

GENOMIC RESEARCH AND DATA-SHARING: TIME TO REVISIT AUSTRALIAN LAWS?

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This article analyses the ethical and legal aspects of data-sharing and genomic research. It begins in Part II with an overview of the nature of genomic information, and whether it is exceptional when compared to other forms of health information. Part III considers the role of data-sharing in genomic research, with the importance of public trust in supporting genomic research considered in Part IV. The Australian regulatory framework for data-sharing in genomic research is considered in Parts V and VI, with reform options discussed in Part VII. The article concludes that advances in genomic research and the complexity of the current regulatory framework make it timely to review Australian laws to ensure that they maintain their relevance for this rapidly developing field of research.

I INTRODUCTION

In the early 2000s the Australian Law Reform Commission ('ALRC') and the Australian Health Ethics Committee ('AHEC') of the National Health and Medical Research Council ('NHMRC') embarked on a two-year inquiry on the protection of genetic information. The report of this inquiry, *Essentially Yours: The Protection of Human Genetic Information in Australia* ('*Essentially Yours*'), was published in March 2003.¹ Drawing on scientific expertise and wide public consultation, *Essentially Yours* identified the characteristics of genetic information that posed particular legal and ethical challenges and considered whether those challenges

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¹ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Report No 96, May 2003) ('*Essentially Yours*').

justified treating genetic information as a special kind of personal information requiring more stringent regulation than other forms of personal information.²

Published shortly after the mapping of the human genome,³ *Essentially Yours* appeared on the threshold of the genetic age. In the 17 years since the publication of the report, genetic research has been transformed. Perhaps one of the most significant changes during this period has been the development of genomics. Genomics is defined as ‘the application of specific technologies to analyse information about the entire genome of an organism’.⁴ While genetics examines isolated genes, ‘genomics addresses all genes and their inter-relationships’.⁵ This might involve the entire genome (whole genome sequencing) or all protein-coding genes (whole exome sequencing).⁶

Genomic research promises exciting new possibilities for understandings of the human body and for the prevention, diagnosis and treatment of disease.⁷ While data-sharing is regarded as important to the development of genomic research,⁸ the expected benefits of data-sharing are accompanied by potential risks to privacy. Understanding the risks of data-sharing, and the options for minimising the potential for harm, requires a discussion of the qualities of genomic information.⁹

Focusing on the issue of data-sharing, this article considers the complex privacy issues raised by contemporary genomic research and argues that a review of Australian regulatory frameworks relating to genomics is timely. Such a review will also help to ensure public trust and confidence in research related to emerging genomic technologies. In Part II we consider the nature of genomic information. We consider whether genomic information can be considered ‘exceptional’ or different from other forms of health information. While much of

² Ibid ch 3.

³ International Human Genome Sequencing Consortium, ‘Initial Sequencing and Analysis of the Human Genome’ (2001) 409 *Nature* 860; J. Craig Venter et al, ‘The Sequence of the Human Genome’ (2001) 291(5507) *Science* 1304.

⁴ National Health and Medical Research Foundation, *Principles for the Translation of ‘Omics’-Based Tests from Discovery to Health Care* (2015) 22 <<https://www.nhmrc.gov.au/aboutus/publications/principles-translation-omics-based-tests>>.

⁵ Ibid.

⁶ National Institutes of Health, ‘What Are Whole Exome Sequencing and Whole Genome Sequencing?’ <<https://ghr.nlm.nih.gov/primer/testing/sequencing>>.

⁷ Australian Health Ministers’ Advisory Council, ‘National Health Genomics Policy Framework’ (2017) 2 <https://www.coaghealthcouncil.gov.au/Portals/0/Genomics%20Framework%20WEB_1.PDF> (‘National Health Genomics Policy Framework’).

⁸ Yann Joly et al, ‘Data Sharing in the Post-Genomic World: The Experience of the International Cancer Genome Consortium (ICGC) Data Access Compliance Office (DACO)’ (2012) 8(7) *PLoS Computational Biology* e1002549.

⁹ Donald RC Chalmers, Dianne Nicol and Margaret F Otlowski, ‘To Share or Not to Share Is the Question’ (2014) 3(4) *Applied and Translational Genomics* 126, 127.

the debate about the nature of genomic information has arisen in the context of genomic medicine, the potentially exceptional nature of genomic information is also relevant to the privacy-related issues that arise in the context of research. Part III explains the role of data-sharing in genomic research and the scientific benefits from data-sharing.¹⁰ In Part IV we analyse the role of public trust in supporting genomic research, highlighting the importance of trust in research participation. Part V discusses the regulatory framework for data-sharing in genomic research in Australia at a national level, through guidelines issued by the NHMRC, and the provisions of the *Privacy Act 1988* (Cth) ('*Privacy Act*'). Our aim here is to analyse the role of these regulatory frameworks in the specific context of genomic data-sharing. Australian information privacy law is a mixture of federal and state legislation. In Part VI we use the case study of Queensland as an example of state-based legislation, and to illustrate the complexities of the regulatory landscape in this area. In Part VII we argue that a review of Australian laws relating to genomic technologies is needed given advances in genomics and to address the current regulatory complexity, and we examine options for reform in this area. Finally, in Part VIII we conclude by arguing that the scale of the changes in genomic research make it timely to consider whether Australian law is able to meet the challenges posed by the genomic era.

II THE NATURE OF GENOMIC INFORMATION

Essentially Yours considered the emerging uses of genetic information and the policy implications of what genetic analysis can reveal about a person. The report identified three characteristics of genetic information that distinguish genetic information from other health information: that 'it is ubiquitous, familial and often predictive'.¹¹ It is ubiquitous in the sense that any form of tissue from a person, including tissue collected in the past, can reveal genetic information.¹² The information, unlike some other forms of personal health data, is not anchored in time — 'genetic information lasts for life'.¹³ It is also familial because, although about the individual, genetic sequences are shared with blood relatives,

¹⁰ Although they may be considered types of data-sharing, the original consent of research participants to allow their data to be used, and the disclosure of research data to non-researchers such as might occur in the return of results, are outside the scope of this article.

¹¹ *Essentially Yours* (n 1) [3.16]. For discussion, see Margaret Otowski and Lisa Eckstein, 'Genetic Privacy', in Ian Freckelton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (Federation Press, 2017) 283, 285–6.

¹² *Essentially Yours* (n 1) [3.17]–[3.21].

¹³ *Ibid* [3.18].

‘including those in preceding and succeeding generations’.¹⁴ This relational characteristic may even extend beyond families to others with common ancestral lineage, such as ‘indigenous, ethnic or ethno-religious communities’.¹⁵ Consequently, a person’s genetic information may be inferred from information known about other members of their family or group.¹⁶ Genetic data is often predictive, as it may reveal latent information about the likelihood of developing a disorder in the future, or passing it on to genetic descendants.¹⁷

Awareness of their genetic information may prove beneficial or detrimental to an individual. For example, while it may enable a person to make informed health decisions, it may also have negative implications for employment, education and benefits or services, such as life insurance, as well as being potentially distressing.¹⁸ Further, such predictive information raises particular ethical and social concerns, such as how such information should be treated where no treatment is available, where the relevance of the information may be unclear, and where the potential impacts on privacy and discrimination require consideration.¹⁹

Genomics builds on genetic technology, capturing distinctive information not just about selected genes, but also about the individual’s full genetic make-up. It is now accepted that genomic information has a high potential to be linked to a specific person despite attempts to remove markers of identity.²⁰ This may make it difficult to assure privacy for participants in genomic research or their genetic relatives.²¹ Genomic data has been described by some as a ‘hyper-barcode’, reflecting a belief that it is always able to be linked to a specific donor.²²

¹⁴ Ibid [3.22].

¹⁵ Ibid.

¹⁶ See, eg, Yaniv Erlich et al, ‘Identity Inference of Genomic Data Using Long-Range Familial Searches’ (2018) 362(6415) *Science* 690; Melissa Gymrek et al, ‘Identifying Personal Genomes by Surname Inference’ (2013) 339(6117) *Science* 321.

¹⁷ *Essentially Yours* (n 1) [3.14].

¹⁸ National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (2018) 47 <<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>> (‘*National Statement*’).

¹⁹ *Essentially Yours* (n 1) [3.15].

²⁰ Leslie E Wolf et al, ‘The Web of Legal Protections for Participants in Genomic Research’ (2019) 29(1) *Health Matrix* 1, 7; Erika Check Hayden, ‘The Genome Hacker’ (2013) 497(7448) *Nature* 172. The potential re-identifiability of genomic data has implications for the regulation of genomic research in Australia: see Jane Kaye et al, ‘Trends and Challenges in Biobanking’, in Freckelton and Petersen (n 11) 415, 422.

²¹ Kaye et al (n 20) 426.

²² William W Lowrance, *Privacy, Confidentiality and Health Research* (Cambridge University Press, 2012) 118.

However, there is disagreement about the magnitude and relevance of this risk. These matters are both legally and ethically complex.

The question of whether genetic information is 'exceptional', or whether it is similar to other forms of health information, has been the subject of much debate.²³ More recently, some have proposed 'genomic contextualism' as a preferred approach to characterising genetic information.²⁴ The exceptionalist position was reflected in moves to introduce specific genetic privacy and discrimination legislation in both the United States and Australia in the late 1990s.²⁵ In the United States, it resulted in the *Genetic Information Nondiscrimination Act* of 2008.²⁶ In Australia, the Genetic Privacy and Non-Discrimination Bill 1998 (Cth) also reflected an exceptionalist approach. The Australian Bill was referred to a Senate Committee, which took the view that legislation on genetic privacy was premature given the uncertain development of technology and continued debate in the area.²⁷ The Committee recommended continued review of emerging issues, and that any required legislative regulation be made through changes to existing statutes.²⁸

Although the *Essentially Yours* report did not adopt an exceptionalist approach, it did 'accept that there are some special features and issues attaching to genetic information'.²⁹ The Inquiry recommended amendments to the *Privacy*

²³ See, eg, *Essentially Yours* (n 1) 137–42; LO Gostin and JG Hodge, 'Genetic Privacy and the Law: An End to Genetics Exceptionalism' (1999) 40(1) *Jurimetrics* 21; Ellen Wright Clayton et al, 'The Law of Genetic Privacy: Applications, Implications, and Limitations' (2019) 6(1) *Journal of Law and the Biosciences* 1, 7–9; James G Hodge, 'Ethical Issues Concerning Genetic Testing and Screening in Public Health' (2004) 125C(1) *American Journal of Medical Genetics Part C: Seminars in Medical Genetics* 66; Ilhan Ilklic, 'Coming to Grips with Genetic Exceptionalism: Roots and Reach of an Explanatory Model' (2009) 1(2) *Medicine Studies* 131; Thomas H Murray, 'Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information?', in Mark A Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (Yale University Press, 1997) 60; Daniel P Sulmasy, 'Naked Bodies, Naked Genomes: The Special (But Not Exceptional) Nature of Genomic Information' (2015) 17(5) *Genetics in Medicine* 331.

²⁴ See, eg, Nanibaa' A Garrison et al, 'Genomic Contextualism: Shifting the Rhetoric of Genetic Exceptionalism' (2019) 19(1) *American Journal of Bioethics* 51; Thomas H Murray, 'Is Genetic Exceptionalism Past Its Sell-By Date? On Genomic Diaries, Context, and Content' (2019) 19(1) *American Journal of Bioethics* 13.

²⁵ George J Annas, Leonard H Glantz and Patricia A Roche, 'Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations' (1995) 23(4) *Journal of Law, Medicine and Ethics* 360; Australian Senate Legal and Constitutional Committee, *Report on the Genetic Privacy and Non-Discrimination Bill 1998* (Report, March 1999) <http://webarchive.nla.gov.au/gov/20000416141615/http://www.aph.gov.au/senate/committee/legcon_cte/genetic/index.htm>.

²⁶ Clayton et al (n 23) 13–14.

²⁷ Australian Senate Legal and Constitutional Committee (n 25) [5.10]–[5.13].

²⁸ *Ibid* Recommendations 1 and 2.

²⁹ *Essentially Yours* (n 1) 141 [3.58]. For discussion, see Otlowski and Eckstein (n 11) 285; Don Chalmers et al, 'Personalised Medicine in the Genome Era' (2013) 20(3) *Journal of Law and Medicine* 577, 588.

Act to include genetic information within the definitions of ‘health information’ and ‘sensitive information’ in the Act.³⁰ Amendments were made to the *Privacy Act* and to privacy legislation in some states and territories.³¹ As Otlowski and Eckstein have noted, ‘[t]he explicit recognition of “genetic information” as a category of “sensitive information” within federal, State and Territory privacy legislation indicates some level of acceptance that genetic information is in some respects “special”.’³² This recognition of genomic information as being somewhat special is also relevant to genomic research, given the role of privacy laws in governing research-related use of personal information. In view of the developments in genomics and personalised medicine, there is a need for ‘ongoing assessment of the adequacy of existing regulation’.³³ Furthermore, as we will argue below, the current Australian regulatory frameworks that are relevant to genomic data-sharing are complex and there is a need for national harmonisation.

III GENOMIC RESEARCH AND DATA-SHARING

Genomic research uses data derived from tissue samples, which may be collected from persons who agree to participate in research, or who are tested in a clinical context. Those tissue samples are often stored in biobanks, which are ‘generally large collections of human biological materials (biospecimens) linked to relevant personal and health information (which may include health records, family history, lifestyle and genetic information) and held specifically for use in health and medical research’.³⁴

Sharing of genomic data is widely regarded as a prerequisite for advances in our understanding and classification of genetic diseases and variants, providing the best available data for both research and clinical decision-making, as well as benefits in the form of standardised approaches and the avoidance of duplicate

³⁰ *Essentially Yours* (n 1) 255. For discussion see Chalmers et al (n 29) 588.

³¹ Australian Law Reform Commission, *For Your Information: Australian Privacy Law and Practice* (Report No 108, 2008) vol 3, 2059 [62.7]–[62.9] (*‘For Your Information’*); Otlowski and Eckstein (n 11) 285, citing *Personal Information Protection Act 2004* (Tas) s 3; *Health Records Act 2001* (Vic) s 3; *Information Privacy Act 2014* (ACT) s 14; *Information Act 2002* (NT) s 4. In New South Wales, personal information includes ‘genetic characteristics’ rather than ‘genetic information’: *Privacy and Personal Information Act 1998* (NSW) s 4; *Health Records and Information Privacy Act 2002* (NSW) s 5; Otlowski and Eckstein (n 11) 285.

³² Otlowski and Eckstein (n 11) 285.

³³ Chalmers et al (n 29) 588.

³⁴ National Health and Medical Research Council, *Biobanks Information Paper* (2010) 6 <<https://www.nhmrc.gov.au/about-us/publications/biobanks-information-paper>> (*‘Biobanks Information Paper’*).

research effort.³⁵ Data-sharing may mean providing other researchers with access to preliminary genomic data derived from tissue samples, or the storage of such data in central repositories that may be accessed by multiple researchers, sometimes internationally (often referred to as 'biobanks').³⁶ In a survey of human genetics researchers, from the United Kingdom and other countries, over 80 per cent of respondents agreed that '[a]ccess to more data means more statistical power for validation', '[a]ccess to more data means better representation of genetic variation', and '[s]haring data reduces duplication of effort'.³⁷

Internationally, linking and sharing data is a common practice and considered a scientific value.³⁸ The culture of data-sharing in genomic research can be traced back to the Human Genome Project and the relevant data release policy, the 'Bermuda Principles'.³⁹ The Human Genome Project was an international collaborative effort to sequence the entirety of the human genome for the first time.⁴⁰ The Bermuda Principles, agreed to by leaders in the scientific community, required that all DNA sequence data be uploaded within 24 hours to the public domain in order to maximise benefit to society.⁴¹ Currently, data-sharing is a condition of funding provided by major research bodies and may even be required for publication in academic journals.⁴² In this context, sharing of data

³⁵ ACMG Board of Directors, 'Laboratory and Clinical Genomic Data Sharing Is Crucial to Improving Genetic Health Care: A Position Statement of the American College of Medical Genetics and Genomics' (2017) 19(7) *Genetics in Medicine* 721, 721–722.

³⁶ Chalmers, Nicol and Otlowski (n 9) 126; Christine Critchley and Dianne Nicol, 'Commercialisation of Genomic Research: The Issue of Public Trust', in Freckelton and Petersen (n 11) 350, 352.

³⁷ Tempest A van Schaik et al, 'The Need to Redefine Genomic Data Sharing: A Focus on Data Accessibility' (2014) 3(4) *Applied and Translational Genomics* 100, 103.

³⁸ Jane Kaye, 'From Single Biobanks to International Networks: Developing e-Governance' (2011) 130(3) *Human Genetics* 377, 377–8; Juli M Bollinger et al, 'BRCA1/2 Variant Data-Sharing Practices' (2019) 47 *Journal of Law, Medicine and Ethics* 88; Edward S Dove, 'Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework' (2015) 43(4) *Journal of Law, Medicine and Ethics* 675; Angela G Villanueva et al, 'Genomic Data-Sharing Practices' (2019) 47(1) *Journal of Law, Medicine and Ethics* 31.

³⁹ BM Knoppers and Yann Joly, 'Introduction: The Why and Whither of Genomic Data Sharing' (2018) 137(8) *Human Genetics* 569; Robert Cook-Deegan and Amy L McGuire, 'Moving Beyond Bermuda: Sharing Data to Build a Medical Information Commons' (2017) 27(6) *Genome Research* 897, 897–8.

⁴⁰ National Human Genome Research Institute, *An Overview of the Human Genome Project* <<https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/>>; International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' (2004) 431(7011) *Nature* 931.

⁴¹ Eliot Marshall, 'Bermuda Rules: Community Spirit, With Teeth' (2001) 291(5507) *Science* 1192.

⁴² Villanueva et al (n 38) 31.

is seen as occurring within a ‘medical information commons’⁴³ or, more specifically in the context of genomic research, within a ‘genomic commons’.⁴⁴

Surveys of biobank participants and the general public reveal that people appreciate the benefit of data-sharing for the progress of genomic science. Prospective participants in a United States biobank viewed the sharing of genomic data to benefit the public through enhanced efficiency, providing value for future generations and hastening outcomes that would benefit public health.⁴⁵ Those participants viewed data-sharing in genomic research to be an additional reason to participate, as their contribution is not limited to the one study; ‘roses keep on growing’.⁴⁶ An Australian study found agreement about the importance of privacy and ethics but that more research was needed on public expectations about data sharing.⁴⁷

Using data for multiple research projects also introduces economies of scale. The scale of genomic data sets and the resources required to sequence and store data also require consideration. For example, sequencing a single whole genome produces more than 100 gigabytes of data.⁴⁸ It can be more cost-effective to use existing genomic datasets rather than undertaking new data collection or genomic sequencing.⁴⁹ Although computing costs may be decreasing, other costs such as sample-acquisition costs are relatively stable and significant in the context of large sample sizes.⁵⁰

The benefits of data-sharing may be in tension with privacy rights.⁵¹ In the case of medical research, an individual’s right to limit the use of their own information may work against broader public interests in scientific progress. This has led to arguments that individuals have a *duty* to allow their information to be used for the purposes of research, in order that the burdens of medical research

⁴³ Robert Cook-Deegan, Mary A Majumder and Amy L McGuire, ‘Introduction: Sharing Data in a Medical Information Commons’ (2019) 47(1) *Journal of Law, Medicine and Ethics* 7; Cook-Deegan and McGuire (n 39); Angela G Villanueva et al, ‘Characterizing the Biomedical Data-Sharing Landscape’ (2019) 47(1) *Journal of Law, Medicine and Ethics* 21.

⁴⁴ Knoppers and Joly (n 39).

⁴⁵ Susan Brown Trinidad et al, ‘Genomic Research and Wide Data Sharing: Views of Prospective Participants’ (2010) 12(8) *Genetics in Medicine* 486, 489.

⁴⁶ *Ibid.*

⁴⁷ Christine Critchley, Dianne Nicol and Rebekah McWhirter, ‘Identifying Public Expectations of Genetic Biobanks’ (2017) 26(6) *Public Understanding of Science* 671, 682.

⁴⁸ Karen Y He, Dongliang Ge and Max M He, ‘Big Data Analytics for Genomic Medicine’ (2017) 18(2) *International Journal of Molecular Science* 412, 413.

⁴⁹ Isaac S Kohane, ‘Using Electronic Health Records to Drive Discovery in Disease Genomics’ (2011) 12(6) *Nature Reviews Genetics* 417, 417.

⁵⁰ *Ibid.*

⁵¹ For discussion, see, eg, Otlowski and Eckstein (n 11) 285–9; Kaye et al (n 20) 431; Lowrance (n 22) 1.

are equitably shared.⁵² It has also been argued that there is a ‘right to science’ and a right to benefit from science.⁵³ There are also established arguments for recognising *group* rights to information, such that community consent is required for participation in research, or obligations exist to ensure that benefits are returned to communities for new knowledge developed from their genetic tissue.⁵⁴ Nevertheless, neither of these positions is reflected in Australian information privacy law, which remains focused on the protection of the individual.⁵⁵

The importance of data-sharing to the development of genomic research highlights the need for clear regulatory frameworks that can support genomic research. Noting that ‘[t]he collection and analysis of genomic data is essential to driving improvements in health outcomes for all Australians and providing a pathway to truly personalised health care’,⁵⁶ Australia’s National Health Genomics Policy Framework lists ‘[r]esponsible collection, storage, use and management of genomic data’ as one its five key priorities.⁵⁷

IV TRUST IN GENOMIC RESEARCH

Genomic research relies on the willingness of participants to donate their genomic material, to share their genomic information, or both.⁵⁸ Public trust is

⁵² See, eg, Ruth Chadwick and Kåre Berg, ‘Solidarity and Equity: New Ethical Frameworks for Genetic Databases’ (2001) 2(4) *Nature Reviews Genetics* 318; John Harris, ‘Scientific Research Is a Moral Duty’ (2005) 31(4) *Journal of Medical Ethics* 242; G Owen Schaefer et al, ‘The Obligation to Participate in Biomedical Research’ (2009) 302(1) *Journal of the American Medical Association* 67.

⁵³ Bartha Maria Knoppers and Adrian Mark Thorogood, ‘Ethics and Big Data in Health’ (2017) 4 *Current Opinion in Systems Biology* 53.

⁵⁴ For discussion of the need to obtain group consent for particular ethnic or cultural groups, see Jason Grant Allen, ‘Group Consent and the Nature of Group Belonging: Genomics, Race and Indigenous Rights’ (2009) 20(2) *Journal of Law, Information and Science* 28; Emily FM Fitzpatrick et al, ‘Seeking Consent for Research with Indigenous Communities: A Systematic Review’ (2016) 17(1) *BMC Medical Ethics* 65. On benefit-sharing, see HUGO Ethics Committee, *Statement on Benefit-Sharing* (9 April 2000) <http://www.hugo-international.org/Resources/Documents/CELS_Statement-BenefitSharing_2000.pdf>; HUGO Ethics Committee, *Statement on Human Genomic Databases* (December 2002) <http://www.hugo-international.org/Resources/Documents/CELS_Statement-HumanGenomicDatabase_2002.pdf>.

⁵⁵ Under the *Privacy Act 1988* (Cth) s 2A, the objects of the Act include promoting ‘the protection of the privacy of individuals’, and providing ‘a means for individuals to complain about an alleged interference with their privacy’. Queensland’s legislation, the *Information Privacy Act 2009* (Qld), provides that personal information is ‘information or an opinion ... about an individual’: s 12.

⁵⁶ National Health Genomics Policy Framework (n 7) 7.

⁵⁷ *Ibid* 3, 7.

⁵⁸ Lisa Eckstein et al, ‘Australia: Regulating Genomic Data Sharing to Promote Public Trust’ (2018) 137(8) *Human Genetics* 583; Critchley and Nicol (n 36) 351.

thus a key element of genomic research. The importance of public trust is recognised in the National Health Genomics Policy Framework. Among the priority areas for action for the Framework's data priority is: 'Strengthen public trust of data systems and mechanisms so that people are empowered to engage with genomic interventions in the health system.'⁵⁹ In addition, among the outcomes listed for the data priority area are: 'The public is confident that genomic data and other clinical information is protected and culturally safe'; and 'The public understands the societal value of agreeing to share genomic data to support genomic research, including those funded through private industry.'⁶⁰ Clear regulatory frameworks for the management of genomic data-sharing will therefore potentially play an important role in supporting public trust in genomic research. However, it is also important to recognise that these issues are not unique to genomic research and that trust plays an important role in data-related regulatory reform generally. The Productivity Commission noted in its recent report on data that a '[l]ack of trust by both data custodians and users in existing data access processes and protections and numerous hurdles to sharing and releasing data are choking the use and value of Australia's data'.⁶¹ In the Commission's view, 'improving trust community-wide is a key objective' of reforms to Australian data regulation.⁶²

Australian and international surveys indicate that willingness to participate in biobank research is strongly associated with trust in researchers, as well as belief in the healthcare benefits of research.⁶³ The use of personal information for research without consent and breaches of privacy are likely to undermine public trust.⁶⁴ Maintaining public trust and confidence is key to the sustainability of research that relies on data-sharing, including biobanking.⁶⁵

⁵⁹ National Health Genomics Policy Framework (n 7) 13 (Priority areas for action 5.1.2).

⁶⁰ National Health Genomics Policy Framework (n 7) 13.

⁶¹ Productivity Commission, *Data Availability and Use* (Report, 2017) 2 <<https://www.pc.gov.au/inquiries/completed/data-access/report>>.

⁶² Ibid.

⁶³ Christine R Critchley et al, 'Predicting Intention to Biobank: A National Survey' (2012) 22(1) *European Journal of Public Health* 139. For surveys in Europe, the United States and Canada, see Åsa Kettis-Lindblad et al, 'Genetic Research and Donation of Tissue Samples to Biobanks: What Do Potential Sample Donors in the Swedish General Public Think?' (2006) 16(4) *European Journal of Public Health* 433; Grainne Cousins et al, 'Public Perceptions of Biomedical Research: A Survey of the General Population in Ireland' (2005) <<https://epubs.rCSI.ie/psycholrep/8>>; Geraldine M McQuillan et al, 'Consent for Genetic Research in a General Population: The NHANES Experience' (2003) 5(1) *Genetics in Medicine* 35.

⁶⁴ '[U]sing data or information [for secondary research purposes] without consent may undermine public trust in the confidentiality of their information': *National Statement* (n 18) 36.

⁶⁵ Critchley and Nicol (n 36); Critchley, Nicol and McWhirter (n 47); Kaye (n 20); *Biobanks Information Paper* (n 34); Richard Tutton, Jane Kaye and Klaus Hoeyer, 'Governing UK Biobank: The Importance of Ensuring Public Trust' (2004) 22(6) *Trends in Biotechnology* 284; Lowrance (n 22) 3–4.

In Australia, there is a relatively high level of public trust in scientific and medical institutions.⁶⁶ However, this must be protected to ensure ongoing public participation in genomic research. Public trust entails expectations that researchers conduct themselves competently and ethically, and respect the rights of participants.⁶⁷ Transparency about the potential uses to which tissue may be put, including how data will be shared, is important.⁶⁸

In the United Kingdom, public trust in research is conceptualised as a social contract between researchers and society.⁶⁹ This relationship entails both benefits and obligations. This, in part, requires designing the system such that people are ‘satisfied that genomic medicine operates in their common interests, whilst protecting their individual privacy, and does not exploit some to benefit others’.⁷⁰ Such a social contract, which engenders trust and confidence, is posited to possibly ‘encourage the growth of “genomic citizenship”’ leading to greater participation in research.⁷¹

Without measures to maintain public trust, the benefits of genomic research cannot be realised. Gaps and uncertainty in Australia’s system of regulating genomic data-sharing are potentially a threat to public trust in genomic research.⁷² There are some groups from whom trust in researchers may be more difficult to secure. For example, Aboriginal and Torres Strait Islander peoples may be hesitant to participate in genomics research due to previous negative encounters with researchers.⁷³ Yet it is essential to include diverse genetic

⁶⁶ Gordana Bruce and Christine Critchley, *Swinburne National Technology and Science Monitor* (Report, 2017) 10 <<https://researchbank.swinburne.edu.au/items/4d553f11-b48c-4032-9505-cd0da8eeef9d/1/>>.

⁶⁷ Critchley and Nicol (n 36) 355.

⁶⁸ AA Lemke et al, ‘Public and Biobank Participant Attitudes toward Genetic Research Participation and Data Sharing’ (2010) 13(6) *Public Health Genomics* 368; Critchley, Nicol and McWhirter (n 47) 679–681. Transparency is framed as a core element of responsible data-sharing in genomics in the International Code of Conduct for Genomic and Health-Related Data Sharing: Sumio Sugano and Regulatory and Ethics Working Group, Global Alliance for Genomics and Health, ‘International Code of Conduct for Genomic and Health-Related Data Sharing’ (2014) 8(1) *HUGO Journal* 1, 2.

⁶⁹ Anneke Lucassen, Jonathan Montgomery and Michael Parker, ‘Ethics and the Social Contract for Genomics in the NHS’, in Sally C Davies, *Annual Report of the Chief Medical Officer 2016: Generation Genome* (2017) ch 16.

⁷⁰ *Ibid* 4.

⁷¹ *Ibid*.

⁷² Eckstein et al (n 58) 583–4. As Eckstein et al note (at 583): ‘The patchwork of Australia’s regulatory environment generates implications for public trust. Regulatory gaps create uncertain expectations as to how Australian institutions will protect the interests of research participants.’

⁷³ Emma Kowal, Lobna Rouhani and Ian Anderson, *Genetic Research in Aboriginal and Torres Strait Islander Communities: Beginning the Conversation* (Lowitja Institute, 2011) 31; Emma E Kowal, ‘Genetic Research in Indigenous Health: Significant Progress, Substantial Challenges’ (2012) 197(1) *Medical Journal of Australia* 19, 19.

groups in genomics research to ensure that the benefits of knowledge are shared equitably, and it is known that Aboriginal and Torres Strait Islander peoples are often underrepresented in genetic research.⁷⁴ The potential for harm must be taken into account when considering trust in genomic research.⁷⁵ Specific NHMRC guidelines exist on the requirements for ethical research with Aboriginal and Torres Strait Islander communities.⁷⁶

Research participants may also be sensitive to the types of entities and persons allowed access to their samples and data.⁷⁷ In a study of Californians, a major finding was that willingness to participate in precision medicine research was contingent on the patients' perception of whether the individuals and institutions involved were trustworthy.⁷⁸ Another study in the United States showed that participants feel comfortable when data can be accessed by close collaborators of investigators as well as non-profit public-interest research institutions.⁷⁹ Those types of organisations were viewed by participants to be 'more legitimate' and involved in 'pure science' for public benefit rather than financial return.⁸⁰

Commercialisation of research may also impact on the attitudes of the public.⁸¹ In the United Kingdom, a study on the factors that influence public attitudes towards commercial organisations accessing genetic data, as well as the governance, safeguarding and communications actions that could improve trustworthiness and enable development of public trust in commercial access to data⁸² found that '[e]ducational attainment, awareness of data usage and social grade all appear to be linked to acceptance of commercial access'.⁸³ Broadly,

⁷⁴ Gareth S Baynam, 'The Need for Genetic Studies of Indigenous Australians' (2012) 196(5) *Medical Journal of Australia* 313; Rebekah McWhirter, Dianne Nicol and Julian Savulescu, 'Genomics in Research and Health Care with Aboriginal and Torres Strait Islander Peoples' (2015) 33(2–3) *Monash Bioethics Review* 203.

⁷⁵ Eckstein et al (n 58) 586.

⁷⁶ National Health and Medical Research Council, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders* (2018) <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/indigenous-ethical-guidelines.pdf>.

⁷⁷ See Kaye et al (n 20) 430–1; Critchley and Nicol (n 36).

⁷⁸ Stephanie A Kraft et al, 'Beyond Consent: Building Trusting Relationships with Diverse Populations in Precision Medicine Research' (2018) 18(4) *American Journal of Bioethics* 3.

⁷⁹ Trinidad et al (n 45) 491.

⁸⁰ Ibid.

⁸¹ Critchley and Nicol (n 36); Gillian Haddow et al, 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal' (2007) 64(2) *Social Science & Medicine* 272; Dianne Nicol et al, 'Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources' (2016) 162 *Social Science and Medicine* 79.

⁸² Ipsos MORI, *The One-Way Mirror: Public Attitudes to Commercial Access to Health Data* (Report Prepared for the Wellcome Trust, March 2016) 1.

⁸³ Ibid 4.

greater knowledge and exposure to the ideas tended to be associated with acceptance.⁸⁴ However, an Australian study found that those who had a university education reported a greater reduction in trust in a public biobank that allows access to other entities compared to when it is restricted.⁸⁵ Given the role of trust in public support for research and data-sharing,⁸⁶ clarity of the role of data-sharing in genomic research and protection of privacy are of particular importance.

V REGULATORY FRAMEWORK FOR DATA-SHARING IN GENOMIC RESEARCH

The National Health Genomics Policy Framework lists, as one of its priority areas for action in relation to data: ‘Develop nationally agreed standards for data collection, safe storage, data sharing, custodianship, analysis, reporting and privacy requirements.’⁸⁷ It notes ‘variable legislation’ among the issues ‘that currently limit data sharing’.⁸⁸ At a state level, New South Wales Health released its *Genomics Strategy* in June 2017, which also recognised the need to address ethical, legal and social issues in the foundation stage.⁸⁹ Other bodies in Australia are also considering the regulatory issues related to genomic data-sharing.⁹⁰ In this Part, and in Part VI below, we consider Australia’s regulatory frameworks for information privacy, arguing that they are overly complex and lack national consistency, presenting challenges to the development of national approaches to this area.

Currently, the regulation of data in Australia is undergoing significant discussion,⁹¹ with the Productivity Commission noting in the findings of their Data Availability and Use Inquiry that ‘frameworks and protections for data

⁸⁴ Ibid.

⁸⁵ Christine Critchley, Dianne Nicol and Margaret Otlowski, ‘The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research’ (2015) 18(3) *Public Health Genomics* 160, 169.

⁸⁶ Ibid.

⁸⁷ National Health Genomics Policy Framework (n 7) 13.

⁸⁸ Ibid 3.

⁸⁹ New South Wales Health, *Genomics Strategy* (2017) 30 <<http://www.health.nsw.gov.au/services/Publications/nsw-health-genomics-strategy.pdf>>.

⁹⁰ Andrea Belcher et al, *Genomic Data and Privacy Law: A Summary of Health Legal’s Report for Australian Genomics* (Australian Genomics Health Alliance, 2018).

⁹¹ See, eg, Carolyn Adams and Judy Allen, ‘Government Databases and Public Health Research: Facilitating Access in the Public Interest’ (2014) 21(4) *Journal of Law and Medicine* 957; Moira Paterson and Normann Witzleb, ‘The Privacy-Related Challenges Facing Medical Research in an Era of Big Data Analytics: A Critical Analysis of Australian Legal and Regulatory Frameworks’ (2018) 26(1) *Journal of Law and Medicine* 188.

collection and access, developed prior to sweeping digitisation, require serious re-examination'.⁹² In particular, they noted that 'privacy law is neither the only lens, nor even the best, through which to view the use of an asset such as data'.⁹³

In response to the Productivity Commission's call for reform, the Australian government has committed to reform the Australian data system.⁹⁴ It is intended that the reforms will be underpinned by three key features, including: (1) '[a] new Consumer Data Right [that] will give citizens greater transparency and control over their own data'; (2) '[a] National Data Commissioner, [who] will implement and oversee a simpler, more efficient data sharing and release framework'; and (3) '[n]ew legislative and governance arrangements [that] will enable better use of data across the economy while ensuring that appropriate safeguards are in place to protect sensitive information'.⁹⁵ Legislation has been passed on the Consumer Data Right,⁹⁶ and an Office of the National Data Commissioner has been established.⁹⁷ With regard to new legislation, a discussion paper has been published on proposed new legislation to govern data-sharing and release.⁹⁸

In terms of existing regulation, data-sharing by genomic researchers is governed by a 'patchwork' of ethical guidelines, legislation and case law addressing areas such as medical research, donation and use of human tissue, and privacy of personal information.⁹⁹ For example, all health and medical research on humans is subject to the *National Statement on Ethical Conduct in Human Research* ('*National Statement*').¹⁰⁰ The removal and use of human tissue is governed by legislation in each state and territory.¹⁰¹ Where the genetic or genomic information amounts to 'personal information', privacy legislation governs the circumstances under which it may be shared.

⁹² Productivity Commission (n 61) 53.

⁹³ Ibid.

⁹⁴ Department of the Prime Minister and Cabinet, 'The Australian Government's Response to the Productivity Commission Data Availability and Use Inquiry'; Australian Government, *Budget Measures: Budget Paper No 2 2018-2019* (2018) 166, 186 <https://budget.gov.au/2018-19/content/bp2/download/bp2_combined.pdf>.

⁹⁵ Department of the Prime Minister and Cabinet (n 94). See also Department of the Prime Minister and Cabinet, *Data Sharing and Release: Legislative Reforms Discussion Paper* (2019).

⁹⁶ *Treasury Laws Amendment (Consumer Data Right) Act 2019* (Cth).

⁹⁷ Office of the National Data Commissioner <<https://www.datacommissioner.gov.au/>>.

⁹⁸ Department of Prime Minister and Cabinet (n 95).

⁹⁹ Eckstein et al (n 58) 583.

¹⁰⁰ *National Statement* (n 18).

¹⁰¹ *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act* (NT); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA). See Eckstein et al (n 58) 585. For a discussion of this legislation in the context of research involving paediatric tissue, see Shih-Ning Then and Stephanie Jowett, 'Removal and Use of Paediatric Tissue for Research Purposes: Legal and Ethical Issues in Australia' (2020) 56(3) *Journal of Paediatrics and Child Health* 359.

A *The NHMRC Framework*

The *National Statement* provides ethical guidance for Australian researchers who undertake research involving human subjects.¹⁰² It is issued jointly by the NHMRC, the Australian Research Council and Universities Australia. There is no legal requirement that researchers follow the *National Statement*; however, it has strong normative power and research funders may impose compliance as a condition of funding.¹⁰³

Chapter 3.3 of the *National Statement* addresses genomic research.¹⁰⁴ This chapter acknowledges that genomic research is an evolving field and that the principles described in the chapter will need to be applied to new technologies as they emerge.¹⁰⁵ Among other things, it requires researchers to take account of the ‘potentially predictive and sensitive nature of genomic information’ by, for example, minimising the risk of re-identification.¹⁰⁶ Sharing of genomic information should only be undertaken in accordance with the consent given by research participants or where a waiver of this requirement has been approved by a Human Research Ethics Committee (‘HREC’).¹⁰⁷

The NHMRC provides guidance for HRECs in two further publications authorised under the respective sections of the *Privacy Act*.¹⁰⁸ The *Guidelines under Section 95 of the Privacy Act 1988* (Cth) (‘*Section 95 Guidelines*’) apply to Commonwealth government agencies who wish to use or disclose personal information for the purposes of medical research but where it is impractical to seek consent.¹⁰⁹ The *Guidelines approved under Section 95A of the Privacy Act 1988* (Cth) (‘*Section 95A Guidelines*’) apply to private sector organisations who wish to use or disclose health information for the purposes of research or the compilation or analysis of statistics relevant to public health or safety.¹¹⁰ These guidelines are discussed in more detail in Part V(B) below.

¹⁰² *National Statement* (n 18).

¹⁰³ Ian Kerridge, Michael Lowe and Cameron Stewart, *Ethics and Law for the Health Profession* (Federation Press, 4th ed, 2013) 793.

¹⁰⁴ *National Statement* (n 18) ch 3.3. For general consent requirements, see ch 2.2.

¹⁰⁵ *Ibid* 47, 48.

¹⁰⁶ *Ibid* 50.

¹⁰⁷ *Ibid*. For discussion see Eckstein et al (n 58) 584–6.

¹⁰⁸ *Privacy Act 1988* (Cth) ss 95, 95A.

¹⁰⁹ National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (November 2014) 2 <<https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>> (‘*Section 95 Guidelines*’).

¹¹⁰ National Health and Medical Research Council, *Guidelines Approved Under Section 95A of the Privacy Act 1988* (March 2014) 3 <<https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>> (‘*Section 95A Guidelines*’). For discussion see Eckstein et al (n 58) 586–7.

The *National Statement* recognises that research participation raises particular issues for Aboriginal and Torres Strait Islander peoples and communities.¹¹¹ Accordingly, there are additional NHMRC guidelines that relate to all research involving Aboriginal and Torres Strait Islander peoples and communities.¹¹² In relation to genomics, for these communities research poses not just individual risks but also the possibility of ‘group harms’.¹¹³

B *Federal Privacy Legislation*

The *Privacy Act* applies to Commonwealth government agencies and most private-sector organisations.¹¹⁴ It requires those entities to comply with the Australian Privacy Principles (‘APPs’) when handling particular types of information.¹¹⁵ Private organisations are governed by the *Privacy Act* unless they fall under a particular exception.¹¹⁶ Private organisations include individuals,¹¹⁷ body corporates, partnerships, other unincorporated associations and trusts.¹¹⁸ Small businesses, with annual turnovers of less than \$3 million are ordinarily exempt;¹¹⁹ however, they are not exempt in certain circumstances, including if they provide a health service to an individual and hold any health information except where it is within an employee record.¹²⁰

Generally, the *Privacy Act* provides protections for *personal* information. This means ‘information or an opinion about an identified individual, or an individual who is reasonably identifiable: whether the information or opinion is true or not; and whether the information or opinion is recorded in a material form or not’.¹²¹ Whether genomic information fits these criteria is not immediately clear.¹²² For information to be considered personal information, it must be both about an individual and the individual must be identified or reasonably identifiable.

Information about an individual can be distinguished from other data that is not directly about an individual but from which an individual’s identity could be

¹¹¹ *National Statement* (n 18) ch 4.7.

¹¹² National Health and Medical Research Council (n 76). See Eckstein et al (n 58) 586.

¹¹³ Eckstein et al (n 58) 586. See also, McWhirter et al (n 74) 205

¹¹⁴ *Privacy Act 1988* (Cth) s 6 (definitions of ‘APP entity’, ‘agency’ and ‘organisation’).

¹¹⁵ *Privacy Act 1988* (Cth), s 15, sch 1.

¹¹⁶ *Ibid* s 6 (definitions of ‘APP entity’ and ‘organisation’), 6C.

¹¹⁷ Information that individuals collect, hold, use or disclose for the purposes of personal, family or household matters are excluded from the scope of the Act: *ibid* s 16.

¹¹⁸ *Ibid* s 6C.

¹¹⁹ *Ibid* s 6D(1).

¹²⁰ *Ibid* s 6D(4).

¹²¹ *Ibid* s 6 (definition of ‘personal information’).

¹²² Eckstein et al (n 58) 587.

reasonably ascertained.¹²³ It is not settled whether genomic information, where it has been uncoupled from identifiers such as name for use in research, should be treated as ‘reasonably identifiable’.¹²⁴ The mere technical possibility of identification is not sufficient for information to be regarded as reasonably identifiable, and therefore as personal information.¹²⁵ The Office of the Australian Information Commissioner recommends that where there is uncertainty, it is preferable to apply the APPs.¹²⁶

Under the *Privacy Act*, genomic information would likely be considered ‘health information’, as that definition includes ‘genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual’.¹²⁷ Regardless of whether an argument could be made that it is not predictive of health of the individual or a genetic relative, it will nevertheless always be considered ‘sensitive information’, as it includes ‘genetic information about an individual that is not otherwise health information’.¹²⁸

The likely implication of this is that Commonwealth government agencies and most private organisations in possession of genomic information would be governed by the *Privacy Act* and therefore required to comply with the APPs.¹²⁹ Under APP 6.1, an ‘APP entity’ must not use or disclose personal information that was collected for a particular purpose (the primary purpose) for another purpose (the secondary purpose) unless an exception applies.¹³⁰ One such exception is where the individual has consented to the use or disclosure.¹³¹ Such consent may be either express or implied.¹³² Other exceptions are set out in APP 6.2 and APP 6.3. Under APP 6.2, an APP entity may use or disclose personal information held by an APP entity in certain circumstances, including if a permitted general situation exists,¹³³ or if ‘the APP entity is an organisation and a permitted health situation

¹²³ This issue was raised in *Privacy Commissioner v Telstra Corporation Ltd* [2017] FCAFC 4. For discussion see: Tim Brookes et al, ‘Is It Really All About You? *Privacy Commissioner v Telstra Corporation Limited* [2017] FCAFC 4’ (2017) 36(1) *Communications Law Bulletin* 1. For further discussion, see also Paterson and Witzleb (n 91) 191–2.

¹²⁴ Eckstein et al (n 58) 587.

¹²⁵ Office of the Australian Information Commissioner, *What Is Personal Information?* <<https://www.oaic.gov.au/privacy/guidance-and-advice/what-is-personal-information/>>.

¹²⁶ *Ibid.*

¹²⁷ *Privacy Act 1988* (Cth) s 6FA(d).

¹²⁸ *Ibid* s 6 (definition of ‘sensitive information’).

¹²⁹ APP entities are required to comply with the Australian Privacy Principles (‘APPs’): *Privacy Act 1988* (Cth) s 15.

¹³⁰ *Ibid* sch 1 APP 6.1(a). For discussion see Eckstein et al (n 58) 586.

¹³¹ *Privacy Act 1988* (Cth) sch 1 APP 6.1(a).

¹³² *Ibid* s 6 (definition of ‘consent’).

¹³³ *Ibid* sch 1 APP 6.2(c).

exists in relation to the use or disclosure of the information by the entity'.¹³⁴ The permitted general situations are set out in s 16A of the Act,¹³⁵ and the permitted health situations are set out in s 16B.¹³⁶

The collection of health information for research purposes is specifically provided for under the provisions of s 16B. Section 16B(2) provides:

- (2) A **permitted health situation** exists in relation to the collection by an organisation of health information about an individual if:
- (a) the collection is necessary for any of the following purposes:
 - (i) research relevant to public health or public safety;
 - (ii) the compilation or analysis of statistics relevant to public health or public safety;
 - (iii) the management, funding or monitoring of a health service; and
 - (b) that purpose cannot be served by the collection of information about the individual that is de-identified information; and
 - (c) it is impracticable for the organisation to obtain the individual's consent to the collection; and
 - (d) any of the following apply:
 - (i) the collection is required by or under an Australian law (other than this Act);
 - (ii) the information is collected in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation;
 - (iii) the information is collected in accordance with guidelines approved under section 95A for the purposes of this subparagraph.

Section 16B(3) contains similar provisions in relation to the use or disclosure of health information for research purposes, with the proviso:

- (d) in the case of disclosure — the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information.¹³⁷

Importantly, the *Privacy Act* also expressly provides a permitted health situation exception to allow an organisation that is a provider of a health service to an individual to disclose genetic information about the individual to a genetic relative of the individual where 'the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety of another individual who is a genetic relative of the first individual' and

¹³⁴ Ibid sch 1 APP 6.2(d).

¹³⁵ Ibid s 16A.

¹³⁶ Ibid s 16B. For discussion, see Eckstein et al (n 58) 586.

¹³⁷ Ibid s 16B(3)(d). For discussion, see Eckstein et al (n 58) 586.

the use or disclosure is in accordance with guidelines issued under s 95AA of the *Privacy Act*.¹³⁸

Agencies and organisations covered by the *Privacy Act* are permitted to disclose data for research purposes in some circumstances. Guidelines have been issued under ss 95¹³⁹ and 95A¹⁴⁰ of the *Privacy Act*. These guidelines enable the use of personal information for research purposes in situations where it is not practicable to obtain the consent of the individual to whom the information relates. The collection, use or disclosure of personal information for research purposes will not be a breach of the *Privacy Act* provided the research has been approved by a properly constituted HREC in accordance with the guidelines.¹⁴¹

The *Section 95 Guidelines* apply to research using personal information collected or held by Commonwealth government agencies.¹⁴² The *Section 95A Guidelines* address the requirements in the APPs and ss 16B(2) and 16B(3) of the *Privacy Act* and apply to private sector organisations.¹⁴³ Both the *Section 95 Guidelines* and the *Section 95A Guidelines* set out the requirements for proposals to an HREC for approval of the collection, use or disclosure of personal information without consent, and provide guidelines for HRECs in the consideration of such proposals. Before approving an application under either s 95 or s 95A, an HREC must have determined that the public interest in the proposed research substantially outweighs the public interest in the protection of privacy.¹⁴⁴ Research that would otherwise breach the *Privacy Act* and the APPs may be allowable where it is conducted in accordance with the *Guidelines*.¹⁴⁵

While the s 95 and s 95A guidelines both have the same approach of weighing the public interest in the research with the public interest in protecting privacy, the guidelines do differ in their scope. As indicated above, the *Section 95 Guidelines* apply to Commonwealth agencies.¹⁴⁶ In addition, the *Section 95 Guidelines* apply only to medical research, which specifically includes epidemiological research,¹⁴⁷

¹³⁸ Ibid s 16B(4); National Health and Medical Research Council, *Use and Disclosure of Genetic Information to a Patient's Genetic Relatives under Section 95AA of the Privacy Act 1988 (Cth)* (March 2014) <<https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95aa-privacy-act-1988-cth>>; Otlowski and Eckstein (n 11) 287–8; Eckstein et al (n 58) 587.

¹³⁹ *Section 95 Guidelines* (n 109). For discussion, see Paterson and Witzleb (n 91) 195–6.

¹⁴⁰ *Section 95A Guidelines* (n 110). For discussion, see Paterson and Witzleb (n 91) 195–6; Eckstein et al (n 58) 586.

¹⁴¹ *Section 95 Guidelines* (n 109) 2; *Section 95A Guidelines* (n 117) 3.

¹⁴² *Section 95 Guidelines* (n 109) app 1 (definition of 'agency').

¹⁴³ *Section 95A Guidelines* (n 110) 2–3, 8; *Privacy Act 1988 (Cth)* s 6C (definition of 'organisation').

¹⁴⁴ *Section 95 Guidelines* (n 109) 3.2(b); *Section 95A Guidelines* (n 110) D.4.

¹⁴⁵ *Privacy Act 1988 (Cth)* ss 16B(3), 95; *Section 95 Guidelines* (n 109) 2; *Section 95A Guidelines* (n 110) 3. See also Eckstein et al (n 58) 586–7.

¹⁴⁶ See above n 109 and accompanying text.

¹⁴⁷ *Privacy Act 1988 (Cth)* s 6 (definition of 'medical research').

involving the use of personal information held by agencies, where it is impractical to seek consent.¹⁴⁸ Notably, the *Section 95 Guidelines* require that any genetic research be conducted in accordance with the section in the *National Statement* that concerns genetic research.¹⁴⁹ The *Section 95A Guidelines* apply to the private sector,¹⁵⁰ and provide requirements for the conduct of research relevant to public health or public safety, the compilation or analysis of associated statistics, and the management, funding or monitoring of a health service. With a public health and public safety focus, these guidelines may be viewed as wider in scope than the *Section 95 Guidelines*, which are confined to medical research.¹⁵¹

In terms of international data-sharing, the APPs also include requirements where an APP entity discloses personal information about an individual to an overseas recipient.¹⁵² The provisions of the *Privacy Act* may therefore be relevant not only to use and disclosure of health information within Australia, but also to international data-sharing.

VI STATE-BASED LEGISLATION: A CASE STUDY OF QUEENSLAND

In addition to federal privacy legislation discussed above, state- and territory-based health and privacy legislation is also relevant to the sharing of genomic data in Australia. In this Part we illustrate the regulatory complexity in Australia by examining the regulatory framework in one state, Queensland.

As discussed above, genetic information is included within the scope of the definition of 'sensitive information' in the *Privacy Act*.¹⁵³ Privacy legislation in the Australian Capital Territory, New South Wales, the Northern Territory, Tasmania and Victoria has also been amended,¹⁵⁴ so that genetic information was clearly brought within the scope of privacy laws in those jurisdictions. However, not all states made similar changes to their privacy laws. Queensland has not amended its privacy legislation, retaining separate Information Privacy Principles ('IPPs') and National Privacy Principles ('NPPs') as existed in the federal *Privacy Act* prior

¹⁴⁸ National Health and Medical Research Council, *Flowchart Determining Whether the s 95 Guidelines Apply* <<https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>>.

¹⁴⁹ *Section 95 Guidelines* (n 109) 4. Note that the *Section 95 Guidelines* specifically refer to ch 3.5 of the *National Statement*, which did cover genetic research. However, the revised *National Statement* covers genomic research in ch 3.3.

¹⁵⁰ *Section 95A Guidelines* (n 110) 3.

¹⁵¹ *Ibid.*

¹⁵² *Privacy Act 1988* (Cth) sch 1, APP 8. For discussion, see Eckstein et al (n 58) 588.

¹⁵³ *Ibid* s 6 (definition of 'sensitive information').

¹⁵⁴ See above n 31.

to the 2012 amendments,¹⁵⁵ and current Queensland privacy laws do not include provisions specific to genetic or genomic information. Queensland thus provides a useful case study of the current regulatory complexity that may arise within Australia's federal legal system.

As outlined in Part V, the *Privacy Act* governs the disclosure of information by Commonwealth government agencies and some private organisations. In Queensland, state legislation — the *Information Privacy Act 2009* (Qld), the *Hospital and Health Boards Act 2011* (Qld) and the *Public Health Act 2005* (Qld) — is also relevant to disclosure of personal information.

The *Information Privacy Act 2009* (Qld) contains both NPPs,¹⁵⁶ which apply to state-based health agencies, and IPPs,¹⁵⁷ which apply to non-health state government agencies. The various entities and the applicable law are set out in Table 1.

Table 1 — Legislative Principles Governing Disclosure of Information by Researchers in Queensland According to Entity Holding the Information

Entity	Queensland Health Agencies	Queensland (Non-Health) Agencies	Commonwealth Government Agencies	Private Organisations ¹⁵⁸
Law	<ul style="list-style-type: none"> • National Privacy Principles (NPPs) (<i>Information Privacy Act 2009</i> (Qld) sch 3) • <i>Hospital and Health Boards Act 2011</i> (Qld) • <i>Public Health Act 2005</i> (Qld) 	<ul style="list-style-type: none"> • Information Privacy Principles (IPPs) (<i>Information Privacy Act 2009</i> (Qld) sch 4) 	<ul style="list-style-type: none"> • Australian Privacy Principles (APPs) (<i>Privacy Act 1988</i> (Cth) sch 1) 	<ul style="list-style-type: none"> • Australian Privacy Principles (APPs) (<i>Privacy Act 1988</i> (Cth) sch 1)

¹⁵⁵ The *Privacy Amendment (Enhancing Privacy Protection) Act 2012* (Cth) replaced the previous Commonwealth IPPs and NPPs with a single set of APPs, which came into effect on 12 March 2014: s 2, sch 1.

¹⁵⁶ *Information Privacy Act 2009* (Qld) sch 5 (definition of 'health agency'), s 31. The NPPs are set out in sch 4.

¹⁵⁷ *Ibid* ss 18, 27. The IPPs are set out in sch 3.

¹⁵⁸ 'Private organisations' here refers to those organisations that are not covered by the small business exception established by s 6D of the *Privacy Act 1988* (Cth), as they either have an annual turnover of over \$3 million, provide a health service and hold health information (other than

Under the *Information Privacy Act 2009* (Qld), ‘personal information’ is defined as ‘information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion’.¹⁵⁹ The Act also includes a definition of ‘sensitive information’, for the purposes of the NPPs that includes ‘information that is health information about the individual for the NPPs’.¹⁶⁰

Under the IPPs, Queensland government agencies must not do or fail to do acts, or engage or fail to engage in practices, in such a way that contravenes or is otherwise inconsistent with a requirement of an IPP.¹⁶¹ This covers acts and practices ‘relating to the agency’s collection, storage, handling, accessing, amendment, management, transfer, use or disclosure of personal information’.¹⁶² Health agencies are required to comply with the NPPs.¹⁶³ Under the NPPs, a health agency must not disclose personal information for a purpose (the secondary purpose) other than the primary purpose of collection unless an exception applies.¹⁶⁴ In relation to research, disclosure of personal information is permitted if the information is health information and the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety, and provided other requirements of the NPPs are met.¹⁶⁵ However, the *Information Privacy Act* is subject to provisions of other Acts.¹⁶⁶ This would include the *Hospital and Health Boards Act 2011* (Qld), which prohibits disclosure of confidential information,¹⁶⁷ defined as ‘information, acquired by a person in the person’s capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified’.¹⁶⁸

There are also general requirements on disclosure under the *Information Privacy Act 2009* (Qld). For non-health agencies governed under the IPPs, there is an obligation on the agency to ‘take all reasonable steps to ensure that the relevant entity will not use or disclose the information for a purpose other than

employee records), or disclose personal information about another individual to anyone else for a benefit, service or advantage.

¹⁵⁹ *Information Privacy Act 2009* (Qld) s 12.

¹⁶⁰ *Ibid* sch 5 (definitions of ‘sensitive information’, ‘health information’).

¹⁶¹ *Ibid* s 27(2).

¹⁶² *Ibid* s 27(3).

¹⁶³ *Ibid* s 31.

¹⁶⁴ *Ibid* sch 4, NPP 2.

¹⁶⁵ *Ibid* sch 4, NPP 2(1)(c).

¹⁶⁶ *Ibid* s 7.

¹⁶⁷ *Hospital and Health Boards Act 2011* (Qld) s 142. The circumstances in which disclosure is permitted are specified in ss 143–161.

¹⁶⁸ *Ibid* s 139.

the purpose for which the information was disclosed by the agency'.¹⁶⁹ For Queensland health agencies, if health information is collected for research, health agencies must take reasonable steps before disclosure 'to ensure that the individual the subject of the personal information can no longer, and can not in the future, be identified from the personal information'.¹⁷⁰ As with the APPs in the federal *Privacy Act*, Queensland legislation also includes provisions that are relevant to cross-jurisdictional transfer of personal information. Queensland agencies, health and non-health, are subject to requirements in the *Information Privacy Act 2009* (Qld) concerning the transfer of personal information outside of Australia.¹⁷¹

The *Public Health Act 2005* (Qld) also contains provisions that could be relevant to disclosure of genomic data for research purposes.¹⁷² Under the *Public Health Act 2005* (Qld), 'health information held by a health agency' includes 'information held by the agency about a person's health or the provision of a health service to a person'.¹⁷³ The chief executive may give information for research under the *Public Health Act 2005* (Qld) despite any other provision of the *Public Health Act 2005* (Qld) 'or any provision of another law that deals with confidentiality', including the *Hospital and Health Boards Act 2011* (Qld).¹⁷⁴ Under the *Public Health Act 2005* (Qld), health information held by a health agency may be released to a researcher by the chief executive.¹⁷⁵

Research under the *Public Health Act 2005* (Qld) is defined to be a 'systematic investigation for the purpose of adding to knowledge about human health and well-being and includes the following: (a) a biomedical study; (b) a clinical and applied study; (c) an epidemiological study; (d) an evaluation and planning study; (e) a monitoring and surveillance study'.¹⁷⁶ A person may apply to be given health information for research purposes by providing the chief executive with an application that includes: 'the purpose of the research; and the methodology of the research; the type of information required; the reasons the information is required; how the privacy of any individual identified will be protected; if the information will be needed at intervals during the research, details of the intervals; the name of the person or entity proposing to conduct the research; the names of all persons who will be given the information for the research; the

¹⁶⁹ *Information Privacy Act 2009* (Qld) sch 3 IPP 11(3).

¹⁷⁰ *Ibid* sch 4 NPP 9(4).

¹⁷¹ *Ibid* s 33.

¹⁷² *Public Health Act 2005* (Qld) ch 6 pt 4.

¹⁷³ *Ibid* sch 2.

¹⁷⁴ *Ibid* s 281(3).

¹⁷⁵ *Ibid* ss 281, 282.

¹⁷⁶ *Ibid* s 280.

duration of the research; and the views of a human research ethics committee about the research, including contact details for the committee'.¹⁷⁷

In deciding whether to grant access to health information for research, the chief executive must be satisfied of a number of things, including that the giving of the information is in the public interest, having regard to 'the opportunities the research will provide for increased knowledge and improved health outcomes', as well as 'the privacy of individuals to whom the health information relates', and that 'the identification of any person by the information is necessary for the relevant research'.¹⁷⁸ The chief executive may grant access to the information subject to conditions, including 'that information given for research must be handled in a confidential and secure way'.¹⁷⁹ Importantly, the chief executive is not required to consult with the individual to whom the health information relates before granting access for researchers.¹⁸⁰ However, individuals given information released through this mechanism are prohibited from using the information for a purpose inconsistent with the research for which it was provided, or otherwise disclosing it.¹⁸¹

As the above discussion demonstrates, the interplay of various regulatory instruments in this space results in a complex set of exceptions to privacy protections that allow for disclosure. At a federal level, the legislation draws a strong line between public and private entities. At a state level, in Queensland for example, the distinction is between health and non-health government entities. These exceptions require compliance with different legislation and guidelines depending on the entity in possession of the genomic data. This is likely to be similar in other Australian jurisdictions; however, a complete examination of the legislative environment of all Australian jurisdictions is outside the scope of this article.

VII REFORMING AUSTRALIAN LAWS

Facilitating data-sharing in genomics research in Australia is necessary and desirable to advance Australian genomic science. However, there are a number of ethical, practical and legal issues that will need to be addressed. Given the rapid developments in genetics and genomics since the *Essentially Yours* report in 2003, we argue that Australian laws and regulatory frameworks relating to genomics should be reviewed to ensure that they are able to meet contemporary challenges. We also recognise that data-sharing is just one of a number of complex legal and

¹⁷⁷ Ibid s 282.

¹⁷⁸ Ibid s 284(2).

¹⁷⁹ Ibid s 284(4).

¹⁸⁰ Ibid s 284(7).

¹⁸¹ Ibid s 290-1.

regulatory issues raised by developments in genomics, making a broad review of the relevant laws and regulatory frameworks related to genomics likely to be of greater value than a narrow, issue-specific approach.

Writing in relation to precision medicine, Nicol et al argue that the regulatory challenges posed by precision medicine

need not — and probably should not — result in new, highly targeted laws, which are liable to be outpaced by scientific change. Instead, and to the greatest extent possible, precision medicine should be regulated by the large body of existing laws and other regulatory instruments that apply to other aspects of clinical care and medical research.¹⁸²

A key issue, then, is how to address the regulatory complexity that we have outlined above. In particular, an approach that enhances public trust in genomic research is essential to ensure that Australians remain willing to participate in genomic research and data-sharing.¹⁸³

Although the National Health Genomics Policy Framework envisages a national approach to data-sharing for genomic medicine, Australia's federal legal system does present some challenges to the development of a national approach, with medical research and information privacy laws comprising a patchwork of legislation and guidelines at both federal and state/territory level.¹⁸⁴ Information privacy law is the realm in which data-sharing is currently enabled or prohibited, as it governs the circumstances under which genomic information, as a subset of personal information, can be released. Furthermore, as we have shown above in Part IV, public trust has been recognised as an important aspect of data-related regulatory reform.

As our analysis has shown, the national and Queensland regulatory frameworks for information privacy are complex. Reform of Australian information privacy laws to develop a nationally consistent approach would help to address many of the complexities in the current regulatory environment identified in Parts V and VI above. An argument could be made for harmonising state and territory privacy legislation with the federal *Privacy Act*. In its 2008 report on privacy, the ALRC noted:

Inconsistency and fragmentation in privacy regulation causes a number of problems, including unjustified compliance burden and cost, impediments to information sharing and national initiatives, and confusion about who to approach to make a

¹⁸² Dianne Nicol et al, 'Precision Medicine: Drowning in a Regulatory Soup?' (2016) 3(2) *Journal of Law and the Biosciences* 281, 292.

¹⁸³ Eckstein et al (n 58) 584; Critchley and Nicol (n 58) 352–3.

¹⁸⁴ Eckstein et al (n 58) 583.

privacy complaint. National consistency, therefore, should be one of the goals of privacy regulation.¹⁸⁵

However, proposals to harmonise Australia's privacy laws are not new and have been advanced before, including by the ALRC and AHEC in *Essentially Yours*,¹⁸⁶ suggesting that reform in this area is unlikely to provide a solution in the short term to the regulatory complexities related to genomic data-sharing. Furthermore, additional legislation, such as health legislation in Queensland, is also relevant to this regulatory space and, as such, simplification of the legal situation through reforming privacy law would be limited. In addition, if the proposed Commonwealth data-sharing legislation that covers the release of data from federal agencies is enacted, complexity will still exist in the interplay of that legislation with state/territory privacy law.

The development of genomic-specific national guidelines or standards could provide an alternative approach for a nationally harmonised approach to genomic data-sharing. As noted above,¹⁸⁷ the National Health Genomics Policy Framework has identified the development of national standards, including for data-sharing, as a priority area for action. The benefit of introducing guidelines is that they would not require any changes to the law and could be implemented quickly. The downside of such an approach is that the guidelines would need to be flexible enough to account for the differing and convoluted state of current privacy legislation and guidelines. The ability to achieve national consistency in approach may be limited by what is achievable within the current legislative environment.

Whether a nationally consistent approach that removes regulatory complexity is achieved through reform of relevant legislation such as information privacy laws, or through the development of genomic-specific national guidelines or standards, any review of Australian regulatory frameworks for genomic data-sharing should also include consideration of relevant international developments and the degree to which Australian laws and regulatory frameworks — or any proposed changes to them — should align with existing international approaches. Among the priority areas for action listed in the National Health Genomics Policy Framework is '[s]upport sector engagement with international genomic alliances to promote shared access to data for research and global harmonisation of data where appropriate'.¹⁸⁸ Internationally, the Global Alliance for Genomics and Health has issued a 'Framework for

¹⁸⁵ Australian Law Reform Commission, 'For Your Information' (n 31) 193.

¹⁸⁶ *Essentially Yours* (n 1) 54, Recommendation 7–1.

¹⁸⁷ See Part V.

¹⁸⁸ National Health Genomics Policy Framework (n 7) 13.

Responsible Sharing of Genomic and Health Related Data'.¹⁸⁹ The argument for data-sharing internationally is that 'global sharing enables the best science and ultimately the greatest contributions to human well-being'.¹⁹⁰ Without global data-sharing, 'researchers cannot gain a complete picture of how genes influence disease unless those data are linked to clinical information and different institutions share data with each other'.¹⁹¹ In particular, accumulating enough data on rare disorders may only occur if all possible cases from around the world are compiled.¹⁹² Interestingly, one study conducted in Australia found that sharing genetic data outside Australia did not impact upon public trust or intention to participate in biobanking.¹⁹³

Although consideration of international legal developments relevant to genomics does not necessarily mean that Australia should adopt international legal approaches, consideration of relevant international developments is important, particularly given the potential for international data-sharing. Recognition of the need for consideration of international developments is not new. Among 'seven attributes of the reform process'¹⁹⁴ listed in *Essentially Yours* was the need to '[c]onsider the cross-border implications of the issues, whether they be federal or international in character.'¹⁹⁵ Nicol et al make a similar point, listing 'consistency/equivalency across geographical, technological, and institutional borders' as one of 'five recurring elements that must be taken into account in the development of any regulatory framework for precision medicine'.¹⁹⁶

There is value in a comparative approach in the development of Australian laws. As was noted by the ALRC and AHEC in *Essentially Yours*: 'An examination of relevant developments in other jurisdictions enables informed choices to be made for Australia based on international best practice in the field.'¹⁹⁷ In Europe, for

¹⁸⁹ Global Alliance for Genomics and Health, *Framework for Responsible Sharing of Genomic and Health Related Data* (9 December 2014) <<https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/>>; see also Bartha Maria Knoppers, 'Framework for Responsible Sharing of Genomic and Health-Related Data' (2014) 8(1) *HUGO Journal* 3; Knoppers and Joly (n 39).

¹⁹⁰ Mary A Majumder, Robert Cook-Deegan and Amy L McGuire, 'Beyond Our Borders? Public Resistance to Global Genomic Data Sharing' (2016) 14(11) *PLOS Biology* e2000206, 2.

¹⁹¹ Erika Check Hayden, 'Geneticists Push for Global Data-Sharing' (2013) 498(7452) *Nature News* 16.

¹⁹² Majumder, Cook-Deegan and McGuire (n 190).

¹⁹³ Critchley, Nicol and Otlowski (n 85) 165.

¹⁹⁴ *Essentially Yours* (n 1) [4.22].

¹⁹⁵ *Ibid* [4.23].

¹⁹⁶ Nicol et al (n 182) 303. Eckstein et al also argue that '[t]he extensive and typically cross-border sharing arrangements that characterise modern genomic research also warrant an assessment of the interactions between multiple, often overlapping, legal regimes': Eckstein et al (n 58) 590.

¹⁹⁷ *Essentially Yours* (n 1) [4.44].

example, the General Data Protection Regulation ('GDPR') has led to discussion about the scope of privacy laws, including the ways that the GDPR may also potentially be relevant for genomics research.¹⁹⁸ A comparison between the legal and regulatory frameworks for genomics in Australia and those in the European Union and the United Kingdom and other jurisdictions may provide valuable insights into different regulatory approaches.¹⁹⁹ More broadly, it may also be important for Australian genomic data-sharing standards to align with those developed at an international level.²⁰⁰

Finally, community engagement must be an essential part of any law-reform process relating to genomic data-sharing. At a general level, community engagement has been recognised as an important element of law-reform processes.²⁰¹ More specifically in relation to genomic research, there is an inherent tension between tightening the law on data-sharing to account for the sensitive nature of genomic information and clarifying the law to enable greater sharing. In *Essentially Yours* the promotion of 'widespread community participation in the formulation of relevant rules and principles'²⁰² was included in the list of 'attributes for the reform process'.²⁰³ It was further noted in the report that '[w]idespread community participation in the process of reform or review is thus seen by the Inquiry as essential to maintaining public trust.'²⁰⁴ Nicol et al also include 'genuine engagement with all relevant stakeholders'²⁰⁵ in their list of elements needed in the development of regulation for precision medicine. Given the importance of public trust in genomic research, reform in this area may require greater engagement with the public to ensure that the law strikes the right balance between the promotion of scientific research and individual privacy protections so that it is reflective of community values. Community engagement may also help to build public trust in genomic research.²⁰⁶

¹⁹⁸ For discussion, see Paul Quinn and Liam Quinn, 'Big Genetic Data and its Big Data Protection Challenges' (2018) 34 *Computer Law & Security Review* 1000; Kaye et al (n 20). For discussion of Australian law and compliance with the GDPR, see Eckstein et al (n 58) 588.

¹⁹⁹ Kaye et al (n 20).

²⁰⁰ For discussion of international approaches, see Knoppers and Joly (n 39).

²⁰¹ See, eg, Natalina Nheu and Hugh McDonald, *By the People, for the People? Community Participation in Law Reform* (Law and Justice Foundation of New South Wales, 2010) 4; Brian Opeskin, 'Engaging the Public — Community Participation in the Genetic Information Inquiry' (2002) 80 (Autumn) *Reform* 53, 54; David Weisbrot, 'From Public Engagement to Public Policy: Competing Stakeholders and the Path to Law Reform', in Kieran O'Doherty and Edna Einsiedel (eds), *Public Engagement and Emerging Technologies* (UBC Press, 2012) 167.

²⁰² *Essentially Yours* (n 1) [4.23].

²⁰³ *Ibid* [4.22].

²⁰⁴ *Ibid* [4.28].

²⁰⁵ Nicol et al (n 182) 303.

²⁰⁶ Critchley and Nicol (n 58) 366.

VIII CONCLUSION

Genomic research promises advances in medicine to improve human health. Sharing of genomic research data can play an important role in supporting genomic research. However, as this article has argued, data-sharing brings with it complex legal and ethical issues, particularly in the context of privacy for research participants, and the complexity of the regulatory landscape. Given the advances in genomics, and the regulatory complexities outlined in this article, it is timely to review Australia's regulatory frameworks to ensure that they are able to meet the challenges posed by advances in genomics, including those relating to data and data-sharing. The review could consider how best to reduce the regulatory complexities identified in this article, for example through harmonisation of information privacy law or through the development of national standards. As outlined above, an international comparative approach and community engagement will be important aspects of this process. Such an approach could simultaneously build the trust of the Australian public while ushering Australia into the era of genomic medicine.