which is not wide enough to include such a right of permanent possession. By whatever name the right is called, I think it exists, and that, so far as it constitutes property, a human body, or a portion of a human body, is capable by law of becoming the subject of property. It is not necessary to give an exhaustive enumeration of the circumstances under which such a right may be acquired, but I entertain no doubt that, when a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it, at least as against any person not entitled to have it delivered to him for the purpose of burial, but subject, of course, to any positive law which forbids its retention under the particular circumstances.

On the facts, Griffith CJ considered the fetus had come into the lawful possession of the medical attendant, some (“perhaps not much”) work and skill had been applied, and the result was something that had “acquired an actual pecuniary value” (at 414-415). As a consequence, an action limiting the right of interference in possession was valid (*detinue*), subject to any positive law forbidding its retention under the particular circumstances (at 415).

Higgins J considered that “[n]o skill or labour has been exercised on [the ‘corpse’]” and “there has been no change in [the ‘corpse’s’] character” (at 417-418).

Under these circumstances, I cannot see any reason for doubting that, if this corpse can be the property of any one, it is the property of the plaintiff as against the defendant. It is enough that the plaintiff was in possession of the corpse, and that the defendant took it having no better title to it than the plaintiff. But, in my opinion, there can be no right to recover in *trover* or in *detinue* in respect of a thing which is incapable of being property. The action of *trover* and the action of *detinue* are actions for wrongfully converting or wrongfully detaining the plaintiff’s property. The foundation of the action is property ... But no one ever heard of an action of *trover* or *detinue* for a human being whether alive or dead unless in the case of a slave.

Later in the judgment Higgins J conceded that there could be “property in a mummy” albeit that “the corpse in the case of a mummy has been turned into something very different by the skill of the embalmer” (at 422), and that “skeletons and other such exhibits in museums and anatomical schools”, “pathological and other specimens exhibited in medical museums” and so on, were “sundry contraventions of the strict law as to dead bodies [that] are winked at in the interests of medical science, and also for the practical reasons that no one can identify the bones or parts, and that no one is interested in putting the law in motion” (at 423). However, he considered he was bound by the principle that there could be no property in corpses (at 419), and as a consequence, considered that the “University museum” was as entitled to it as the plaintiff (at 424).

Subsequent decisions have confirmed that lawful “possession” founds a right to a remedy¹¹⁸ and establish a basic proposition that there is “no property in a body” that is then modified depending on the circumstances of the case.¹¹⁹ The effect of “possession” is to enable the possessor to direct and control the object. In *Doodeward v Spence* this was the right to “possession” of the fetus and to (presumably) continue the fetus’s display for monetary gain. The key question in the case of newborn screening cards, therefore, is whether there has been sufficient “lawful exercise of work or skill” to

¹¹⁶ For Griffith CJ these were that “the reason must be that such possession is injurious to the public welfare, and the notion that it is so injurious must be founded upon considerations of religion or public health or public decency” (at 413).

¹¹⁷ Notably, Griffith CJ clearly had in mind “the many valuable collections of anatomical and pathological specimens or preparations formed and maintained by scientific bodies” (at 413).

¹¹⁸ See eg the cases cited in Brown and Then, n 26 at 340-342; Goold, n 32 at 334-335; Lynch, n 113 at 351-352. See also Magnusson, n 113.

¹¹⁹ Lynch, n 113 at 352.

establish a right of “possession”. It seems likely that VCGS Ltd supplying a newborn screening card according to a particular design for the collection of appropriate information and placing of blood samples, followed by use of those cards for a highly skilled laboratory procedure, might be expected to satisfy the “lawful exercise of work or skill”. As a consequence, VCGS Ltd (or Murdoch Children’s Research Institute Ltd) might expect to exercise the bundle of rights associated with “possession” that most probably include “control”, “use”, “commercially exploit”, and so on, albeit this is a lesser right than outright “ownership”. However, for blood samples collected after 2 October 2007 (the date the varied contract was finally signed) where “ownership” of the “newborn screening cards” was expressly awarded to the State of Victoria, it is uncertain whether the “possession” of the blood sample by VCGS Ltd is sufficient to coincide with the “ownership” by the State of Victoria, and whether these blood samples can be used for other purposes without the agreement of the Victorian Government’s Department of Human Services.

Again, if the question of “ownership”/“possession” had been addressed at the time the newborn screening card was made (the data, identifying information and blood were placed onto the card), the content of the consent would almost certainly be resolved as between VCGS Ltd, the Department of Human Services *and* the blood donor. This does not, however, resolve the “ownership”/“possession” of the existing collection of cards and blood samples derived from those cards.

“Possession” of the results from using the cards and/or blood samples

The consequence of VCGS Ltd’s (or Murdoch Children’s Research Institute Ltd’s) “ownership”/“possession” becomes particularly problematic where the newborn screening cards and blood samples have secondary uses that have not been addressed at the time consent was obtained to collect the blood sample (assuming that consent was obtained). The potential secondary uses include diagnosis of other conditions that are not part of the initial screening (as part of the public health program), uses by other blood relatives (such as paternity testing), uses for research, uses for law enforcement, other governmental uses (such as forensic identification by a coroner), and so on.¹²⁰ The analysis in this article shows that the existing arrangements between the Victorian Government’s Department of Human Services and VCGS Ltd (and Murdoch Children’s Research Institute Ltd) have not resolved these issues although they appear to be being addressed through variations to the contract. So, eg, the varied contract requires VCGS Ltd to “[m]anage the Records in accordance with the standards and associated specifications” issued by the Public Record Office Victoria. Further, the varied contract also provides that VCGS Ltd “agree to consult ... regarding any Records not covered, to agree to a *disposal schedule*” (emphasis added). The Public Record Office Victoria has issued revised standards that will presumably apply to future contracts that expressly address the secondary uses of the blood samples attached to the cards.¹²¹ A central element of these standards is the requirement for consent (unless it is not required) and a clearer articulation of the likely secondary uses and a clearly articulated disposal schedule.¹²²

MEANINGFUL CONSENT

The previous part asserts that meaningful consent would resolve the contentious issues of “ownership” of the cards and “possession” of the blood samples and the results from using the cards. In the context of newborn screening, consent

is the process by which an individual chooses to participate in a medical procedure or healthcare activity. Crucial elements to this process include knowledge of the purpose and nature of the

¹²⁰ See eg Victorian Newborn Screening Committee, n 2, pp 11-14.

¹²¹ Public Record Office Victoria, n 18.

¹²² See Public Record Office Victoria, n 18, pp 15-18 (ss 3.2.1-3.2.5).

intervention, potential risks and benefits, and reasonable alternatives to participation. The level of information detail necessary for “informed” consent is different for different individuals, depending on their desire to know.¹²³

What might constitute meaningful consent? Two models have been proposed that might assist in identifying the relevant concerns and they are considered next.

Genetic Privacy and Non-Discrimination Bill 1998 (Cth)

The *Genetic Privacy and Non-Discrimination Bill 1998* (Cth)¹²⁴ required, before any “DNA sample”¹²⁵ was collected, an authorisation “[e]xcept as otherwise provided by law” (presumably addressing court orders, law enforcement, and the like)¹²⁶ that addressed the following matters:

- (a) the authorisation must be in writing, signed by the individual, and dated on the day of signature; and
- (b) the authorisation must identify the person authorised to collect the DNA sample; and
- (c) the authorisation must state the tissue to be collected and the method of collection; and
- (d) the authorisation must include a description of all authorised uses of the DNA sample; and
- (e) the authorisation must indicate whether the individual permits the sample to be retained after the analysis is completed, and if not, how the sample is to be disposed of after the analysis; and
- (f) the authorisation must include provisions that permit the individual to consent to:
 - (i) use of the DNA sample for research; and
 - (ii) commercial use of the DNA sample, with a waiver of, or a provision for, economic benefit to the individual; and
 - (iii) if the individual consents to use under subparagraph (i) or (ii), use without identifiers, or use with individual identifiers or codes retained, of the DNA sample; and
 - (iv) notification, if individual identifiers or codes are retained, about information resulting from such use that may have implications for the individual or a family member of the individual; and
- (g) the authorisation must comply with additional provisions requiring informed consent by human subjects in research.¹²⁷

In addition to the authorisation, the following information and materials were also required:

The person who collects the DNA sample for genetic analysis must provide the individual, prior to the collection of the DNA sample, and any other person upon request, with a written notice of rights and assurances that contains the following information and assurances:

- (a) that the DNA sample will be used only as authorised in the written authorisation; and
- (b) that the individual has the right to order the destruction of an identifiable DNA sample at any time; and
- (c) that the DNA sample will be destroyed upon the completion of the genetic analysis or the genetic test, unless the individual has consented in writing to further use of the sample; and
- (d) that the individual may specify another person as the person authorised to make decisions regarding disposition of the DNA sample after the death of the individual and, if any person is so designated, that the individual should notify the facility in which the DNA sample is stored; and
- (e) that the individual has the right to examine records containing genetic information, to obtain copies of such records, and to request amendment of such records; and

¹²³ Victorian Newborn Screening Committee, n 2, p 7. Such a proposition is founded on the basis of autonomy, justice and beneficence: see eg Thomson C, “Records, Research and Access: What Interests Should Outweigh Privacy and Confidentiality? Some Australian Answers” (1993) 1 JLM 95 at 95.

¹²⁴ See *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 16(1). See also Commonwealth Parliament, Senate, *Parliamentary Debates* (11 March 1998) pp 838-841 (Natasha Stott Despoja).

¹²⁵ Defined to mean, inclusively, “(a) a human tissue sample from which DNA is intended to be extracted; or (b) DNA extracted from such tissue sample and other molecules (such as ribonucleic acids and polypeptides) from which DNA may be derived; but does not include a tissue sample that is taken: (c) as a biopsy or an autopsy specimen, or as a clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a DNA test; or (d) as a blood sample solely for the purpose of storage in and distribution by a blood bank”: *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 7. This would not include a newborn screening sample collected *only* for the screening tests.

¹²⁶ *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 12(1)(a).

¹²⁷ *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 16(1).

- (f) that researchers may be granted access to a DNA sample only as specified in the written authorisation of the individual; and
- (g) that the collection, storage and analysis of the DNA sample and the genetic information characterised from the sample are protected by this Act, and that an individual whose rights under this Act are violated may seek redress as provided for in this Act; and
- (h) about the availability, or the lack of availability, of optional genetic counselling.¹²⁸

And:

Prior to the collection of a DNA sample from an individual for genetic analysis, the person who collects the sample must inform the individual, in language understandable to the individual:

- (a) that consent to the collection of the DNA sample is voluntary; and
- (b) about the genetic information that can reasonably be expected to be derived from the genetic analysis; and
- (c) about the implications of genetic information derived from the genetic analysis, for the individual and the family members of the individual; and
- (d) about the ways in which the genetic information derived from the genetic analysis will be used; and
- (e) about the information that the individual can expect to receive on completion of the genetic analysis; and
- (f) about the extent of the right of the individual to have the DNA sample removed from a research study and, if possible, to have the genetic information characterised from the DNA sample destroyed; and
- (g) about the right of the individual to revoke consent to the genetic analysis at any time prior to the commencement of the genetic analysis; and
- (h) that revocation of consent for genetic analysis does not absolve the individual of responsibility for all relevant costs of the genetic analysis; and
- (i) that the genetic analysis may yield information that should be communicated to a family member of the individual; and
- (j) about the existence of, and protections afforded by, this Act; and
- (k) about the availability, or the lack of availability, of optional genetic counselling.¹²⁹

While this approach has been rejected by the Australian Government,¹³⁰ and many of the organisations undertaking or representing those undertaking genetic testing,¹³¹ it did comprehensively address the issues of consent, use, and destruction, and benefit sharing at the time the blood sample was collected.¹³² Most importantly, however, the *Genetic Privacy and Non-Discrimination Bill 1998* (Cth) conceived of an indefinite collection available for research and subject to protections of privacy, against unwanted disclosure and against discrimination in employment and insurance.¹³³ While

¹²⁸ *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 16.

¹²⁹ *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cls 14 (“Notice of rights and assurances”) and 15 (“Information to be provided to the individual”).

¹³⁰ See Commonwealth Parliament, House of Representatives, *Parliamentary Debates* (22 June 2006) p 3 (Phillip Ruddock, Attorney-General).

¹³¹ See eg the submissions to Senate Legal and Constitutional Legislation Committee, *Provisions of the Genetic Privacy and Non-Discrimination Bill 1998 (As Introduced in the 38th Parliament)* (Senate Printing, 1999), including Human Genetics Society of Australia, Submission 6 (pp 2-3), Murdoch Institute for Research into Birth Defects, Submission 10 (p 2), John Curtin School of Medical Research, Submission 34 (p 1), Law Council of Australia, Submission 36 (p 1), New South Wales Department of Health, Submission 44 (p 2), South Australian Department of Premier and Cabinet, Submission 47 (p 1), and so on. For a contrary view see eg Privacy Commissioner, Submission 40 (p 8). See also Mould A, “Implications of Genetic Testing: Discrimination in Life Insurance and Future Directions” (2003) 10 JLM 470; Karpin I, “The Genetic Connection: Owning Our ‘Genetic Heritage’” (2000) 7 JLM 376; Stulic M, “Genetic Non-discrimination, Privacy and Property Rights” (2000) 7 *Murdoch University Electronic Journal of Law* [1]; Lawson C, “Genetic Privacy: A Predisposition to Inconsistency” [1999] *Privacy Law and Policy Reporter* 25.

¹³² Albeit the Bill’s author and others have expressed reservations about an approach directed to the “autonomous individual” and protections dependent on an initial “informed consent”: Senate Legal and Constitutional Legislation Committee, n 131, p 119; Commonwealth Parliament, Senate, *Parliamentary Debates* (5 October 2000) pp 18006-18007 (Helen Coonan). See also Karpin, n 131 at 383-387.

¹³³ See *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 12-24.

apparently onerous, there seems little likelihood that a blood donor (or their legal guardian) would have any doubts about the likely uses of the blood sample and the results from using the cards, and might have some assurance (public trust and legitimacy) that the blood and any results would not be misused or misappropriated.¹³⁴ Significantly, these requirements were enforceable and subject to sanctions for breach¹³⁵ providing a further assurance for blood donors (or their legal guardians).

National Statement on Ethical Conduct in Human Research

Similarly to the *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), although less comprehensively, the National Health and Medical Research Council's published *National Statement on Ethical Conduct in Human Research* provides, in part:

3.4.1 Institutions should develop a policy for the collection, storage, use and disposal of human tissue in research. This policy should cover:

- (a) what information needs to be recorded about the source, nature and reason for collection of the tissue;
- (b) requirements about participant consent ... including circumstances where waiver of consent may be justified ...;
- (c) confidentiality;
- (d) privacy of samples and information;
- (e) access to samples and information;
- (f) disposal of samples;
- (g) socio-cultural considerations bearing on these issues.

...

3.4.5 Participants should receive clear information about whether their tissue samples will be identified, and if so, how.

3.4.6 If the research is likely to produce information relevant to the health and wellbeing of the person from whom the tissue was derived, procedures to allow participants to be identified for appropriate follow-up should, wherever possible, be included in the research proposal.

3.4.7 Consent for the use of tissue may be specific, extended or unspecified ... When consent is given for the use of human tissue in specific research only, that tissue should not be used for any other purpose without the consent of the tissue donor unless an [Human Research Ethics Committee] or other review body has waived the requirement to seek further Consent ...¹³⁶

The requirements for consent provide, in part:

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it ...

2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.

2.2.3 This information must be presented in ways suitable to each participant ...

2.2.4 The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.¹³⁷

Again, there seems little likelihood that a blood donor (or their legal guardian) would have any doubts about the likely uses of the blood sample and the results from using the cards, and might have some assurance (public trust and legitimacy) that the blood and any results would not be misused or misappropriated. However, unlike the proposed scheme in the *Genetic Privacy and Non-*

¹³⁴ See Senate Legal and Constitutional Legislation Committee, n 131, pp 53-61.

¹³⁵ See *Genetic Privacy and Non-Discrimination Bill 1998* (Cth), cl 25-27.

¹³⁶ National Health and Medical Research Council et al, n 27, pp 39-40.

¹³⁷ National Health and Medical Research Council et al, n 27, p 19.

Discrimination Bill 1998 (Cth),¹³⁸ the National Health and Medical Research Council's published *National Statement on Ethical Conduct in Human Research* is not enforceable.¹³⁹

CONCLUSIONS

The analysis presented here highlights that the "possession" of the blood sample founds the ability to use and control the secondary uses of the artefact blood on the newborn screening cards. The gatekeeper to creating these cards and leading to their subsequent "possession" is the consent obtained at the time of the blood collection from the heel of the child. While consent to the secondary uses may not be a mandatory legal requirement, that consent is central to a meaningful understanding addressing public trust (and legitimacy) and the likelihood that fully informed prospective parents will be satisfied that the personal data and information and blood will not be misused or misappropriated. As the National Health and Medical Research Council's published *National Statement on Ethical Conduct in Human Research* provides, the "aim is mutual understanding between researchers and participants".¹⁴⁰ Available models of consent show that the necessary elements have been identified and could easily be adopted.

The analysis in this article also demonstrates that many of the earlier criticisms of VCGS Ltd's practices under its contract with the Victorian Government's Department of Human Services have been addressed.¹⁴¹ The prospect that future contracts will implement the more rigorous retention standards of the Public Record Office Victoria will likely address many of the remaining concerns about access and secondary uses. However, the article clearly demonstrates that the existing web of regulations (and for some newborn screening cards there may be no applicable regulations) is complex, that the terms of the contract are critical to the coverage of regulation, and that a number of critical issues (such as the control over the existing collection of cards and their blood samples) remain to be resolved. Unfortunately, complex and uncertain regulation confounds accountability and transparency that can only further undermine the credibility of assurances against the likely misuse and misappropriation of blood samples. As the response of decreased participation in West Australia following police uses of stored blood samples has demonstrated, clear regulation is necessary to maintain public trust (and legitimacy). Without clear regulation imposing accountability and transparency, there will not be adequate assurances about the uses and protections of stored blood samples. More broadly, this case study of the Victorian arrangements confirms that public trust (and legitimacy) are critical to establishing and maintaining tissue collections – hence the re-assurance provided by the Victorian Government and the VCGS Ltd (and its various other incarnations) about the quality of regulatory protections in place – and suggests that meaningful consent is the gatekeeper that addresses most of the likely concerns that might arise.

¹³⁸ See *Genetic Privacy and Non-Discrimination Bill 1998 (Cth)*, cl 25-27.

¹³⁹ Although there may be funding consequence for a failure to comply: see National Health and Medical Research Council et al, n 27, p 96. See also Brown and Then, n 26 at 343; Australian Law Reform Commission, n 4, pp 387-390; Magnusson R. "The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees" (2000) 7 JLM 390 at 391-393.

¹⁴⁰ National Health and Medical Research Council et al, n 27, p 19.

¹⁴¹ See eg Lawson and Smith, n 3.