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Indigenous Health Genomics: The legal, ethical and social issues

Terri Janke and Company

Commissioned by the Department of Health



Australian Government
**Department of Health
and Aged Care**



Indigenous Health Genomics: The Legal, Ethical and Social Issues

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Contents

1	Introduction.....	7
1.1	About this report	7
1.2	Who is it for?.....	7
1.3	How to read it?.....	8
1.4	Terminology.....	8
1.5	Glossary	10
1.6	Detailed methodology and stakeholder consultation list	13
2	Executive Summary.....	17
3	Context.....	19
3.1	Past projects	19
3.1.1	The Human Genome Diversity Project (HGDP) (the “Vampire Project”).....	19
3.1.2	The Genographic Project.....	20
3.2	The Co-design principle	21
4	What issues arise ethically, socially and culturally for Indigenous Genomics?	21
4.1	What makes Aboriginal and Torres Strait Islander genomics unique?.....	25
4.2	What rights do Aboriginal and Torres Strait Islander peoples want over their genomic samples and data?	26
4.3	Access to health outcomes	28
4.4	Collection and use of information	29
4.4.1	Who needs to give consent?.....	30
4.4.2	What does the consent cover?.....	30
4.4.3	How was the consent obtained and when?	31
4.5	Management of personal genomic information.....	32
4.6	Secondary uses & incidental findings.....	32
4.7	Distinction between health-based research and population research.....	33
4.8	Cultural security for Aboriginal and Torres Strait Islander Researchers.....	33
4.9	University research integrity and ethics protocols & funding bodies expectations .	33
4.10	Data Management Infrastructure & Data Sovereignty	34
4.11	Legal ambiguity & uncertainty	35
4.12	Emerging Issues	36
5	What are the legal issues?	37
5.1	Does copyright law protect genomic information?	38
5.1.1	Copyright and ownership of medical records – clinical setting.....	39
5.1.2	Copyright in Research: Genomic Studies and Publications.....	40



Indigenous Health Genomics: The Legal, Ethical and Social Issues

5.1.3	Copyright protection in film and sound recordings.....	40
5.1.4	Copyright in the Genome Sequencing - is DNA subject to copyright?	42
5.1.5	Databases and copyright	42
5.1.6	Exceptions for the use of copyright material.....	43
5.1.7	Summary	44
5.2	Privacy and Personal Information	44
5.2.1	Australian Privacy Law and Aboriginal and Torres Strait Islander Health Related Information	44
5.2.2	Where does genomic information fit in the Privacy framework?	45
5.2.3	When is genomic information not protected by the Privacy Act?	47
5.2.4	Permitted Health Situations for the non-Consensual use of Health Information 47	
5.2.5	Does the Privacy Act apply overseas?	51
5.2.6	Concluding Comments.....	51
5.3	The Rights of Patients in a Clinical Setting.....	52
5.3.1	Substantive Rights	53
5.3.2	Procedural Rights	60
5.3.3	Conclusion	60
5.4	IP and Commercialisation – Patents Act	61
5.4.1	Patents in Australia	61
5.4.2	Where does Australia stand with gene patenting?	63
5.4.3	Patents over diagnostic methods	64
5.4.4	Patents and Morality Debates	65
5.4.5	Patents over existing Aboriginal and Torres Strait Islander knowledge systems and practices	66
5.4.6	International Examples	66
5.4.7	Conclusion	67
5.5	Consumer law and consumption of health services.....	67
5.5.1	Misleading or deceptive conduct or representations	68
5.5.2	Unconscionable Conduct	68
5.5.3	State and territory consumer protections.....	69
5.6	Who controls access to existing genetic material?	70
5.6.1	Access of law enforcement to data	71
5.6.2	Can researchers access Aboriginal and Torres Strait Islander samples in museum collections?	73



Indigenous Health Genomics: The Legal, Ethical and Social Issues

5.7	Health records laws	80
5.8	Managing research agreements.....	82
5.9	Documenting consents	84
5.9.1	Documenting consents in the doctor/patient relationship	84
5.9.2	Documenting consents when samples are obtained from existing collections	85
5.9.3	Documenting consents when samples are obtained by private companies	86
5.10	Right of access to medical benefits & health outcomes.....	86
5.10.1	Australian Human Rights Acts	88
5.11	Biobanks and genomic data storage areas	89
5.11.1	Legal and policy framework	89
6	Gap Analysis: Impact of the law on social and cultural issues.....	91
6.1	Do Aboriginal and Torres Strait Islander people own their genes?	91
6.2	Do the privacy laws that regulate accessing and sharing genomic data provide enough protection for Indigenous genomics?.....	92
6.3	Are Aboriginal and Torres Strait Islander people getting fair access to health outcomes?.....	92
6.4	Does the law promote (or impede) Aboriginal and Torres Strait Islander co-design and management of genomic projects?	93
6.5	How is community consultation impacted?.....	94
6.6	Is the legal standard for consent enough to meet ethical and cultural needs?.....	94
7	Policy.....	95
7.1	<i>National Statement on Ethical Conduct in Human Research</i> (2007, updated 2018), National Health and Medical Research Council (NHMRC).....	95
7.1.1	What is it?.....	95
7.1.2	Who does it apply to?	96
7.1.3	Overview of provisions.....	96
7.2	<i>Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders</i> , National Health and Medical Research Council (NHMRC).....	97
7.2.1	What is it?.....	97
7.2.2	Who does it apply to?	97
7.2.3	Overview of provisions.....	97
7.3	<i>Keeping Research on Track II</i> , National Health and Medical Research Council (NHMRC).....	98
7.3.1	What is it?.....	98
7.3.2	Who does it apply to?	98



Indigenous Health Genomics: The Legal, Ethical and Social Issues

7.3.3	Overview of provisions.....	98
7.4	<i>Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research</i> , National Health and Medical Research Council (NHMRC).....	99
7.4.1	What is it?.....	99
7.4.2	Who does it apply to?	99
7.4.3	Overview of provisions.....	99
7.5	<i>Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS)</i> , Australian Aboriginal Institute of Aboriginal and Torres Strait Islander Studies.....	100
7.5.1	What is it?.....	100
7.5.2	Who does it apply to?	100
7.5.3	Overview of provisions.....	100
7.6	Genomics Partnerships, QIMR Berghofer	100
7.7	Central Australian Academic Health Science Network	101
7.8	Kimberley Land Council Policies.....	101
7.9	<i>Strengths and Limitations of a Guidelines Approach</i>	101
8	Best practice models: leading practices in Indigenous genomics.....	102
8.1	Case studies.....	102
8.1.1	The Ochre Plan.....	102
8.1.2	Footprints in Time – The Longitudinal Study of Indigenous Children.....	103
8.2	Best practice and project planning	103
9	International Indigenous Health Genomics	105
9.1	What are the international law instruments that give guidance for Australian law and policy on Indigenous genomics?	105
9.1.1	United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)	105
9.1.2	Universal Declaration on the Human Genome and Human Rights.....	106
9.1.3	International Declaration on Human Genetic Data	106
9.1.4	Universal Declaration on Bioethics and Human Rights	107
9.2	What case law in other jurisdictions?	108
9.2.1	Moore v Regents of the University of California (1990)	108
9.2.2	The OncoMouse case.....	108
9.2.3	Henrietta Lacks Immortal Cells	109
9.2.4	Myriad Genetics US.....	110
9.2.5	Havasupai Tribe v Arizona Board of Regents.....	110
9.3	What International examples are there of best practice research methodologies?	

Indigenous Health Genomics: The Legal, Ethical and Social Issues

9.3.1	The Slim Initiative for Genomic Medicine in the Americas (SIGMA)	113
9.3.2	Wellcome Trust/NIH Human Heredity & Health in Africa (H3Africa) project (>\$50M) 113	
9.3.3	Te Mata Ira: Guidelines for Genomic Research with Māori	114
10	Conclusion: Opportunities for improvement	116
11	References	120



1 Introduction

1.1 About this report

The Department of Health (the Department) has commissioned Terri Janke and Company to prepare this issues paper on the legal, ethical and social issues relevant to the collection and use of Indigenous health genomics samples and information. Terri Janke and Company (TJC) is an Indigenous owned and run law firm. TJC has been operating for 20 years, specialising in commercial law, Intellectual Property law (IP) and Indigenous Cultural and Intellectual Property (ICIP).

This issues paper identifies the legal issues arising from the collection and use of Aboriginal and Torres Strait Islander genomic samples and information in the clinical and research settings. It focuses on the current and emerging ethical, legal, social and cultural issues, identified by Aboriginal and Torres Strait Islander stakeholders. This includes the issues related to community engagement, governance, consent, sharing, privacy, disclosure, discrimination, commercialisation, ownership, return of benefit and management of personal genomic information

TJC undertook an assessment of national and international literature and legislation; and consulted stakeholders including with the Department's Aboriginal and Torres Strait Islander Advisory Group (the Advisory Group) and with the leaders on the related projects:

- The Ethical, Legal and Social Project Team from the University of Tasmania and the University of Melbourne, and
- The Environmental Scan Project Team, led by Karabena Consulting

1.2 Who is it for?

This issues paper centralises the key legal, ethical, social and cultural issues relevant to the collection and use of Indigenous health genomics information in Australia. It had the significant advantage of being able to consult individually with all members of the Advisory Group. The members of the Advisory Group were from a wide variety of Aboriginal and Torres Strait Islander and non-Indigenous backgrounds and all worked within the genomics sector in a variety of ways. This meant that the issue identification process was broad (ensuring key issues were not overlooked) but it also meant that as key themes emerged across the consultations, those themes were better understood from a number of perspectives.

This paper is a consolidation of those key themes and perspectives, combined with a survey of the impact of relevant legislation on the Indigenous Cultural and Intellectual Property embodied in the genomics samples and data. The purpose of this issues paper is to provide the Department with a holistic overview of current and emerging issues. This will assist the Department to identify key risk areas that are (or could potentially) cause harm to Aboriginal and Torres Strait Islander peoples and develop policy accordingly. Genomics is a rapidly evolving area of scientific research, and this issues paper, and a proactive approach to policy making, in collaboration with Aboriginal and Torres Strait Islander communities will help to promote equitable access to positive health outcomes, and minimise harm to communities.



1.3 How to read it?

This report begins by identifying the key ethical, social and cultural issues relevant to the collection and use of genomics information of Aboriginal and Torres Strait Islander peoples.

The legal issues relating to the collection, management and use of Aboriginal and Torres Strait Islander genomics information are then identified. The legal analysis will include intellectual property, primarily patents and copyright, privacy laws, health laws relating to genome research and contract laws. The second stage of the legal analysis will examine the extent to which the law addresses the ethical, social and cultural issues identified with the Advisory Group. Does the law provide guidance and protection? Does the law fall short? Does the law augment these concerns?

The issues paper will then examine the relevant policy documents that provide further guidance, bearing in mind that these policies can be given legal force through contract law.

Best practice models will then provide further insight into the respectful and culturally safe collection and use of Aboriginal and Torres Strait Islander genomic information.

An international perspective concludes the issue identification and analysis. The section starts by examining relevant international law for standards and guidelines relevant to Aboriginal and Torres Strait Islander health genomics. This is followed by a comparative law analysis in which the domestic case law, legislation and policy documents of other countries are examined to the extent that they may provide insight into an Australian application.

Finally, the paper concludes by examining the opportunities for improvement. In particular this section will identify the key risk areas in Aboriginal and Torres Strait Islander health genomics that must be addressed promptly and in collaboration with Aboriginal and Torres Strait Islander stakeholders in order to ensure that a culturally appropriate framework for managing sovereignty over samples and data is in place in the earliest possible stages of genomic research.

1.4 Terminology

The question of terminology is not a straight forward one. In general, the term 'Indigenous' refers to the world's First Nations peoples. However, in Australia it is frequently used to refer to Aboriginal and Torres Strait Islander peoples. Increasingly, the terminology of Aboriginal and Torres Strait Islander peoples, is being used rather than Indigenous. This is because the word 'Indigenous' can be too broad, and can fail to reflect the diversity of Aboriginal and Torres Strait Islander cultures. Instead, the term Aboriginal and Torres Strait Islander peoples (using the plural), is more specific to Australia's First Nations peoples, and it acknowledges the diversity of Aboriginal and Torres Strait Islander cultures.

This paper continues to use the word Indigenous in some specific contexts, for example when it is in a quote. In addition, sometimes it is used, because the point being made relates to the world's First Nations peoples as well as Aboriginal and Torres Strait Islander peoples. For example, this report includes a number of International case studies, in which the issues raised for that place's First Nations' peoples, can provide insight into issues relevant to Aboriginal and Torres Strait Islander peoples. For the same reason, we have referred to 'Indigenous Genomics' or 'Indigenous Health Genomics' as this area of study frequently

Indigenous Health Genomics: The Legal, Ethical and Social Issues

crosses national borders and this issues paper is focused on identifying issues relevant to Aboriginal and Torres Strait Islander peoples in the broader context of Indigenous Health Genomics.

In all other contexts, as far as possible this report has endeavoured to prioritise the use of the term Aboriginal and Torres Strait Islander peoples.



1.5 Glossary

Abbreviations

Abbreviation	Full Form
The Advisory Group	The Department of Health's Aboriginal and Torres Strait Islander Advisory Group
AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies
ANU	Australian National University
The Department	The Department of Health
DVI Database	Disaster Victim Identification database
HeLEX@Melbourne	Health, Law and Emerging Technologies Melbourne
NACCHO	National Aboriginal Community Controlled Health Organisation
NATSIHSC	National Aboriginal and Torres Strait Islander Health Standing Committee
NCIDD	National Criminal Investigation DNA Database
NCIG	National Centre for Indigenous Genomics
QAIHC	Queensland Aboriginal and Islander Health Council
TJC	Terri Janke and Company
SAHMRI	South Australian Health and Medical Research Institute

Terms

Terms	Meaning
Aboriginal and Torres Strait Islander person	<p>Australian person of Aboriginal or Torres Strait Islander descent who identifies as an Aboriginal or Torres Strait Islander person and is accepted as such by the community in which they live.</p> <p>Aboriginal and Torres Strait Islander peoples are the many sovereign nations of culturally diverse Aboriginal and Torres Strait Islander communities.</p>

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Terms	Meaning
First Nations peoples	An increasingly favoured term that recognises all Indigenous persons
Genome	The NHMRC provides a basic definition of the human genome: 'The human genome consists of the complete set of human genetic material that is contained in a human cell. In most human cells, the genetic material is made up of long DNA strands that are packaged into 23 pairs of chromosomes. A genetic disease or condition is caused by one or more genetic changes to the DNA code' ¹
Genetic testing	Changes (mutations) in inherited genes can result in genetic diseases, which can in turn be passed down to an individual's children. Genetic testing involves testing an individual's genes in order to detect these mutations and infer the probability of a disease or condition developing or being passed down to that person's children. ²
Indigenous peoples	The term Indigenous refers to persons of Aboriginal and Torres Strait Islander descent, and the clans or language groups and communities they belong to.
Indigenous Cultural and Intellectual Property (ICIP)	'Indigenous Cultural and Intellectual Property' or 'ICIP' is widely used in Australia following the report <i>Our Culture: Our Future</i> . ICIP includes intangible and tangible aspects of cultural heritage from cultural property and cultural sites. It includes, human remains and documentation of Indigenous peoples, sciences and technologies, and human and genetic resources. ICIP is transmitted from generation to generation. It is constantly evolving, and its creation is ongoing.
Indigenous Cultural Expression	Manifestations of Indigenous culture including performance, dance, stories, art, designs, language, names, symbols, handicrafts and ceremonies. Indigenous knowledge of sciences and technologies are often recorded and transmitted through Indigenous Cultural Expressions.

¹ National Health and Medical Research Council, *Genomics resources for consumers* (Web Page) <<https://www.nhmrc.gov.au/health-advice/genomics/genomics-resources-consumers>>.

² National Health and Medical Research Council, *The Human Genome*, NHMRC REF# G6, (online at 9 July 2020) < <https://www.nhmrc.gov.au/about-us/publications/human-genome>>.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Terms	Meaning
Indigenous Knowledge	Knowledge passed down through the generations and pertaining to Indigenous peoples and their region. It includes ecological knowledge of Country and plants, healing, ways of Indigenous knowing and cultural practices.
Intellectual Property (IP)	Intellectual property laws protect, for a limited time, creative expression that has been reduced to material form. This includes protection of: <ul style="list-style-type: none">• artistic and other creative works through copyright law;• industrial and commercial designs (what makes a product look the way it does) through design law;• business brands through trade mark law; and• newly invented devices, substances, methods or processes through patent law.• New plant varieties are also protected through plant breeder rights legislation.
Public domain	Public domain generally refers to work that does not have any intellectual property law restriction upon its use by the public.
Sui Generis	Means stand alone or specific legislation



1.6 Detailed methodology and stakeholder consultation list

TJC had 16 detailed discussions with key stakeholders, including the members of the Advisory Group and the project teams on the related Ethical, Legal and Social Project and Environmental Scan Project.

Our approach to the discussions was to hold one-on-one telephone or video conferencing sessions. This individual approach achieved more in-depth conversations than could have been achieved in larger workshops. It meant issue identification was broader, and issue examination more detailed.

Preparation for each discussion involved identification of key questions or discussion areas specific to the individual's area of research or work. However, we also found that keeping the meeting conversational in tone, and allowing the participant to lead, allowed discussion of the ethical, social, cultural and legal issues most relevant to them. This avoided the risk of our questions leading discussion away from important topics and in fact frequently led to issue identification that we might otherwise have missed or underestimated.

Each discussion lasted between 60-90 minutes. The Advisory Group members and team leaders from the related projects were incredibly generous with their time and knowledge, and this issues paper owes a deep debt of gratitude to them. TJC would like to acknowledge and thank each of them individually:

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Table 1: The Department of Health's Aboriginal and Torres Strait Islander Advisory Group

The Department of Health's Aboriginal and Torres Strait Islander Advisory Group

Person	Workplace
Professor Gareth Baynam, Clinical Geneticist	Genetic Services of Western Australia and the Western Australian Register of Developmental Anomalies, WA Heath
Ms Janine Mohamed, <i>CEO</i>	Lowitja Institute
Ms Lowanna Norris, Executive Assistant to CEO Janine Mohamed	Lowitja Institute
Ms Phoebe Dent, <i>Policy Team</i>	Lowitja Institute
Ms Leonie Williamson, <i>Policy Team</i>	Lowitja Institute
Ms Nicole Bowman, <i>Policy Team</i>	Lowitja Institute
Professor Alex Brown, Leader, Aboriginal Health Research Unit	South Australian Health and Medical Research Institute (SAHMRI)
Ms Azure Hermes, Indigenous Community Engagement Coordinator	National Centre for Indigenous Genomics (NCIG), Australian National University College of Health & Medicine
Professor Margaret Kelaher, Head, Evaluation and Implementation Science, Centre for Health Policy, Melbourne School of Population and Global Health	The University of Melbourne
Associate Professor Stephen Leslie, Associate Professor, Centre for Systems Genomics, Faculty of Science	The University of Melbourne
Ms Tanya McGregor, <i>Chair</i>	National Aboriginal and Torres Strait Islander Health Standing Committee (NATSIHSC)
Mr Greg Pratt, Aboriginal and Torres Strait Islander Health Research Manager	QIMR Berghofer Medical Research Institute

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Person	Workplace
Dr Nic Waddell, Group Leader, Medical Genomics	QIMR Berghofer Medical Research Institute
Dr Simone Reynolds, Research Fellow, The End Rheumatic Heart Disease Centre for Research Excellence, Institute for Glycomics, Griffith University & Co-chair, NCIG Board	Griffith University & National Centre for Indigenous Genomics (NCIG), Australian National University College of Health & Medicine
Ms Samantha Faulkner, Director, Ethics and Research Leadership	Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS)
Ms Kate Thomann, Assistant Secretary, Primary Health Data and Evidence Branch, Indigenous Health Division	Department of Health
Ms Angela Young, General Manager, Policy and Research	Queensland Aboriginal and Islander Health Council (QAIHC) for the National Aboriginal Community Controlled Health Organisation (NACCHO)
Dr Mark Wenitong, Public Health Medical Advisor	Apunipima Cape York Health Council
Ms Summer May Finlay, Advisory Group Facilitator	Department of Health

Table 2: Ethical, Legal and Social Project Team

Ethical, Legal and Social Project Team

Person	Workplace
Professor Dianne Nicol, Project Supervisor & Professor of Law, Director of the Centre for Law and Genetics, Faculty of Law	University of Tasmania
Associate Professor Mark Taylor, Melbourne Project Supervisor & Deputy Director of Health, Law and Emerging Technologies Melbourne (HeLEX@Melbourne)	University of Melbourne
Dr Rebekah McWhirther, Project Lead & Research Fellow	University of Tasmania



Table 3: Environmental Scan Project Team

Environmental Scan Project Team

Person	Workplace
Professor Kerry Arabena, <i>Project Supervisor</i>	Karabena Consulting
Ms Tessa Hancock, Executive Assistant	Karabena Consulting

2 Executive Summary

This issues paper commences at Chapter 3 which provides some context for Indigenous health genomics' contentious history. We touch on some of the past genomics projects that exemplified many of the fundamental risks of ill-conceived and poorly designed Indigenous genomics projects; the foundation of much of the mistrust of Aboriginal and Torres Strait Islander communities' when it comes to genomic research. From these examples it is clear that the co-design principle – the principle that genomic research should be designed and constructed in collaboration with communities – is an essential component of any best practice model.

Chapter 4 then unpacks in more detail the ethical, social and cultural issues that arise in the Indigenous Genomics sphere as experienced by the Advisory Group. Many of the issues flow from a central question: *If an Aboriginal or Torres Strait Islander person, or their community, provides genomics samples for clinical or research purposes, what legal rights do they have?*

Chapter 5 considers the laws' interaction with Indigenous health genomics through this central question. Key themes emerge in ownership of data, management of access to information and the rights of the individual. The legal issues are analysed through the lenses of copyright law, patents and commercialisation, contract law, and access to health records. The chapter further considers the role that consumer and anti-discrimination laws as well as prior informed consent as they relate to the key concerns raised by the Advisory Group. In analysing how health and personal information is protected, privacy law is analysed with a focus on permitted health situations for non-consensual use of health information.

Chapter 6 builds on from Chapters 4 and 5 in considering the impact of the law on the social and cultural issues through a gap analysis. These social and cultural issues include the communal or individual ownership of genes, the adequacy of privacy laws in protecting the individuals, family and community and whether the legal standard of consent is enough to meet ethical and cultural needs. These needs include the co-design and management of Indigenous genomics, the role of community consultation and benefit sharing.

Chapter 7 examines the key policies, protocols and guidelines that apply to Aboriginal and Torres Strait Islander research, and therefore, apply to genomic research involving Aboriginal and Torres Strait Islander peoples and their genes. This includes the National Statement on Ethical Conduct in Human Research and the National Health and Medical Research Council's *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders*. It also includes the *Guidelines for Ethical Research in Australian Indigenous Studies*.

Chapter 8 discusses several genomics projects that exemplify culturally appropriate and respectful approaches to working with Aboriginal and Torres Strait Islander peoples and their data.

Chapter 9 focuses specifically on Aboriginal and Torres Strait Islander human rights in the context of their own genomic material and kinship ties. Here we consider the United Nations

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Declaration on the Rights of Indigenous Peoples, particularly article 31 and the rights of Aboriginal and Torres Strait Islander peoples to own, maintain and control their cultural heritage, traditional knowledge and traditional cultural expression. Other international documents such as the International Declaration on Human Genetic Data (UNESCO) are outlined. There is also a review of international legal cases involving human genes. This includes gene patent cases but also the Havasupai People's case against Arizona Board of Regents. There are also a number of best practice international research methodologies noted where the gene research has aimed at providing an ethical framework or encourages inclusion in research of marginalised peoples.

Finally, Chapter 10 concludes with a consolidation of the key issues around ownership, consent provisions, governance, data sovereignty, privacy, return of benefits, disclosure, discrimination, capacity building in the workforce, patents, and secondary uses. The critical assessment of these issues will highlight opportunities for improvement and which in turn, will assist policy and law makers when working towards better health outcomes for Aboriginal and Torres Strait Islander peoples.



3 Context

Indigenous health genomics has a contentious history throughout the world. For Aboriginal and Torres Strait Islander peoples, scientific research and analysis raises ethical, social and cultural issues. Mismanagement has been culturally damaging, damaging to the dignity of Aboriginal and Torres Strait Islander peoples, and dangerous to their physical and mental health.

Genomics research adds an additional layer of complexity – and risk – to this already difficult situation. Genomic data is physically and culturally intimate knowledge. It is personal and sensitive information that has repercussions not only for an individual, but also their family, clan and community. The mistreatment of Aboriginal and Torres Strait Islander genomic information is enormously physically and culturally damaging. That damage can continue for generations and engender mistrust in genomics research and medicine.

All Indigenous genomic research and medicine must be guided by the principle of self-determination. Article 31 of the United Nations Declaration on the Rights of Indigenous Peoples states:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as their sciences, technologies and cultures, including human and genetic resources...³

The inherent justice of this statement is self-evident – if Aboriginal and Torres Strait Islander peoples are unable to have a controlling say in how their own genes are handled and used, how can there ever be any equity? Without self-determination, the study of Aboriginal and Torres Strait Islander genomics runs the risk of becoming a new wave of colonisation.

Several recent genomic studies exemplify that lack of strong guidance from Aboriginal and Torres Strait Islander peoples will only result in mistrust, and in extreme cases, exploitation. Genomics research must recognise from the outset, Aboriginal and Torres Strait Islander peoples' right to own, control, and benefit from their own genetic data.

3.1 Past projects

3.1.1 The Human Genome Diversity Project (HGDP) (the “Vampire Project”)

In 1984 researchers at Yale University Genetics Department began a program to produce cell lines from a number of Indigenous populations throughout the world. The project was problematic from its establishment. In the first instance, it took a view of Indigenous peoples as scientific curiosities. There was an undercurrent of false urgency in the language used by the researchers – Indigenous peoples were evidence of the past and their unique genetic profiles should be documented before the information is lost forever to history.

³ Declaration on the Rights of Indigenous Peoples, GA Res 61/295, UN GAOR, 61st sess, 107th plen mtg, UN Doc A/RES/61/295 (13 September 2007) art 31.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

There were also well-founded concerns about economic exploitation, concerning the patenting of genes and the development of prohibitively expensive medications. The project proponents stressed that the HGDP was not a commercial enterprise, and that any profits would be returned to communities. For many, this reassurance was insufficient or unconvincing, not least because there remained concerns over their patenting policies.⁴

While discussion of “prior informed consent” at the individual and community level was present in the project, the extent to which the consents were freely given based on well informed judgements, was debatable.⁵

The Central Australian Aboriginal Congress re-named the HGDP ‘the Vampire Project’.⁶

Professor Mathew Rimmer, Professor of Intellectual Property and Innovation at the Queensland University of Technology’s Law School summarised the core issue as one of fundamental lack of community participation (a failure to follow the principle of self-determination).

The HGDP was designed without proper community-based research participation. As a result, the protocols first developed in respect of informed consent and benefit-sharing were inadequate⁷

In this summation, Professor Rimmer evinces the central necessity of any successful project involving Indigenous health genomics – the requirement of Indigenous co-design. There is no remedy to a lack of Aboriginal and Torres Strait Islander involvement at the earliest stages of project planning. Without Aboriginal and Torres Strait Islander involvement there is likely to be significant mistrust of any project, which will in turn compromise consultation and consent processes. It will also lead to significant concern over ownership and control of the samples, and the data derived therefrom – as it did in the HGDP project when Aboriginal and Torres Strait Islander stakeholder groups raised well-founded concerns about ownership of any patent rights.

This same pattern was again played out in the Genographic Project.

3.1.2 The Genographic Project

In 2005 the Genographic Project was launched through the National Geographic. The project proposed to collect over 100,000 samples from across five continents with the aim of mapping historical human migration patterns.⁸ Again, a lack of diverse stakeholder involvement at the earliest stages, meant that inherent flaws and risks were embedded in the project plans.

The project’s advisory board was chaired by Dr Luigi Luca Cavalli-Sforza – the same geneticist who led the HGDP, and it appeared to repeat many of the mistakes of the HGDP

⁴ Mathew Rimmer ‘The Genographic Project: Traditional Knowledge and Population Genetics’ (2007) 11(2) *Australian Indigenous Law Reporter* 36-38.

⁵ Ibid 37.

⁶ Ibid 37.

⁷ Ibid 38.

⁸ Ibid 43.

project. The Indigenous Peoples Council on Biocolonialism and its Executive Director Debra Harry, expressed several concerns about the project including concerns over the quality of the consents (and whether they amounted to being free, prior and informed), the potential commercialisation of genes (while the project proponents claimed that this was not a commercial venture there remained the concern that the database created by the project could be commercially exploited by third parties) and the use of ancient remains of Indigenous peoples to extract DNA samples.⁹

A January 2020 Update on the National Geographic's website writes that nearly 1 million people have participated in The Genographic Project through the "Geno" DNA Ancestry kits, although the public participation phase of the research project has now ended. Past participants are able to check the website for graphics, interactive features, video, stories and learn about the broader historical context of their results.¹⁰

3.2 The Co-design principle

Research on humans raises many ethical complexities. Add to these complexities, the specific concerns that make Indigenous genomics research distinct from broader genomic studies and it becomes obvious that there is likely to be great diversity of opinions among Aboriginal and Torres Strait Islander peoples and communities. All this is to say that there is no unified Aboriginal and Torres Strait Islander opinion to genomics. And of course, much depends on the conditions and parameters of any research project. As a result, project approvals must be on a case by case basis. For instance, the Goldfield Land and Sea Council approved research of an Aboriginal hair sample collected by Alfred Haddon in the 1920s.¹¹

Increasingly, Aboriginal and Torres Strait Islander stakeholder groups are designing best practice approaches to the collection and use of Aboriginal and Torres Strait Islander genomic data. A common through line in these guides and procedures, is their development in consultation with communities as well as their emphasis on Aboriginal and Torres Strait Islander co-design of research projects and continuing Aboriginal and Torres Strait Islander control over how their samples are collected and used in clinical and research settings. What issues arise ethically, socially and culturally for Indigenous Genomics?

4 What issues arise ethically, socially and culturally for Indigenous Genomics?

The introduction to this issues paper emphasised the importance of the principle of self-determination and the rights of Aboriginal and Torres Strait Islander peoples to co-design genomics research projects, and have a determinative role in the collection, management and use of genomic data in both the research and clinical settings. This gives rise to a

⁹ Ibid 46.

¹⁰ National Geographic *Genographic Project – January 2020 Update* (2020) <<https://genographic.nationalgeographic.com/>> viewed 9 April 2020.

¹¹ Emma E Kowal 'Genetic research in Indigenous health: significant progress, substantial challenges' (2012) 197(1) *The Medical Journal of Australia*, 19. <https://www.mja.com.au/system/files/issues/197_01_020712/kow10531_fm.pdf>.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

foundational question: **If an Aboriginal or Torres Strait Islander person, or their community, provides genomics samples for clinical or research purposes, what legal rights do they have?**

Many of the ethical, social, cultural and legal questions that arose during the consultations bore a relationship to this foundational question. To illustrate the inter-relatedness of these issues, we have summarised some of the key questions in the table below. The questions were framed as questions of law, but grouped according to ethical, social and cultural concerns.

See Table 4 below, for a summary of the Issues of Concern and Key Legal Questions. Note, many of the Issues of Concern stem from the foundational uncertainty about what control individuals and communities have over their samples and Genomic data.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Table 4: Issues of Concern and Key Legal Questions

Issues of Concern	Key Legal Questions
<i>Ownership and control</i>	<ul style="list-style-type: none"> • Does the patient own their genes? • Does the patient control their gene samples? • Does the community or individual own their genes? • What are the legal rights of Aboriginal and Torres Strait Islander peoples to control the samples? • Can the community require the results of the research to come back the community?
<i>Consent</i>	<ul style="list-style-type: none"> • Is the patient informed about their genes being researched? What is the necessary standard of prior informed consent? • Are consent forms legally binding? • Can patients stop use for other purposes and future research? • Do descendants have the right to stop research on their ancestors' genes?
<i>Access and equity</i>	<ul style="list-style-type: none"> • Will the individual be re-consented for secondary uses of samples? • How will the consent of the community be obtained for secondary uses? • Can the individual/community withdraw consent? • How will the individual/community be kept informed of the management and use of their samples so that can know if they want to withdraw consent? • What rights does the individual/community have to return of benefit? • Can third parties access samples without consent?
<i>Discrimination issues</i>	<ul style="list-style-type: none"> • How does the patient control against discriminatory or offensive use of their genes? • Are there any remedies for the cultural and commercial harm caused from error or misuse?
<i>What actions for misuse of gene research?</i>	<ul style="list-style-type: none"> • Can the Aboriginal or Torres Strait Islander donor or community sue the researcher? • Can the Aboriginal or Torres Strait Islander donor or community sue the university or research entity?
<i>Aboriginal and Torres Strait Islander cultural integrity and safety issues</i>	<ul style="list-style-type: none"> • How will the individual, family, clan and community be consulted? • How will the individual and community be attributed? • Can researchers access old samples held in historic collections, for example in universities or museums? If so, how will descendants be consulted?

Issues of Concern

Key Legal Questions

- Where the notes are incomplete, and don't identify the individual, how will the appropriate consent authority be identified?
- What happens if data is contrary to cultural understandings of kinship and family?
 - For example, traditional adoption in Torres Strait Islander Cultures or genetic inheritance from fathers' side in Yolngu understandings
- What are the risks of that a register of Aboriginal and Torres Strait Islander peoples might be created?¹²
- Could genetic reference genomes be used in Native Title claims?
- When can law enforcement use genetic material outside of consent guidelines without breaching contract and privacy?
- How can we ensure data will be interpreted by Aboriginal and Torres Strait Islander academics, following the principle of self-determination and guarding against dignitary harms?¹³
- What if data and samples are held off-Country? What then for ownership and control?
- How can cultural safety be ensured when these issues are discussed with community? Cultural safety in these discussions is essential for community to understand what is being discussed and therefore provide free, prior, informed consent.

Given that Aboriginal and Torres Strait Islander genomics research amasses large amounts of Aboriginal and Torres Strait Islander data, IP is often looked to for answers to questions about the management of this data. Unfortunately, in many respects IP law provides few answers. This is because IP law is ideologically positioned to incentivise innovation by granting economic rights to researchers either by way of copyright or patents. IP law is focused on the commercialisation of an end product. However, it is far more likely that Aboriginal and Torres Strait Islander peoples' concerns will be engaged at a much earlier stage. In fact, issues of ownership and control are engaged even at the conceptual stages of research when the genes are sampled, or where they are accessed for use.

¹² Several Advisory Group members raised this concern and cited conservative commentators such as Mark Latham, Pauline Hansen and Josephine Cashman whom they considered might support such a register. For example, in 2019, One Nation released a policy proposing to have DNA tests for people identifying as Indigenous: Fryer, 'Brooke No DNA test exists for Aboriginality: Scientists' on *NITV* (16 March 2019) <<https://www.sbs.com.au/nitv/article/2019/03/16/no-dna-test-exists-aboriginality-scientists1>>.

¹³ Dignitary harms are defined and discussed in greater detail in section 5.3 The Rights of Patients in a Clinical Setting.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

This section will identify the ethical, social and cultural factors that make Aboriginal and Torres Strait Islander genomics unique from broader genomic study. As a result, there are key requirements for any genomics project intending to work with data belonging to Aboriginal and Torres Strait Islander peoples, which raises the question: *What rights do Aboriginal and Torres Strait Islander peoples want over their genomic data?*

4.1 What makes Aboriginal and Torres Strait Islander genomics unique?

Aboriginal and Torres Strait Islander genomics study is distinct from genomic study more broadly. In fact, an Advisory Group member actually identified a lack of this understanding as a particular issue: the assumption that the taking of a sample from an Aboriginal and Torres Strait Islander person is the same as taking a sample from a non-Indigenous person, reflects a lack of understanding of the connections between person, culture and place. Dislocation of person (including samples) from place can produce cultural harm that will in turn translate into harm to the person's (and their community's) physical, mental and spiritual health.

A lack of understanding of the social, ethical and cultural issues can also cause a delay in ethics implementation.

Institutional racism and unconscious bias also plays a role in the delivery of health services to Aboriginal and Torres Strait Islander people generally, and in genomic study in particular. One Advisory Group member reported that racism and unconscious bias in delivery of health services has sometimes led to misdiagnosis. For example, when kids present to the medical services with a condition that causes them to have brittle bones, they may be referred to Family & Community Services on the assumption that their injuries are related to their care rather than an underlying medical condition. It was reported that Aboriginal and Torres Strait Islander peoples were underrepresented in all areas of genomics, except in undiagnosed categories – largely due to lack of diversity in data sets (most references have a European bias).

The point was also made that equitable treatment (treating everyone the same regardless of their cultural identity) does not equate to equitable access to medical services. Genomic study means different things to Aboriginal and Torres Strait Islander peoples, and those cultural differences must be respected in order to ensure that Aboriginal and Torres Strait Islander peoples share in health outcomes.

Another interesting comment was that this area of research must come to terms with acknowledging genetic differences between peoples, without playing into racist stereotypes. So as research into people's genetic diversity continues, the interpretation of those results must be balanced and respectful. Both outright racism, and unconscious bias, must be guarded against. This presents yet another argument for the necessity of Aboriginal and Torres Strait Islander co-design of research projects; Aboriginal and Torres Strait Islander peoples must play a role in the interpretation of their results.

The potential link between genetics and intergenerational trauma was discussed. This is a potential area of epigenetic research in the context of atrocities perpetrated against



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Aboriginal and Torres Strait Islander peoples. Considered in the context of other comments about acknowledging genetic difference and ethical interpretation of results, this kind of research is a good example of acknowledging that genetic difference in a constructive way that could deliver better diagnostic outcomes for patients. It is also a good example of how vital it is that Aboriginal and Torres Strait Islander people play a direct and active role in interpretation of results to avoid compounding trauma or interpreting trauma through a Eurocentric lens.

Several Advisory Group members identified the issue of having to grapple with the overriding narrative of urgently needing to 'unlock' Indigenous genomics. These Advisory Group members acknowledged the beneficial outcomes that could potentially be derived from Indigenous genomics studies. However, simultaneously there is a 'hard sell' that often has to be managed. The 'hard sell' emphasises the revolutionisation of healthcare through genomic studies. It implies that if Aboriginal and Torres Strait Islander peoples do not join in the revolution, they will lag behind and that this will be their own fault. This leaves Aboriginal and Torres Strait Islander researchers in a difficult position, where their aim is to protect Aboriginal and Torres Strait Islander interests and participate in genomic study, but also keep at bay the voracious appetite for more and more data.

A similar concern was raised when another Advisory Group member expressed concern that the enthusiasm for biomedical applications of genomic information is causing people to overlook (or not consider at all) other ethical, cultural and legal implications of the science.

Another Advisory Group member echoed this concern when they noted that Aboriginal and Torres Strait Islander research students are often at risk of burn out before even qualifying; the students are being asked to contribute to so many projects. Yet another person alluded to this issue when they underlined that Aboriginal and Torres Strait Islander peoples should be involved at various levels of governance and leadership in the project. Although this point was also made to emphasise that over reliance on a single (or just a few) Aboriginal and Torres Strait Islander voices on a steering committee is really insufficient collaboration.

Discussions with the Advisory Group made clear that there are two essential features of a good research project:

- (1) a good research plan, and
- (2) a good data management plan.

These combined, set the scene for the next project.

4.2 What rights do Aboriginal and Torres Strait Islander peoples want over their genomic samples and data?

Genomic research in the broader community context focuses almost exclusively on data. The samples themselves – blood, saliva etc – are given very little consideration. In fact, in most cases the original samples may be destroyed. In contrast, everyone we spoke to acknowledged on-going concerns for both the samples and data of Aboriginal and Torres Strait Islander genomics.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

So whether a sample is collected in a clinical context (with the option of research at a later date) or collected for a specific research project, Aboriginal and Torres Strait Islander peoples have continuing connections to their samples as well as the data. The following graphic illustrates this continuing connection, right from the point of collection, and how maintenance of this connection is necessary for self-determination.

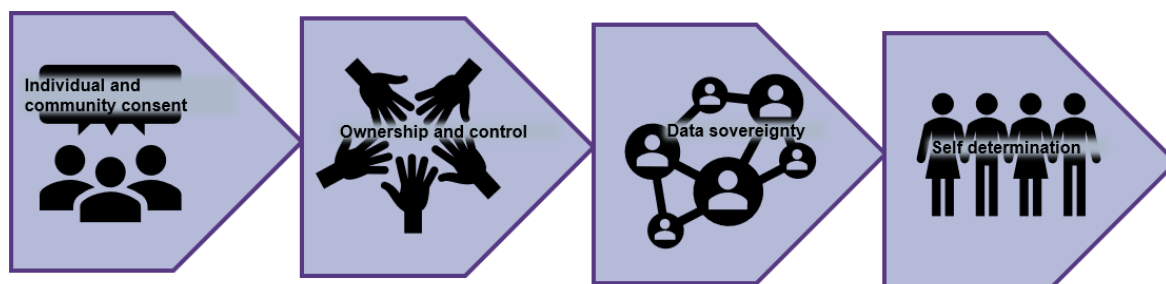


Figure 1: Continuing connections and self determination

In our discussions with the Advisory Group, several requirements of culturally appropriate management and use Aboriginal and Torres Strait Islander samples and data were discussed, including:

- the need for transparency in the storage and management of their samples and data;
- ongoing ownership and control over how samples are used including what research projects they are used in;
- necessary protections against the use of samples or research to disadvantage Aboriginal and Torres Strait Islander peoples;
- necessary measures to ensure that Aboriginal and Torres Strait Islander peoples receive equitable access to health outcomes; and
- planning for who will have responsibility for their samples when the donor passes away.

This list covers just a few of the on-going concerns of Aboriginal and Torres Strait Islander peoples over their genomic materials. No list can be exhaustive as every Aboriginal and Torres Strait Islander community will have different needs and requirements. And as one Advisory Group member underlined, communities are best placed to know what they need. They may already have policies and procedures in place guiding how consultations should be conducted, and how permission to research should be sought. In which case, of course, these procedures should be followed.

Research must include Aboriginal and Torres Strait Islander peoples right from the start and discussion of potential risks and benefits must begin very early in the conversation. Discussion should also make clear that benefits could be immediate, or long term. Alternatively, if there is a risk that no benefits will come from the research at all this must also be stated clearly. Aboriginal and Torres Strait Islander peoples must retain access to and control over the samples and data. This includes return, or destruction of samples when requested.

4.3 Access to health outcomes

Genomic studies rely on reference genes. An individual's genes may be compared to the reference genetic profile, and any genetic variation could suggest a genetic cause for a medical condition, or predisposition to a medical condition. However, genomic studies have largely focused on donors of European descent. This means that the majority of reference genes may be accurate to people of mostly European descent only. To compare the genetic profile of, for example, a Wiradjuri woman to a European genetic reference is going to be of limited utility – the researcher may not be able to say whether the woman's genetic variation is indicative of a medical condition, or just a common genetic variation among Wiradjuri people. In addition, there can be no such thing as an "Aboriginal and Torres Strait Islander reference profile" as Aboriginal and Torres Strait Islander peoples are enormously genetically diverse. The genetic profile of a Noongar man, is going to be vastly different from the genetic profile of an Anmatyerre woman and both are different again from a Meriam man. This was noted by a number of advisors.

The lack of appropriately diverse reference genomes contributes to inequitable access to health outcomes.

To illustrate, we will paraphrase a hypothetical situation suggested by one of the Advisory Group members:

A doctor gets consent from a patient to run a blood test to diagnose condition A. However, when the results come back, they reveal a genetic variation that could suggest a predisposition to condition B. The doctor informs the patient of this potential condition B and together they decide to run further diagnostic tests. Given the genetic condition (if it exists) is likely to be hereditary, the doctor and the patient decide to bring the patient's immediate family into the conversation. The patient's family are concerned, and the decision is made to do further testing. Bearing in mind that there is an element of risk with all medical procedures, what if the patient's grandmother suffers a complication? And what if, once further data is collected, it is found that the genetic variation is a common variant among Aboriginal people from that area, and did not signify any medical issues?

In short, lack of diverse data has meant that there are variants of unknown significance, which could lead to either (a) medically significant variants being overlooked, or (b) patients going through unnecessary procedures based on non-medically significant variations.

Another Advisory Group member, speaking to the same issue, referred to a US case study in which a study involving African Americans showed that African American reference data varied in a statistically significant way from the existing reference data (the reference data being drawn from the broader US population). This led to false positives and false negatives, meaning African American patients were given inappropriate medical care.

Another potential (and timely) example was also given: there are genomic differences in some Aboriginal and Torres Strait Islander people, in the ACE2 receptor site (where COVID 19 enters the cell) and its currently unknown how much these insertion/deletions affect infectivity in Aboriginal and Torres Strait Islander peoples or the course of the disease.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

In another example, in 2014 a study of Inuit people in Greenland found that 23% of Inuit people had an unusual gene variation which meant that they were 10 times more likely to get diabetes than other people. However, this unusual variation is not found anywhere else in the world.¹⁴ This suggests the possibility that the diabetes of Inuit people may be slightly different from diabetes of other people, which in turn means that diabetes medication that is suitable for the general population may not give the same benefits to Inuit people with diabetes.¹⁵

4.4 Collection and use of information

In fact, collection and use of information is a broad term that covers a range of activities, all of which are of significant concern to Aboriginal and Torres Strait Islander peoples. These activities include:

- collection of samples from the individual;
- storage of the samples;
- extraction of data from samples, and storage of that data;
- use of that data in research and clinical applications; and
- disclosures about the individual and their family and clan.

Concerns include:

- misuse of samples in culturally unsafe or disrespectful ways;
- misuse of data in culturally unsafe or disrespectful ways;
- use of data to disadvantage Aboriginal and Torres Strait Islander peoples, at law or in the health care system; and
- misuses of data or samples that compromises the individual's standing in their family or clan.

Concerns over misuse, positions consent (and in particular the circumstances under which consent is sought and given) as a central issue when it comes to collection and use of information. This section looks at several key consent questions that arise when discussing the collection and use of information.

As we look at these key questions, it is important to remember that consent is an on-going issue rather than a threshold requirement. The following graphic illustrates the on-going consent cycle necessary for on-going ownership and control.

¹⁴ National Centre for Indigenous Genomics, *Public Lecture by Prof Simon Easteal* (YouTube, 16 June 2015) <<https://www.youtube.com/watch?v=UieBgf9AuPw>> viewed 15 April 2020.

¹⁵ *Ibid.*



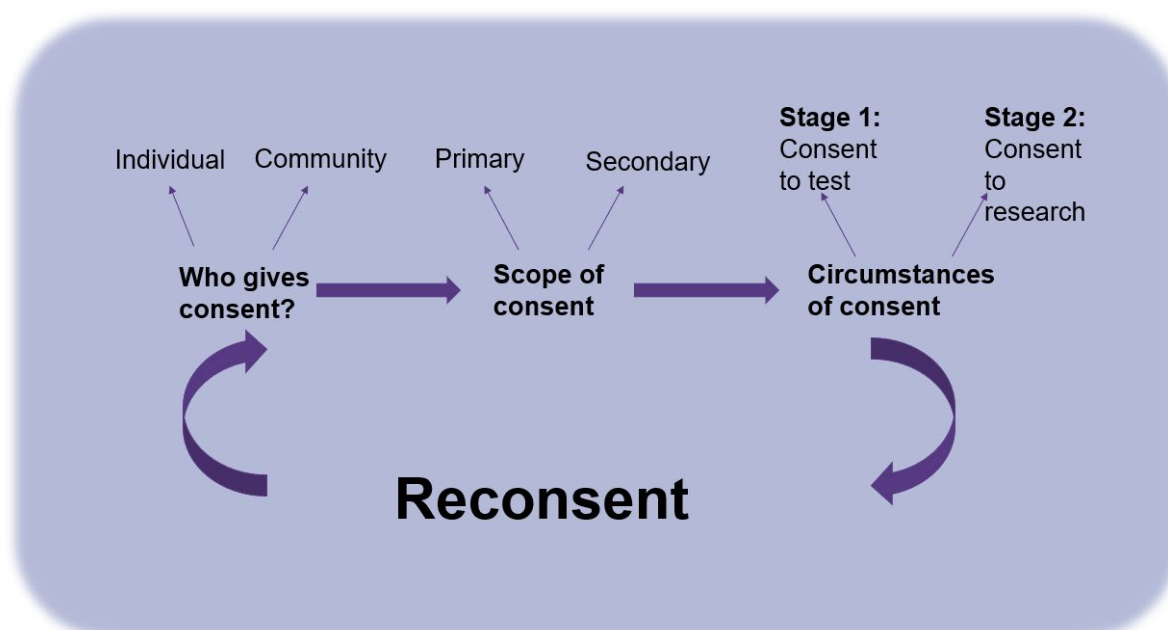


Figure 2: The on-going consent cycle

4.4.1 Who needs to give consent?

Western medicine has prioritised individual consent in medical care. However, in the context of Aboriginal and Torres Strait Islander genomic research, consent of the individual only is unlikely to be sufficient. Instead, consultation with and consent from the individual's family or clan may be necessary.

One Advisory Group member expressed concerns for consenting on behalf of family, and future family. How can an individual consent behalf of their family? And when it comes to obtaining community consent, what is the process for identifying who has authority to consent on behalf of the community? In this advisor's own consultations on this topic, there was a great variety of opinion.

This question of who has capacity to consent continues well beyond the initial consent to take the sample and includes who has on-going authority to re-consent. What if the donor passes away or loses capacity? Do the consent responsibilities fall to their family? What if that person has no family?

4.4.2 What does the consent cover?

The scope of the consent is also of concern.

Discussions of the scope of consent raised the question of trust. There could easily be uncertainty about how broad the scope of the consent is – *what if my consent covers a use that is not immediately obvious to me from what has been described?*

There is also a concern over secondary uses, and whether and how researchers will seek further permission for secondary uses.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

In addition, there is concern that a researcher will act outside the scope of consent. The Havasupai case study, discussed in more detail in 9.2.5 is a good example of this.

A couple of advisors expressed concern about private commercial enterprises such as Ancestry.com. It is common for the fine print of these businesses to require participants to authorise broad use and sale of their DNA to third parties. For example, in 2018 a genealogy website led to the arrest of the alleged Golden State Killer, a serial killer operating in the 1970s, well before DNA was sequenced. A distant relative of the alleged killer uploaded their DNA to the open source genealogy website GEDmatch. US law enforcement accessed this online platform, and this led to the identification of the alleged killer¹⁶ In fact, GEDmatch is an open source website, unlike companies like Ancestry.com, but the example still asks the question, *under what circumstances could private companies sell, or make available, the DNA sequences within their control?*

4.4.3 How was the consent obtained and when?

The circumstances under which consent was obtained is also important. In the clinical context, it is common practice for there to be 2 stages of consent: The first, is consent from a patient to take a sample in order to do a diagnostic test. The second is consent to retain the sample, and possibly use it for research purposes. Several of the Advisory group members we spoke to noted that in the move towards precision medicine, the separation between clinical and research is blurring, and so too are these consent stages. It has become more common for both stages of consent to be discussed and asked for in the same meeting. This was raised as a concern.

One of the Advisory Group members raised a hypothetical situation. When a clinician is requesting permission to take a diagnostic sample, the patient is in an environment of heightened anxiety, and in all likelihood is not very well. In most cases, they will not be in an appropriate frame of mind to be able to consider whether or not they want to consent for any further uses of their genomic information.

In fact, the validity of asking to use a sample for a secondary purpose at all was questioned.

One Advisory Group member said that in their own research, they have found that many Aboriginal and Torres Strait Islander patients frequently did not completely understand what they were consenting to. In some instances, mental health may have been a factor, and in many cases methods of consultation and communication could have been improved. There were also reports that there was room for improvement in a lot of the follow up support services.

In the consultation and consent process people and communities must be given as much time as necessary to make decisions. The dual elements of consultation and consent are not something that should be rushed or run together. The conversations that need to be had can be difficult. In addition, there are often language barriers, both literal language barriers and

¹⁶ Sarah Zhang *How a Genealogy Website Led to the Alleged Golden State Killer* (27 April 2018) <<https://www.theatlantic.com/science/archive/2018/04/golden-state-killer-east-area-rapist-dna-genealogy/559070/>>.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

barriers created by the use of scientific language. All this is to say that consultation is never a single conversation. People need time to consider, to speak to family and to ask further questions. The initial consultation process necessarily takes a number of meetings.

Consultations must be clear about both the benefits and risks of genomics study. This includes being clear that the results or benefits of the study may be very long term or may never vest at all. There is also a risk that the research may produce unwelcome or unexpected information. For example, genetic testing may reveal that your father may not actually be your genetic father. One Advisory group member described genomics as a Pandora's box of sorts.

4.5 Management of personal genomic information

Sections 5.2 and 4.4 focus on the role of consent as it relates to misuse of samples and data – consent being a control against misuse. In addition, several Advisory Group members raised concerns about misuse of data, or legally permitted uses of data without consent. For example, when can the police compel researchers to release data so that it can be used in a criminal investigation? Another frequently raised concern is around the potential for geneticists to be called as witnesses in Native Title claims.

Several Advisory Group members pointed out that there needs to be a way of keeping biological samples close to country. Isolation of samples from country risks disconnection of the samples from cultural values. Also, centralising samples in one place, is inherently problematic; centralising them away from country is completely at odds from the cultural needs of Aboriginal and Torres Strait Islander peoples. This was raised by several Advisory Group members who had expressed a desire to keep all data on-country.

4.6 Secondary uses & incidental findings

The issue of secondary uses and incidental findings also reoccurred through a number of consultations.

Secondary uses occur when samples or data derived therefrom, are used for purposes beyond the scope of the original consent. For example, an Aboriginal person may consent to have their blood withdrawn and used to contribute to a reference genome that will help diagnosis of, for example, diabetes. However, to use that data to research an entirely different disease would be a secondary purpose. On-selling the data to a third party could also be a use beyond the scope of the original consent (depending on the scope of the original consent).

Incidental findings occur where a doctor may be taking a sample for a patient in order to test for a suspected illness, but, when the test results return they reveal information unrelated to the original purpose of the test, but nevertheless relevant to the patient's health. For example, a blood test to diagnose one disease, might reveal that the patient carries a gene that pre-disposes them to a particular form of cancer. What is the doctor's duty to notify the patient of these findings? And, given that the gene is inherited, what is the doctor's duty to that person's family?

The current precedents on how to manage incidental findings are of limited assistance because with genomics the order of magnitude is so much greater – further testing has



implications far beyond the individual, and concerns their family and clan. It was noted by one of the Advisory Group members that in the past, the approach to managing incidental findings was to externalise risk. That is, the clinician was encouraged to declare all findings to the patient, and leave the decision to them. The advisor was mindful of the distinction between full disclosure so that the patient could make a fully informed decision, and an information dump (whether the patient fully understood the situation or not) in order to push responsibility onto the patient and avoid risk to the research institution.

4.7 Distinction between health-based research and population research

Several of the Advisory Group members drew a clear distinction between health-based research and population research. Health based research directly and quickly influences provision of clinical care. While population research is more concerned with sequencing a wide variety of people and then studying the data for a range of purposes that have no clinical or health use (e.g. using the data to make inferences about migration patterns over time). This is a relevant distinction to bear in mind.

Several Advisory Group members noted that Aboriginal and Torres Strait Islander peoples tend to be more supportive of genetic studies in the context of delivery of health services (mainly for diagnostic purposes), and more wary of genomic research (where samples are retained and used in larger studies). However, as genomic study is driving precision medicine, the line between these two areas are becoming increasingly blurred. This blurring of the line was noted by many of the people we spoke to.

A related issue that was raised many times, is the concern that genomic data could be used as a way to test Aboriginality. This kind of use must be guarded against.

4.8 Cultural security for Aboriginal and Torres Strait Islander Researchers

Several Advisory Group members expressed concern for the cultural security of Aboriginal and Torres Strait Islander researchers. Involvement of Aboriginal and Torres Strait Islander researchers in projects is an important element to Aboriginal and Torres Strait Islander co-design and ensuring that Aboriginal and Torres Strait Islander concerns are represented throughout the project. However, to involve just a few Aboriginal or Torres Strait Islander people in a project, and expect them to carry the burden of *all* Aboriginal and Torres Strait Islander concerns is an unfair and impossible burden. And if a project goes wrong, it will be those Aboriginal and Torres Strait Islander researchers that live with the cultural harm brought to their community and the damage to personal relationships. Several Advisory Group members warned against having only 1 (or just a few) Aboriginal or Torres Strait Islander people on a project's steering committee.

4.9 University research integrity and ethics protocols & funding bodies expectations

One Advisory Group member identified research funding (particularly the manner of funding approaches) as a significant hurdle to Aboriginal and Torres Strait Islander peoples participating, on their own terms, in genetic research, and sharing in the benefits. The

Indigenous Health Genomics: The Legal, Ethical and Social Issues

advisor was disappointed by under resourcing, and the fact that there was not yet any nationally led approach. The advisor identified three tensions that commonly exist in the way projects are planned (funding arrangements frequently being a guiding factor in the way projects are structured). The three tensions are:

1. **Trust** – much needs to be done to build a relationship of trust between a community and a research organisation;
2. **Co-design** – Aboriginal and Torres Strait Islander peoples must be co-designers of any research project where their genes are the subject of the research; and
3. **Timeframes** – again, funding agreements tend to set the pace for timeframes. However, it is difficult to collaboratively co-design a research project, when one project partner comes to the negotiating table with pre-set timelines based on an already anticipated methodology.

The same advisor identified another risk in this sector: duplication. Communities can get burnt out when research projects are not appropriately co-ordinated or duplicate work already done. A community might rightly wonder why they are participating in yet another study, remarkably similar to the last, when they are yet to see any return of benefit from the first research project. Another advisor also recognised that confusion or duplication can occur through competing state and federal policies.

A related concern is that many research projects have a disappointing tendency to tack on Aboriginal and Torres Strait Islander concerns at the end of a project almost as an afterthought. These approaches in turn, undermine trust (identified as the first tension above). One member of the Advisory Group referred to this as a lack of social capital.

Knowledge of precision medicine is relatively low, but the historical atrocities including in relation to scientific research is extremely well known. For the consultation process to appear as little more than a tick-box at the end of a project plan cannot engender trust.

Several Advisory Group members noted with great admiration the work of the NCIG, and commented that this work needs to be empowered and built upon, not duplicated.

Another advisor noted that where researchers don't follow guidelines, they are critiqued when the research is published. This critique could negatively impact their future funding. This may go some way to encouraging best ethical practice, however, there is still potential cultural harm to communities if criticism comes only after the breach of ethics.

An Advisory Group member raised concern that despite a complicated ethics approval landscape there is often insufficient practical guidance for researchers. For example, where the ethics guidelines ask the researcher whether they are satisfied that the community understands their legal rights, the researcher may consider the answer to that question to be 'no'. But what then? There is nothing that empowers researchers to provide better understanding to the community.

4.10 Data Management Infrastructure & Data Sovereignty

A data management infrastructure and a sovereignty framework recognising Aboriginal and Torres Strait Islander peoples' rights over their samples and data must be established at the



Indigenous Health Genomics: The Legal, Ethical and Social Issues

outset. This infrastructure needs to be funded the right way, and with the right conditions. There is a concern that Australia does not have the infrastructure to store genomic data. There is a reliance on cloud servers, many of which are not even based in Australia. It is a concern that the data could be stored so far from country, and also at the potential loss of control that could come with relying on international data servers. Storing data overseas also raises the possibility that the data may be subject to the legal regimes of other countries – regimes that will have no understanding of the needs of Aboriginal and Torres Strait Islander peoples.

Several Advisory Group members raised concerns about the digital platforms they work with in research. For example, there was concern that the digital platforms used to store data may have some ownership rights over the data. There also were concerns that the providers of the digital platforms might be able to access and use the data. They were concerned that the digital platforms they use to store and analyse the data might be able to use a backdoor way of accessing and using the data. This concern held whether this access was permitted (e.g. through fine print on the software licence agreement) or not-permitted (simply taking the information).

Another concern related to on-going data management. It was noted by one of the Advisory Group that funders often expected researchers to make their data open and accessible. This is problematic for a number of reasons. In the first instance, for small communities, even anonymised data is potentially identifiable. Free, open access also sits at odds with on-going ownership and control by the Aboriginal and Torres Strait Islander donor communities.

The process of keeping initial consents within specific parameters (rather than having donors sign away all rights to their samples and data) and returning to the donor to consent for any secondary uses, is a challenge to the orthodoxy in the scientific community that promotes data sharing. This tension between *public/private* and *free access/private commercial* is a recurring theme in genomic research and was commented on in several discussions.

Several Advisory Group members state that data sovereignty should be written into any research project right from the start, although the actual arrangements should be flexible according to the needs of the community. They also noted that it is important to have recourse when data is mishandled.

Block chain was posited as a possible means of maintaining connections between individuals, community, their samples and data. In particular it could be used to assist in the return of benefit to community.

4.11 Legal ambiguity & uncertainty

When asked what role they saw for the law in this space, several advisors commented that having worked with a variety of specialists in the health services, research, ethics and community, the conversation almost always met with difficulty when talking about the law. It was noted that people are particularly concerned about:

- Who can use samples, and for what purposes?
- How does the law protect Aboriginal and Torres Strait Islander genomic data from exploitation by big companies?



Indigenous Health Genomics: The Legal, Ethical and Social Issues

- How does the law protect data sovereignty and Aboriginal and Torres Strait Islander IP?

Several people noted that it seemed that the lack of knowledge about the law, was itself a barrier to informed consent.

In fact, concern over lack of legal knowledge as a problem in itself was raised several times. While the medical sector is generally pretty adept at advertising itself, the legal profession remains opaque: most people would have a basic understanding of what chronic disease was, but few people could provide a legal definition for their personal information.

In a related comment, the need for Aboriginal and Torres Strait Islander genomics counsellors was noted. However, there were anecdotal reports that the degree of support offered by genetic counsellors can vary. So in fact, the mere availability of genetic counsellors would not be sufficient in itself.

4.12 Emerging Issues

When one of the Advisory Group was asked about emerging issues in the field of Aboriginal and Torres Strait Islander genomics, they identified the following:

- ongoing challenges to building relationships of trust;
- continuing development and improvement of the way benefit and risk is discussed with communities; and
- ensuring use of knowledge is fairly compensated.

There is already inequitable delivery of healthcare to Aboriginal and Torres Strait Islander people. Genomics study has the potential to compound that issue in many ways. In particular via financial manipulation. As momentum behind genomics study gathers speed, every research company will be scrambling to be the one to integrate Aboriginal and Torres Strait Islander genomics into the health care system. This presents the risk that unscrupulous companies could act unethically, or use undue financial influence to further their research. This in turn, presents the risk that examples of exploitative research could mean that Aboriginal and Torres Strait Islander peoples become unwilling to participate in any research at all. This will set Aboriginal and Torres Strait Islander genomic research back even further and produce even more inequality in delivery of health services to Aboriginal and Torres Strait Islander peoples.

One of the Advisory Group saw a potential role for community organisations to be custodians of samples and data (acknowledging that this would depend on the circumstances, the wants and needs of particular communities and existing governance bodies). Under this model, the community organisation could be responsible for collection and management of samples and data. Then if a researcher wanted to use the sample, they can request permission from organisation, and the organisation can grant or deny permission, with appropriate conditions. However, there could be funding issues with community owned biobanks.

Many of the Advisory Group saw a need for national policy frameworks. Ideally, a framework in which national policy provided the broad requirements, followed by state and territory



frameworks providing more specific details. This integrated approach could also help to build knowledge of the resources already in place and avoid duplication. A Commonwealth Ombudsman equivalent could then provide national level oversight. However, if this did come into place, the availability and accessibility of this service would need to be communicated to the public and each service should have a complaints mechanism on their website.

5 What are the legal issues?

What do we mean when we talk about ‘ownership’ of data? Privacy rights, for example, are not rights of intellectual property, and yet they have very real impacts on how people’s information is used and accessed by third parties. In other words, privacy laws don’t give people proprietary rights over their data, but they do allow people to defend themselves against invasions of privacy, which in practical terms amounts to much the same thing – a right to protect their personal information.

This section takes an expansive view of the meaning of ‘ownership’ and examines the legal regimes that impact Aboriginal and Torres Strait Islander peoples’ ability to protect their genomic information and control how it is shared and used.

This section begins with an examination of copyright law. If data is thought of through the lens of intellectual property, then copyright law is the first consideration. While copyright law does not generally protect facts (see section 5.1.5), the reality is that many of the projects handling Aboriginal and Torres Strait Islander genomic data will create reams of material that *is* subject to copyright protection. It is also possible that research agreements will contain broad definitions of copyright which will capture many forms of data and content.

Privacy law has both strengths (e.g. its strict adherence to consent for primary purpose only) and its weaknesses (e.g. numerous exceptions in which information can be used without consent of the donor).

Patient rights reflect the duty of care doctors and researchers owe to their patients and donors and commercialisation is a particularly live issue in the genomics field. The *Patents Act* is an area of intellectual property law when people can register proprietary rights, not necessarily over genes, but over treatments and diagnostic techniques. The potential ability of research companies to claim proprietary rights over treatments and techniques that (a) have been contributed to by Aboriginal and Torres Strait Islander genomic information, and (b) could impact on the delivery of health outcomes to Aboriginal and Torres Strait Islander peoples, raises many social, ethical and cultural issues.

Like patient rights, consumer law has the potential to impact how doctors conduct themselves in relation to the health services they provide to Aboriginal and Torres Strait Islander patients.

Health records laws, and in particular, the MyHealth Scheme, are designed to facilitate ease of sharing patient notes amongst the medical sector. In this context ease of data sharing can deliver significant positive health outcomes. However, as precision medicine continues to

Indigenous Health Genomics: The Legal, Ethical and Social Issues

develop, sharing of large amounts of de-identified information will become more common place; the de-identified information can contribute to research studies, that will in turn, help medical services deliver more precisely tailored care to the patient.

While it is more common for genomics research to source its samples from patients and donors, it is also important to consider the possibility that researchers may turn to existing collections of samples. This may include galleries and museums, making it relevant to consider current heritage laws and the controls Aboriginal and Torres Strait Islander peoples have over third party access to collection items originating from their communities.

Contract law regulates the obligations between parties. Written agreements set out parties' rights over their data and provides a mechanism for enforcing those rights. Research agreements impact ownership of data and benefit sharing for research outcomes. Clear and precise consent documentation sets parameters for use of samples and data and future control mechanisms (e.g. who gets to control the samples when the donor passes away?).

The rest of this section will examine these areas of law in greater detail, before moving on in section 6 to a gap analysis in which the impact of these legal issues on the social, and cultural issues raised by the Advisory Group, will be considered.

5.1 Does copyright law protect genomic information?

Copyright is a set of rights granted to the creators of literary, dramatic artistic or musical works and the makers of sound recordings, films, broadcasts and published editions. Copyright rights are granted under Commonwealth legislation in the *Copyright Act 1968* (Cth) (the *Copyright Act*). Copyright protects the expression of how an original idea has been written down, captured in digital form, drawn or recorded. It does not protect ideas or information, nor does it protect styles or techniques. Copyright law is designed to protect the rights of creators giving rise to economic incentives based upon competition policy.

For copyright to subsist in a work, the work must be original and the author must be identifiable. There is no need for rights to be registered, they are automatic. Generally, rights exist in works for 70 years after the death of the author.

Copyright generally belongs to the creators of the copyright works and the makers of copyright subject matter. However, there are rules that can change this. See Figure 3 for a summary of circumstances which displace the presumption of author as owner.



When employees create works	When copyright is assigned	Works created as a result of collaborations	Government works
As a general rule the employer will own the copyright in works and other subject matter created or made by employees in the course of their job, unless otherwise agreed in writing.	Written agreements signed by the copyright owner can be used to assign or give away copyright (including future copyright) in a work to somebody else.	Works produced in collaboration or partnership with another organisation or person, may result in shared copyright or ownership dependent upon the consent or research agreement.	Works and other subject matter created under the direction of the Government will be owned by the Government, unless otherwise agreed in writing. It is important to read government contracts carefully, including any additional terms and conditions referred to.

Figure 3: Who owns copyright?

Copyright issues in Aboriginal and Torres Strait Islander genomics may arise in the following areas:

- Medical records (see section 5.1.1)
- Research and publication of genomic material (see section 5.1.2)
- People being filmed/interviewed and performers rights (see section 5.1.3)
- Copyright in DNA and gene sequencing (see section 5.1.4)
- Databases (see section 5.1.5)

5.1.1 Copyright and ownership of medical records – clinical setting

The Australian courts have found that copyright can exist in patient/medical records however only when all the authors are identified and there has been the application of “independent intellectual effort” in the creation of the copyright works.¹⁷ The application of independent intellectual effort in practice means that “even the barest statement of a medical diagnosis” will have skills and expertise embedded in reaching that diagnosis”, however, it does not give a person “an exclusive right to state or to describe particular facts”, such as writing the name of medication.¹⁸ To determine when health records will be subject to copyright, there is no blanket approach, instead the question of whether copyright subsists in particular medical records “can only be determined after careful examination of the records in question”.¹⁹

¹⁷ *Primary Health Care Ltd v Commissioner of Taxation* [2010] FCA 419, [36].

¹⁸ *Ibid* [38].

¹⁹ *Ibid* [45].

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Regardless of ownership, patients still have rights to access to their medical records, refer to **5.7 Health records laws** where this is discussed further).

5.1.2 Copyright in Research: Genomic Studies and Publications

In the case of genomic research, copyright materials and subject matter are created by researchers including data, written reports, films and sound recordings. Whilst not protecting Aboriginal and Torres Strait Islander Intellectual property holistically, copyright applies to written research and databases, software and content on websites. Ownership over published material will generally belong to either the employer or the author(s). As mentioned above, works created as a result of collaboration can give copyright protections to the donors or communities, depending on the consent agreement. Issues can arise when discussions of ownership are not embedded into the planning stage of project or raised at an appropriate time with Community.

5.1.3 Copyright protection in film and sound recordings

As stated earlier, the owner of the copyright in film and sound recordings, is generally the maker. Of course, this general rule can be altered in a number of ways (e.g. legislative exception, or through agreement).

Separate to that, however, are performers rights. Performers rights under the *Copyright Act* provides three basic areas of protection: the right of consent, co-ownership of copyright in sound recordings, and moral rights.

How does this apply to Indigenous Genomics? Arguably, film and sound recordings of interviews with patients or research subjects are performances. This can give interviewees greater control over the film and sound recordings made of them. For example, the right to consent, or not consent, to the recording in the first place.

Unpaid interviewees may also jointly own the copyright in the sound recording. For example, where an unpaid interviewee provides genomic information to an interviewer by talking about their family or kinship knowledge, it is possible that the interviewee will share copyright in the recording.

See Table 5 for a more detailed summary of performers' rights



Table 5: Summary of performers' rights

Issues of Concern	Key Legal Questions
<i>Right of consent</i>	<p>The right of consent allows the performer to grant or refuse the recording, or grant or refuse communication of it to the public. Performers also have rights relating to unauthorised recordings.</p> <p>In the context of Aboriginal and Torres Strait Islander genomic research, where a doctor or researcher requests permission to record an Aboriginal and Torres Strait Islander patient, the patient has the legal right to:</p> <ul style="list-style-type: none">• refuse consent; and• if consent is granted, place conditions on how the recording will be used.²⁰
<i>Co-ownership of copyright in sound recordings</i>	<p>When a sound recording is made, copyright belongs to the maker of the record e.g. the doctor who presses 'record' or, more likely, the medical practice which owns the recording equipment.²¹</p> <p>When sound recordings of live performances are made, and where the performer was not paid a fee, the performer will share copyright in the recording. This could apply where researchers make a sound recording of an Aboriginal or Torres Strait Islander donor, and the donation was unpaid.</p> <p>Legal issues can therefore arise when information is recorded/collected and used in ways that the performer did not consider, or was not informed of, despite co-owning the copyright in the recording. Where the performer is a donor or patient, this places obligations on the researcher to acknowledge the co-ownership of the patient over the recording, and seek their permission for any use of the recording.</p>
<i>Moral Rights</i>	<p>Moral rights are different to copyright. Moral rights give the performer rights in relation to correct attribution of a performance, not to be falsely attributed, and integrity of performance.²²</p> <p>In the context of genomic research, donors or patients who have agreed to being recorded have the right to:</p>

²⁰ *Copyright Act 1968* (Cth), s 113B.

²¹ *Ibid* s97.

²² *Ibid* Part IX.

Issues of Concern	Key Legal Questions
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- be correctly attributed in the recording;
- not be incorrectly attributed (e.g. have someone else's name listed as the person in the recording); and
- not to have the recording altered in a way that is damaging to the donor/patient's reputation.

5.1.4 Copyright in the Genome Sequencing - is DNA subject to copyright?

Copyright over sequenced DNA is an area subject to continuous debate. In 2004 the Australian Law Reform Commission considered whether the DNA would be subject to copyright. The ALRC considered that “copyright could potentially subsist in the representation of a genetic sequence provided sufficient skill, labour and effort is involved in creating that expression” such as a diagram.²³ However, it considered that a nucleotide or amino acid molecule in and of itself would probably not satisfy the requirements of a ‘literary work’ because it “provides no information, instruction or entertainment to human beings—unlike its written representation.”²⁴

In another light, the High Court in *D'Arcy v Myriad Genetics* ruled unanimously against gene patents – the decision excluded from patent eligibility only isolated naturally-occurring gene sequences and non-naturally occurring gene sequences that encompass naturally-occurring genetic information – including artificially created sequences such as cDNA.²⁵ This suggests that naturally-occurring genetic information or sequences would be considered facts, and therefore out of the scope of copyright protection once identified.

All this is to say, that it currently appears that genes themselves are not considered subject to copyright protections. This means that Aboriginal and Torres Strait Islander individuals will not be able to use copyright law to exert control over their own individual DNA sequence and protect it from misuse. Furthermore, reference genomes that are inherent to particular language groups or identifiable communities will probably not be able to use copyright law as a means of exercising rights as a collective peoples over their reference genome.

5.1.5 Databases and copyright

In Australia, copyright protections can exist in databases that comprise information only. The Court in *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* found that the compilation of numbers in a telephone directory would be considered copyright works as a

²³ Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) 638.

²⁴ *Ibid* 639.

²⁵ *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

whole based on the “sweat of the brow” in obtaining and compiling the information.²⁶ As applied to genomic databases, disregarding whether DNA can be subject to copyright in and of itself, the compilation of a genomic database can be subject to copyright protections. This results in issues around data sovereignty: Who controls access to the data on the database? Who benefits from this access? How does benefit arising from research, return to community?

There is a policy issue associated with recognising intellectual property right in databases: recognition of propriety rights must be balanced against the public’s need for open access to medical data needed to develop vaccines and medicine. Historically, genetic research has gravitated towards open access and objections have been raised when limitations are placed on access to databases or samples that could impact lifesaving research.²⁷

In the context of Aboriginal and Torres Strait Islander genomic research, could open access to existing databases facilitate health outcomes, when restrictive intellectual property rights would slow innovation? Would open access to databases undermine on-going ownership and control over Aboriginal and Torres Strait Islander control over samples and data? The answer is potentially ‘yes’ to both questions.

5.1.6 Exceptions for the use of copyright material

Under the *Copyright Act*, there are exceptions that allow for the use of copyright material which otherwise would constitute copyright infringement, these are for ‘fair dealings’ and the ‘health use exception’.²⁸

The health use exception allows for use of copyright work in healthcare or related purposes, or permitted health or general situations authorised by the *Privacy Act 1988* (see section 5.2 for more on privacy laws).²⁹

Fair dealing exceptions exist for research or study.³⁰ Section 40(2) of the *Copyright Act* provides guidelines for determining whether the reproduction (in whole or part) is considered fair dealing for research or study. Factors considered include:

- the purpose and character of the dealing;
- the nature of the work or adaptation;
- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or value of, the work or adaptation; and

²⁶ *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, see also ALRC, *Genes and Ingenuity*, (n 25) 640.

²⁷ ALRC *Genes and Ingenuity* (n 25) 644.

²⁸ *Copyright Act 1968* (Cth) s44BB, Fair dealing” is the use of a copyright work for the purpose of research or study, criticism or review, reporting news, judicial proceedings, or giving professional advice: *Copyright Act 1968* (Cth) ss 40–43.

²⁹ *Copyright Act 1968* (Cth) s 44BB (1)

³⁰ *Ibid* s 40(1).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

- in a case where part only of the work or adaptation is reproduced—the amount and substantiality of the part copied taken in relation to the whole work or adaptation.³¹

Fair dealing exceptions can therefore raise significant issues in relation to control of Aboriginal and Torres Strait Islander genomic information. Once copyright material (containing genomic information) is published, it becomes subject to the fair dealing exception. This diminishes community and custodian control over that information.³²

5.1.7 Summary

Copyright law gives exclusive rights to the creators of original work and the makers of other subject matter. Databases (including those kept by biobanks etc) may be subject to copyright protection. However, the owners of that copyright will most likely be the research institution who created the database. Genomic study, including the study of Aboriginal and Torres Strait Islander genomics, requires the collation of masses amount of data, and databases are pivotal in the management of that data. It is clear then, that control over access and use of genomics databases engages issues of consent, privacy, consultation, and economic exploitation.

Data sovereignty and questions around copyright ownership and control over databases need to be discussed at the earliest stages of consultation and planning to ensure that donors and community know what they are consenting to and can make informed decisions about whether to participate.

5.2 Privacy and Personal Information

5.2.1 Australian Privacy Law and Aboriginal and Torres Strait Islander Health Related Information

In Australia, the privacy rights of individuals in relation to the use, disclosure and collection of health information is regulated by a mix of state and federal legislation, common law, ethical guidelines and codes of practice. Whilst attempts have been made to come to a nationally consistent system of health privacy principles, there is yet to be a cohesive agreement between states and the Commonwealth on how this looks in practice. At a national level, the *Privacy Act 1988 (Cth)* (*Privacy Act*) and the *Australian Privacy Principles (APP)* sit at the centre and regulate the control of personal information by all private health service providers and the federal public sector. States also have their own legislation that provides another layer of compliance for their own public health systems. See **Figure 4** for a summary of national and state health legislation.

³¹ Ibid s 40(2).

³² ALRC *Genes and Ingenuity* (n 25) 638.



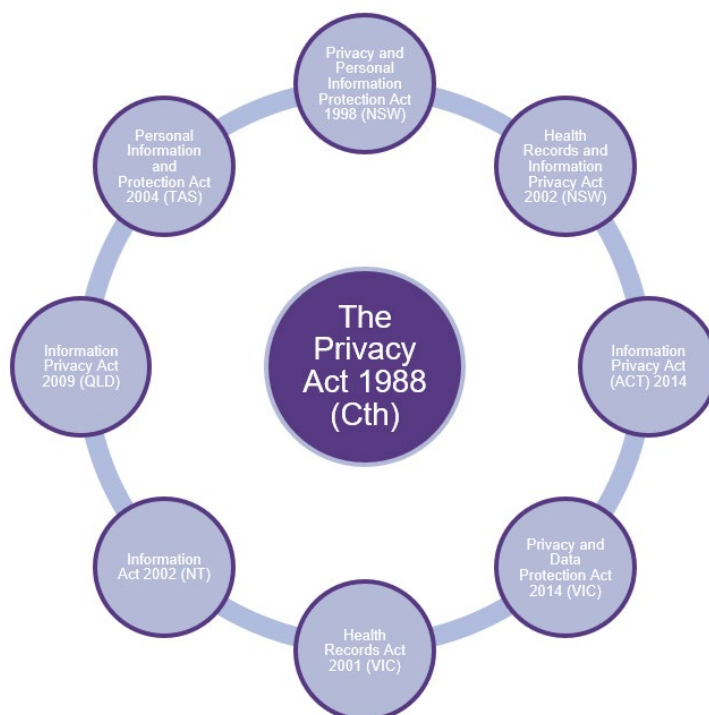


Figure 4: Summary of Australian Privacy laws

The *Privacy Act* empowers the individual to consent to the collection, use or disclosure of their health information. However, there are also situations in which information can be used or disclosed without the individual's consent. These are referred to as 'permitted health situations'.³³

5.2.2 Where does genomic information fit in the Privacy framework?

Genomic information filters into the *Privacy Act* through the broad definition of 'personal information'. Section 6(1) of the *Privacy Act* defines personal information³⁴:

Personal Information means information, or an opinion, about an identified individual, or an individual who is reasonably identifiable.

Information may still be personal information whether the information/opinion is true or not, and whether the information is recorded in material form or not.

³³ Office of the Australian Information Commissioner, *Australia Privacy Principles Guidelines*, (at July 2019) Chpt D, Para 1.

³⁴ *Privacy Act 1988* (Cth) s 6(1); See *Telstra Corporation Limited and Privacy Commissioner* [2015] AATA 991 (18 December 2015) at [112], and *Privacy Commissioner v Telstra Corporation Limited* [2017] FCAFC 4 (19 January 2017), at [43] and [63]- [64] per Kenny and Edelman JJ.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Sensitive information is a sub-category of *Personal Information*. Sensitive information includes:

- **Health information:** information or opinion about:
 - the health of an individual; or
 - genetic information of an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual;
- **Information about a person's racial or ethnic origin;** and
- **Genetic information** (when it does not already fall within the scope of 'health information').³⁵

See **Figure 5** for a summary of this information.

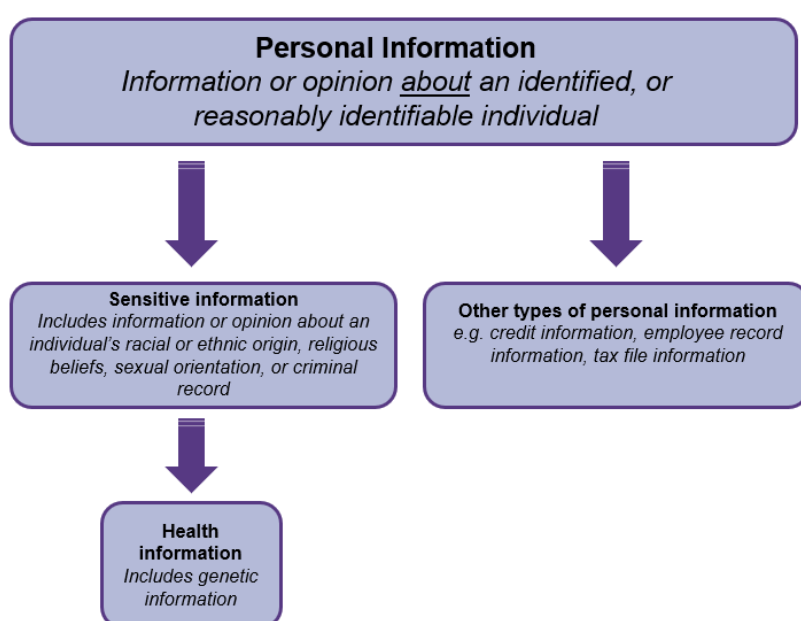


Figure 5: Classification of personal information

When is information about an individual?

Whether information is 'about' a person will depend on the circumstances.³⁶ Particular attention will be paid to whether the person is the subject matter of the information. It is possible for information to have several subject matters and still be the personal information

³⁵ *Privacy Act 1988* (Cth) ss 6(1) & 6FA(d).

³⁶ See *Telstra Corporation Limited and Privacy Commissioner* [2015] AATA 991 (18 December 2015) at [112], and *Privacy Commissioner v Telstra Corporation Limited* [2017] FCAFC 4 (19 January 2017), at [43] and [63]- [64] per Kenny and Edelman JJ.

of an individual. In addition, information may still be deemed personal information if the data is de-identified but is reasonably identifiable when collateral information is considered.³⁷

Genetic information whilst highly personal, may also be considered the personal information of a relative. This cross-over leads to tensions between the individual's right to privacy and shared genomic information. For example, the genomic data of one person, could have implications for a genetic relative.³⁸

5.2.3 When is genomic information not protected by the Privacy Act?

The handling requirements of personal information only applies to individuals the *Privacy Act* defines as natural persons. This excludes deceased individuals.³⁹ Information that is not about an individual, or information that has been stripped of identifying data is not considered personal information.⁴⁰ However, as referred to above, whether information is 'about' someone is determined on a case-by-case basis.

Information that is about an individual who is deceased can still be personal information about a living relative, such as in the case of genetic information.

In addition, there is uncertainty whether whole-genome sequencing is necessarily de-identified. Some individuals have demonstrated that identity can still be identified through cross-referencing seemingly deidentified genomic data with publicly available information.⁴¹

In light of these risks, revisions have been made to *National Statement for Ethical Conduct in Human Research (The National Statement)* in an attempt to minimise the chance of this occurring by imposing an undertaking on researchers that they will not permit or attempt to reidentify genomic material.⁴² Despite this, there are still concerns that information can be reidentified, and whether or not data is ever truly de-identified in today's age of information.

5.2.4 Permitted Health Situations for the non-Consensual use of Health Information

The right to privacy in Australia is not an absolute right and as such the *Privacy Act* and accompanying APP guidelines provide for five 'permitted health situations' for the non-

³⁷ See *Telstra Corporation Limited and Privacy Commissioner* [2015] AATA 991 (18 December 2015) at [112], and *Privacy Commissioner v Telstra Corporation Limited* [2017] FCAFC 4 (19 January 2017), at [43] and [63]- [64] per Kenny and Edelman JJ.

³⁸ Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* ALRC Report 96 (2003), Para 7.15-7.16; Rebekah McWhirter, Carolyn Johnston, and Jo Burke. "Disclosure of Genetic Results to At-risk Relatives without Consent: Issues for Health Care Professionals in Australia." *Journal of Law and Medicine* 27, no. 1 (2019): 108-121, 108.

³⁹ *Privacy Act 1988* (Cth) Pt II, s6.

⁴⁰ *Ibid*, s6.

⁴¹ This issue is raised in Lisa Ekstein et al. 'Australia: regulating genomic data sharing to promote public trust', (2018) 137(8) *Human Genetics* 583, 587.

⁴² *The National Statement* (no 44) para 3.3.22.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

consensual collection, use or disclosure of health information.⁴³ The five permitted health situations listed in s16B are:⁴⁴

- 1) collection of health information to provide a health service;⁴⁵
- 2) collection health information for certain research and other purposes;⁴⁶
- 3) use or disclosure of health information for certain research and other purposes;⁴⁷
- 4) use or disclosure of genetic information;⁴⁸ and
- 5) disclosure of health information for a secondary purpose to a responsible person for an individual.⁴⁹

These permitted health situations are considered in more detail below.

1) COLLECTION: Provision of a health service

The first exception allows for collection of health information about an individual or associated third party, in the provision of a health service to the individual.

The collection of information about an individual is allowed if necessary for the provision of the health service to that individual and the collection is either required by law or collected in accordance with the rules established by a competent health or medical body that deals with obligations of professional confidentiality.⁵⁰

Collection of health information about a person associated with the individual and relevant to their family, social or medical history of the patient is permitted where collection is necessary to provide a health service to the patient.

2) COLLECTION: Research

The collection of health information is permitted if it is related to research arising relevant to public health or safety, including statistics. Collection without consent is only permissible where it is impractical to obtain consent, and de-identified information cannot serve the same purpose.⁵¹ In addition, the collection must be required by Australian law, in accordance with

⁴³ Section 16B, Australia Privacy Principles guidelines Chapter D.

⁴⁴ Australia Privacy Principles guidelines Chapter D, Paragraph D.2.

⁴⁵ *Privacy Act 1988* (Cth) s 16B (1), Note: this includes information about a third party if that information is necessary for the provision of a health services to the patient.

⁴⁶ Australian Privacy Principle Guidelines (n 35) Chpt D, Para 2; *Privacy Act* s16B(2).

⁴⁷ *Privacy Act* s16B(3).

⁴⁸ *Ibid*, s16B(4).

⁴⁹ Australian Privacy Principle Guidelines (n 35) Chpt D, Para 2; *Privacy Act 1988* (Cth) s16B(5).

⁵⁰ *Privacy Act 1988* (Cth) s16B(1).

⁵¹ *Ibid* s16B(2).



Indigenous Health Genomics: The Legal, Ethical and Social Issues

rules established by health or medical bodies, or in accordance with guidelines approved under section 95A.⁵²

3) USE OR DISCLOSURE: Research

Most relevant to the application of Aboriginal and Torres Strait Islander health related genomics is the use or disclosure of health information for research. The legislation and APP guidelines allow for the disclosure of health information about an individual in a research capacity or for the compilation of analysis of statistics, relevant to public health or safety, and:

- it is impracticable for the organisation to obtain the individual's consent to the use or disclosure; and
- the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes of this paragraph (see **Figure 6** for details of the s95A Guidelines prepared by the NHMRC) ; and
- 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.

S95A Guidelines for Australian Privacy Principles about health information

The NHMRC Guidelines, issued under s95A, provide a framework for researchers, human research ethics committees (HRECs), and other parties interested in the non-consensual collection, use or disclosure of personal health information. These guidelines have clarified as:

for the use, or disclosure to be considered 'necessary' for research, an HREC must determine that 'the outcome of the research activity would have an impact on or provide information about public health or public safety' and 'the relevant purpose of the research activity cannot be achieved by the collection, use, or disclosure of de-identified data'.

(Lisa Eckstein, Donald Chalmers, Christine Critchley, Ruthie Jeanneret, Rebekah McWhirther, Jane Nielsen, Margaret Otlowski and Dianne Nicol, 'Australia: Regulating Genomic Data Sharing to Promote Public Trust' (2018) 137(8) *Human Genetics* 583-591, 586)

The guidelines provide procedures to be followed when preparing proposals to submit to ethics committees. Currently, there is no dedicated Indigenous ethics committee of the NHMRC, and no requirement for all research ethics committees to have Aboriginal and Torres Strait Islander representation. Although there are Indigenous ethics committees that while not part of NHMRC are registered and endorsed by the NHMRC, for example:

- The Western Australian Aboriginal Health Ethics Committee (WAAHEC), which is coordinated by Aboriginal Health Council of WA;
- AIATSIS Human Research Ethics Committee; and
- Aboriginal Health and Medical Research Council of NSW.

Does this provide sufficient safeguards or cultural critique to ensure that concerns are identified and discussed?

Figure 6: Section 95A Guidelines

⁵² Ibid s16B(2).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Furthermore, the NHMRC Guidelines issued under s95A apply only to organisations and agencies subject to the *Privacy Act*. Therefore, there are gaps in the framework.

4) USE OR DISCLOSURE: Genetic information

The use or disclosure of genetic information about an individual is permitted if in the process of treating an individual, genetic information becomes available that leads to a reasonable belief that the use or disclosure is necessary to lessen or prevent a serious threat to the life of the individual's genetic relative. These are sometimes referred to as incidental findings (see section 4.6 for discussion of the social, cultural and ethical issues raised in relation to incidental findings).

In these circumstances, use or disclosure must be in accordance with the Guidelines approved under Section 95AA of the *Privacy Act*, issued by the NHMRC (see section 7.1 for more information on NHMRC Guidelines).⁵³

The issues that arise in this instance were discussed during discussions with the Advisory Panel. For example, if a study is undertaken on an individual and some markers arise that may give rise to a reasonable belief that the recipient and/or a genetic relative may be at high risk for a rare disease or condition, then the treating physician may have reasonable grounds to disclose those findings to the relative. However, due to the lack of a genomic reference for Aboriginal and Torres Strait Islander peoples the probability of false positives/negatives increases. This can compel doctors to disclose unnecessarily information which can lead to anxiety and distress for patients, or alternatively not disclosing and putting the patient's relatives at risk.

5) USE OR DISCLOSURE: For a secondary purpose to a responsible person

Under the *Privacy Act*, a *responsible person* for an individual is a:

- A parent of the individual;
- A child or sibling of the individual if they are over 18 years old;
- A spouse or de factor of the individual;
- A relative of the individual who is at least 18 years old and a member of the individual's household;
- A guardian of the individual;
- A person exercising power of attorney for the individual (provided the powers granted include making decisions about the individual's health);
- A person in an intimate personal relationship with the individual; or
- A person nominated by the individual as their in-case-of-emergency contact.⁵⁴

⁵³ *Privacy Act 1988* (Cth) s16B(4).

⁵⁴ *Ibid* s16AA(1).



A permitted health situation exists where an organisation providing health services to an individual, discloses information about the individual to their responsible person. This is permitted on the condition that the individual is physically or legally incapable of giving consent to the disclosure and the health service provider is satisfied that the disclosure is necessary for the individual's care or treatment or is made for compassionate reasons. The disclosure is not permitted if the health service provider is aware (or should reasonable be aware) that the individual previous expressed a wish for the disclosure not to be made.⁵⁵

5.2.5 Does the Privacy Act apply overseas?

The *Privacy Act* applies to entities that 'hold' the personal information of an individual. The Act defines 'hold' as having 'possession or control'.⁵⁶ The *Privacy Act* also applies extra-territorially through section 5B, extending to acts engaged overseas when there is an Australian link, this may be in the form an organisation or operator that is an Australian citizen, body corporate or Australian trust.⁵⁷ In regard to the cross-border transfer of information, entities disclosing personal information to an overseas entity, 'must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the Australian Privacy Principles in relation to that information'.⁵⁸

During discussions with the Advisory Group concerns were raised that Australia may lack the infrastructure needed for largescale storage of genomic information. As such, much of the information must be stored outside Australia, on the cloud or on other external servers. In addition, it is common for academic journals to make it a requirement of publication, that an article be made publicly available, or be kept on their servers. In these circumstances compliance with *Privacy Act* can be challenging.

Digital storage of information is also vulnerable to security breaches: custodians of health related genomic information may be able to add in safeguards and limitations on access to the data held on the cloud or outside the country in accordance with s16C but nevertheless, breaches of privacy, or misuse of data could still occur.

Another challenge to holding and controlling information arises in the context of funding. Studies are generally funded on the understanding that results will be published. However, publication involves sharing information, which may lead to its misuse. This is a sensitive topic area requiring careful consideration of risk management procedures. The risks must also be discussed with the community; the positives, negatives and potential implications of publishing data.

5.2.6 Concluding Comments

The *Privacy Act* contains guidelines to allow for the non-consensual use of personal information for research purposes. This give researchers a large amount of discretion. For this reason, the framework has been criticised as ineffective. The use of guidelines to set the framework passes responsibility and discretion to individuals – the researchers, scientists

⁵⁵ Ibid s16B(5).

⁵⁶ Ibid s6(1).

⁵⁷ Ibid s5B (1)-(2).

⁵⁸ Ibid s16C; Australian Privacy Principle Guidelines (n 35) Principle 8.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

and geneticists for example, who may or may not have expertise to identify cultural issues when dealing with Indigenous health genomics. The Policies, discussed in Section 7, can provide safeguards within themselves, however with a lack of a permanent national or state based representative(s) or a committee on Indigenous genomic research, there remains a large possibility for research to be approved without an Aboriginal or Torres Strait Islander voice at the table to give light to potential cultural concerns within a proposal.

A further key concern arises when the use or disclosure is authorised under Australian law or a Court/Tribunal order.⁵⁹ Throughout discussions with the Advisory Group the importance of consent was clear, as was the importance of strict compliance with the parameters of consent as essential to maintenance of community trust. In several discussions, concern was raised about whether genomic information could be used for criminal matters, against donor and community wishes. Furthermore, serious concerns have been raised regarding potential registers around using genetics to determine connection to Country, such as in Native Title Cases and fear of moving down a blood quantum path as is seen in some First Nations communities in North America.

Given the misuse of Indigenous health information and mistreatment of Indigenous peoples, the Court-ordered use of Aboriginal and Torres Strait Islander genomic information without the consent of the community is a serious issue that can derail many advancements made in community trust towards genomics research and health care.

5.3 The Rights of Patients in a Clinical Setting

The rights and privileges afforded to patients derive from common law, statute or the professional obligations of healthcare providers. There is an important distinction between regulation through common law and statute, and regulations published by professional bodies. Through common law and statute, the parliament and courts provide rights to patients. However, professional standards regulations, published by professional bodies, are methods of self-regulation setting minimum standards for professionals. Maintenance of professional standards upholds the reputation and integrity of that profession by indirectly recognising patient rights.

That said, while professional obligations may only result in indirect remedies, they can however force cultural change within an organisation. In the case of the healthcare system, professional standards have the potential to address the systematic issues faced by Aboriginal and Torres Strait Islander peoples.

For the purposes of this section, the patient rights will be split into substantive rights and procedural rights:

- **Substantive rights** are the basic rights and duties applying to individuals;
- **Procedural rights** are the rules and remedies available to enforce the substantive rights

⁵⁹ *Privacy Act 1988* (Cth) Sch 1; Australian Privacy Principle Guidelines (n 35) Part 3, s6.

5.3.1 Substantive Rights

Patients have the following substantive rights:⁶⁰

- 1) Right to be treated with reasonable medical care
- 2) Right of informed consent
- 3) Right to confidentiality
- 4) Right to access medical records
- 5) Right to refuse treatment

1) Right to be treated with reasonable medical care

The right to reasonable medical care is grounded in contract law and tort law (common law), legislation and the professional obligations of a healthcare provider.

Common law

The tort of negligence provides a clear duty of care, often established through contract, in a patient/doctor relationship. Similar duties arise between patients and other allied healthcare professionals.

Note: This contractual relationship between patient and doctor, also provides remedies through the Australian Consumer Law in Sch 2 of the *Competition and Consumer Act 2010* (Cth). This is discussed further in section 5.5.

Given that genomic research requires a large amount of reference data, class actions for breach of this right, may provide an avenue for dealing with large-scale misuse of samples or reference data.⁶¹ Class actions usually occur when a manufacturer has a product on the market that has caused harm to these plaintiffs, such as defective surgical implants. It may be difficult to define the harm inflicted on the patients in genomic research if data is de-identified, however there may be avenues if data is used without consent in studies resulting in dignitary harms.⁶² Such harms were inflicted on the *Havasupai People* following the misuse of their data by university researchers, this is discussed further in 9.2.5 Havasupai.

Legislation

For patients receiving healthcare services, misleading and deceptive conduct regulations can set standards on the services provided, and empower individuals to action against healthcare practitioners. Australia has both national and state-based legislation regulating

⁶⁰ These rights are analogous to those in the Australian Charter of Healthcare Rights developed by the Australian Commission on Safety and Quality in Health Care.

⁶¹ *Federal Court of Australia Act 1976* (Cth) 33C. **Note:** A class action is a means by which a large group of persons can bring a claim in Australia. These claims are often complex with high costs and result in significant publicity. A plaintiff refers to someone who brings a claim against another.

⁶² Dignitary harms are harms that do not require a physical injury or manifestation, but are harms to the plaintiffs interest in privacy. These invasion of privacy give rise to deeply personal and subjective injury. See *Havasupai Tribe v Arizona Board of Regents*, 204 P.3d, 1063, 48-49 (Ariz, Ct App 2008).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

the supply of goods and services, potentially including some medical services. See section 5.5 for more detailed overview of Australia's consumer law.

Protection against discrimination is a key concern that constantly arises in the genomics field.⁶³ Importantly, all states and territories have anti-discrimination legislation in place which seeks to protect individuals from discrimination in the provision of services, including health services.⁶⁴

Consultations confirmed deep institutional racism inherent within the health system from the pre-testing right through to the interpretation of results.⁶⁵ Experiences included not being taken seriously when communicating symptoms to treating physicians and misdiagnosis based on race. The Advisory Group reported cases where children had been referred onto specialists because they were "funny looking" or in the case of children with brittle bones, not even referred to clinical genetic services and instead having the Department of Community Services called due to welfare concerns.

In addition to institutional racism, unconscious bias also plays a role. Unfortunately, it is common for doctors to fail to recognise symptoms in people from racial or cultural backgrounds different from their own. This can lead to misdiagnosis in Aboriginal people or those of non-European descent. Ironically, this results in Aboriginal people being underrepresented in all areas of the health service, except for misdiagnosis.

The issue is that despite the right to reasonable medical care, reinforced by anti-discrimination legislation, discrimination is still prevalent through institutionalised racism, unconscious bias and cultural insensitivity. As the collection and use of Indigenous health related genomic information in the clinical and research setting increases, these issues will increase if these issues are not actively engaged.

Professional obligations

The professional obligations of health practitioners grant patients an indirect remedy through complaints to professional bodies to enforce standards of reasonable care. The *Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia* outlines "good patient care" in Section 2.2:⁶⁶

⁶³ ALRC *Essentially Yours* (n 40) 290.

⁶⁴ *Racial Discrimination Act 1975* (Cth) s 13, Part VII, Schedule 1, *International Convention on the elimination of all forms of racial discrimination* Art 5, s (3), *Anti-Discrimination Act 1977* (NSW) ss 4,33; *Equal Opportunity Act 2010* (Vic) ss 4,44; *Anti-Discrimination Act 1991* (Qld) ss 4,46; *Discrimination Act 1991* (ACT) ss 2,20; *Equal Opportunity Act 1984* (SA) ss 5, 39; *Anti-Discrimination Act 1998* (Tas) ss 3, 22; *Equal opportunity Act 1984* (WA) ss 4, 46, *Anti-Discrimination Act 1992* (NT) ss 4, 41.

⁶⁵ *QFG & Anor v JM* [2001] 1 Qd R 373, [1998] QCA 228, *Commonwealth of Australia & Anor v Human Rights and Equal Opportunity Commission* [1997] FCA 664 (18 July 2007).

⁶⁶ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, (2014) March, Chapter 2.21-2.2.4 available at <<https://www.medicalboard.gov.au/documents/default.aspx?record=WD10%2F1277&dbid=AP&chksu m=eNjZ0Z%2FajN7oxjvHXDRQnQ%3D%3D>> accessed 21 April 2020.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

- recognising and working within the limits of the doctor's competence and scope of practice;
- ensuring that the doctor has adequate knowledge and skills to provide safe clinical care;
- maintenance of adequate records;
- the balance of benefit and harm in all clinical-management decisions;
- communicating effectively with patients;
- providing treatment options based on the best available information; and
- taking steps to alleviate patient symptoms and distress, whether or not a cure is possible.

These obligations provide additional protections for patients, and avenues to ensure ethical and appropriate conduct for practitioners.

2) Right of informed consent

Doctors and health professionals must get the prior informed consent of the patient before performing medical procedures. There are certain exceptions to this rule.⁶⁷

Industry established professional obligations for informed consent are set out in the Medical Board of Australia's, *Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia*⁶⁸ and detailed in the guidelines issued by the National Health and Medical Research Council.⁶⁹ Section 3.5 of the Code states that informed consent is good medical practice that ensures the patient understands the benefits and risks involved. This involves:⁷⁰

- providing information to patients in a way that they can understand before asking for their consent;
- obtaining informed consent or other valid authority before the doctor undertakes any examination, investigation or provides treatment (except in an emergency), or before involving patients in teaching or research;
- ensuring that patients are informed about the doctor's fees and charges; and

⁶⁷ *Rogers v Whitaker* (1992) 175 CLR 479, Exceptions include emergency treatment and some psychiatric treatment. *Secretary of the Department of Health and Community Services v JWB (Marion's Case)* (1992) 175 CLR 218 at 234.

⁶⁸ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, (2014) March, Chapter 3.5, available at <https://www.medicalboard.gov.au/documents/default.aspx?record=WD10%2F1277&dbid=AP&chksu m=eNjZ0Z%2FajN7oxjvHXDRQnQ%3D%3D> accessed 21 April 2020.

⁶⁹ *The National Statement* (no 44) 2.2.1

⁷⁰ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, (2014) March, Chapter 3.5, 1-3.5.4, available at <https://www.medicalboard.gov.au/documents/default.aspx?record=WD10%2F1277&dbid=AP&chksu m=eNjZ0Z%2FajN7oxjvHXDRQnQ%3D%3D> accessed 21 April 2020.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

- when referring a patient for investigation or treatment, advising the patient that there may be additional costs, which patients may wish to clarify before proceeding.

Failing to obtain consent can result in tort or criminal offences such as battery, assault or trespass against the person, and for health care providers being liable to be sued for damages.⁷¹ As such, to obtain informed consent requires effective communication of 'inherent risks' associated with a treatment and the chances of those risks happening. It is not relevant whether risks actually materialise or not.⁷²

The harms associated with Indigenous health related genomics do not fit neatly in this concept. The western view of harm focuses on physical illness or injury to the person, e.g. illness resulting from an infection following an operation. From an Aboriginal and Torres Strait Islander perspective, the scope of harm can be much wider, including spiritual and cultural harms. Also, the western definition of 'physical' is more limited than it is under customary law. From an Aboriginal and Torres Strait Islander perspective, your body and samples are still your person even after they leave the body, and spirit can still remain with those samples; those samples carry your DNA and that of your ancestors. Misuse of these samples, can result in significant harm to Aboriginal and Torres Strait Islander donors, their family and community. These harms may result in dignitary harms, inequitable access to medical benefits or a lack of prior informed consent. Therefore, it is critical that patients are aware of what they are consenting to and what will happen with their sample.

Across most states, legislation often explicitly excludes liability arising in connection with the giving of (or failure to give) a warning, advice or other information, in relation to the risk of harm to a person in the provision of a professional service.⁷³ Instead, the standard imposed derives from common law. The High Court in *Rogers v Whitaker* endorsed taking the following factors to take into consideration when determining what risks to disclose to the patient: patients personality, temperament and attitude, patients level of understanding, nature of the treatment (major procedures demanding a more detailed explanation) and the likelihood of adverse effects resulting from treatment.⁷⁴

In addition to the above factors, the standard the law demands of medical practitioners in providing information, was further clarified in *Rosenberg v Percival*:⁷⁵

"a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if... a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it...

In the context of Indigenous health related genomics, a material risk may arise when a patient does not fully understand the scope of their consent. This could occur when research

⁷¹ CCH Australia, *Australian Health & Medical Law Report* (online at 22 April 2020) [¶ 27-130].

⁷² *Ibid.*

⁷³ *Ibid.*

⁷⁴ *Rogers v Whitaker* (1992) 175 CLR 479, 488.

⁷⁵ *Rosenberg v Percival* [2001] HCA 18, [63].



Indigenous Health Genomics: The Legal, Ethical and Social Issues

outcomes are inadequately explained. This is likely if the researcher or doctor has little or no understanding of the cultural and community implications of the research. In those circumstances, the doctor may fail to provide all material information precisely because they don't have the cultural background to know what *is* material.

Consent under duress of moments of high emotional stress will also undermined the effectiveness of the consent. For example, requesting the donation of an umbilical cord right after birth or donation of an individual's body after death. Again, this could have a cultural dimension; if the doctor does not have an understanding of the community they could misjudge when the patient is under emotion stress or is anxious about cultural harm.

Informed consent is a core principle for ICIP self-determination. In the context of Indigenous health related genomics, it is critical that Aboriginal and Torres Strait Islander patients and communities are provided with accurate and relevant information on all proposed uses of their genomic material. Patients and community must be advised about the implications of their consent.⁷⁶

Given the long history of the exploitation of Indigenous peoples and knowledge in the name of 'science', dynamic, informed consent from both individual and community is crucial to achieving positive outcomes. This makes informed consent one of the most, if not the most, important aspect of all medical care and relationships between institutional bodies and Aboriginal and Torres Strait Islander peoples.

The Advisory Group reported patients may go to a specialist to undertake testing based on a chronic disease or illness, without actually be aware of what they are fully consenting to beyond the straight forward diagnostic test. Doctors need to ensure that patients are adequately informed and patients need to understand if their diagnostic sample is going to be used for research. This is increasingly relevant as the division between clinical and research practices are blurring, and as diagnostic data is retained for research.

To establish a legal claim of lack of consent under common law, patients must also establish causation: that had the risk been communicated, they would not have gone ahead with the proposed treatment.⁷⁷

Consider this hypothetical:

A patient goes to his doctor for a diagnostic test. When he consents to have a blood sample taken, he assumes the sample will only be used to diagnose his illness. His doctor does not give him any further information on how the sample will be disposed of, or how his data will be recorded. However, the consent form he signs explains in small print that his sample will be retained. The sample will be stored with his sex, age, and clan name. By signing the consent form, he authorises the lab to use that sample for further testing.

⁷⁶ Dr Terri Janke, *True Tracks: Indigenous Cultural and Intellectual Property Principles for putting Self-Determination into practice* (PhD Thesis, Australian National University, 2019) 333.

⁷⁷ *Rogers v Whitaker* (1992) 175 CLR 479 and *Wallace v Kam* 2013) 250 CLR 375.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

The undiagnosed illness is giving him a splitting headache. He has known this doctor for years, and trusts that she has explained all the relevant information. He signs the form without reading the small print.

Several years later, he hears that the local university is conducting a population study, with his clan as the subject. His Elders are deeply offended by this study, and so is he. 'Where did they get the information?', he thinks. And then he thinks of his blood test several years ago.

In this scenario, the harm could be the cultural and social ramifications of the test – to the patient and his community. But to establish causation, the patient would need to demonstrate that if he had been aware of the risk, he would not have signed the consent form. Put another way, he needs to be able to demonstrate that the harm was caused by the lack of adequate explanation about the scope of consent.

Invalidation of Consent

In some instances, the Courts have found that consent is invalidated if a health professional's undisclosed purpose is solely non-therapeutic.⁷⁸ Additionally, if treatment is conveyed as necessary when in fact it is unnecessary, then consent may also be vitiated.⁷⁹

In practice however, practitioners may have non-therapeutic motivations for recommending a procedure (e.g. the income they receive from delivering medical services). It remains an open legal question whether "treatment which is exclusively non-therapeutic is sufficient [to invalidate consent], or whether it must be accompanied by a fraudulent or reckless state of mind, in order for a patient's consent to be invalid".⁸⁰

Even with the uncertainty, the case law to-date raises the question: if practitioners are motivated by private commercial gain to take genomic samples from Aboriginal patients for non-therapeutic purposes does this vitiate consent?

These are key issues that practitioners and professional bodies must take into account when assessing whether their consent processes for Aboriginal and Torres Strait Islander patients, amount to free, prior, informed consent.

3) Right to confidentiality

The right to confidentiality of medical information is underpinned by both criminal and civil sanctions. Rights to confidentiality, also known as privacy rights, are discussed in detail in paragraph 5.2.

⁷⁸ *White v Johnston* (2015) 87 NSWLR 779.

⁷⁹ *Ibid* 73.

⁸⁰ *Ibid* 73.



4) Right to access medical records

The High Court in *Breen v Williams* established that records created by private medical practices, in the absence of specific legislation, are the ownership of that practice and that patients have no general right of access to those records or information in them.⁸¹ Therefore, an individual's right to access to their medical records depends firstly on what kind of health practice they attend (public or private) and the information type of information contained within the records. See section 5.2 and 5.7 for more information of the patients privacy rights, and rights under the MyHealth Records scheme introduced by the Commonwealth government.

5) Right to refuse treatment

The right of a patient to refuse medical treatment is recognised at an international level under Article 7 of the *International Covenant on Civil and Political Rights*,⁸² and in common law in Australia.⁸³ Prima facie, adults are capable of deciding to consent to or refuse medical treatment.⁸⁴ An adult is presumed to have the capacity to consent to or to refuse medical treatment unless and until that presumption is rebutted'.⁸⁵ The determination of whether an individual has capacity to consent is based upon whether they can:⁸⁶

- comprehend and retain the information which is material to the decision and its consequences; or
- weight and use the information as part of the process of making a decision.

The circumstances where this can be rebutted include:⁸⁷

- emergencies when it is not practicable to obtain consent;
- when a person has made an advanced care directive (e.g. do not resuscitate);
- if there is a genuine and reasonable doubt as to the validity of an advanced care directive;
- by a spouse, close friend or relative of the person;
- by the person's guardian;
- situations permitted by mental health related legislation; and
- next of kin, if they fall into a category listed above, under the *Guardianship Act*.

⁸¹ *Breen v Williams* (1996) 186 CLR 71.

⁸² *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976).

⁸³ *Hunter and New England Area Health Service v A* [2009] NSWSC 761.

⁸⁴ *Ibid* 21.

⁸⁵ *Ibid* 23 citing Butler-Sloss LJ in *Re MB* [1997] 2 FCR 514 at 553.

⁸⁶ *Ibid*.

⁸⁷ *Ibid* 40, See *Mental Health Act 2007* (NSW) ss 14-15.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

In the context of Indigenous health genomics, it is important that individuals and communities are aware of their rights to refuse treatment.

If medical treatment is forced on an individual without their consent and a rebuttable presumption does not apply, there may be remedies available in the tort of battery.

5.3.2 Procedural Rights

Procedural rights are the avenues in which individuals can enforce their substantive rights and seek remedies for harms. Despite there being no nationally unified regulatory body, there is a level of uniformity to disciplinary practices that can assist in a consistent approach to the regulation of substantive patient rights. Across all jurisdictions, legislation that confers the ability to bring disciplinary proceedings by the relevant authority, refers to:

- professional misconduct;
- unsatisfactory professional conduct; and/or
- unprofessional conduct.⁸⁸

Under the National Registration and Accreditation Scheme, the Medical Board of Australia has disciplinary powers over registered health practitioners in all jurisdictions except for New South Wales and Queensland.⁸⁹ In New South Wales, health practitioners are disciplined by the Medical Council of NSW and in Queensland, the Health Ombudsman.⁹⁰ In addition to this, statutory health bodies, can in some circumstance also refer complaints between each other or produce reports to corresponding boards or the Medical Council of New South Wales.⁹¹ This approach ensures that if professional misconduct, or unprofessional conduct occurs in the collection and use of Indigenous health related genomics by health practitioners or practices, then disciplinary proceedings can be brought to enforce the rights of patients.

5.3.3 Conclusion

Despite the lack of an entrenched system of rights for medical patients, there are a number professional, statutory, and common law obligations on doctors to ensure that patients receive an adequate standard of care from health practitioners and practices. Protections against purely non-therapeutic practices and requirements of informed consent provide some safeguard against unfair targeting of Aboriginal and Torres Strait Islander patients,

⁸⁸ *Health Practitioner Regulation National Law Act 2010 (ACT)* s 5, 182, *Health Practitioner Regulation National Law (NT)* s 5, 182; *Health Practitioner Regulation National Law 2009 (Qld)* s 5, 182; *Health Practitioner Regulation National Law Act 2010 (SA)* Sch 2 s 5, 182; *Health Practitioner Regulation National Law (Tas) 2010* s 5, 182; *Health Practitioner Regulation National Law (Vic) 2009* s5, 182; *Health Practitioner Regulation National Law Act 2010 (WA)* Sch s 5, 182; *Health Care Complaints Act 1993 (NSW)* s 3, 8(2), *Public Health Act 2010 (NSW)* Part 7, Division (1),(3).

⁸⁹ *Health Practitioner Regulation National Law 2010 (ACT)* Pt 8, *Health Practitioner Regulation National Law 2010 (NT)* Pt 8, *Health Practitioner Regulation National Law Act 2010 (SA)* Sch 2 Pt 8, *Health Practitioner Regulation National Law 2010 (Tas)* Pt 8, *Health Practitioner Regulation National Law 2009 (Vic)* Pt 8, *Health Practitioner Regulation National Law Act 2010 (WA)* Sch Pt 8.

⁹⁰ *Health Practitioner Regulation (Adoption of National Law) Act 2009 (NSW)* ss 6, 7A-7C, Pt 8; *Health Practitioner Regulation National Law (Qld)* Pt 8.

⁹¹ *Halsbury Laws of Australia, [28-]222] (c) Disciplinary Matters and Offences – Registration of Medical Practitioners*, (updated 6 April 2016), accessed 24, April 2020).



however greater education for patients and expectations of practitioners are needed in this area. The standards of informed consent appear to have the strongest grounding to safeguard against issues relating to wide ranging and vague consent parameters to the collection and use of Aboriginal and Torres Strait Islander health related information. Furthermore, despite not being nationally unified, the *Health Practitioner Regulation National Law Act* operating across most states and territories provides a strong starting point to be able to ensure nationally consistent approaches to regulation and enforcement of obligations.

5.4 IP and Commercialisation – Patents Act

In the biotechnology sector, patents are critical to ensure a competitive and healthy industry. Nevertheless, in the context of gene technology, there is a fine balance between invention and discovery of fact.

Patent law provides incentives for scientists and inventors to develop new and innovative technology by granting an exclusive 20 year monopoly to exploit their invention.⁹² Patents can allow for highly advanced and technical medicines and diagnosis systems which can magnify the effectiveness and implementation of health care initiatives. For Indigenous peoples, this can have tremendous impacts to reduce the wide gap in health and life expectancy. However, a system that allows patents of genes and genomic material could also expand the health gap due to financial costs of such medicines.

Another risk is the possibility of biocolonialism of Indigenous genes and genomic information. Biocolonialism refers to extending “the reach of the colonial process into the biomes and knowledge systems of Indigenous peoples in the search for marketable genetic resources and traditional knowledge”.⁹³ This is not a farfetched concept, as in Australia, non-Indigenous peoples and corporations have sought to register patents over plant genetic resources and traditional medicines of Aboriginal and Torres Strait Islander peoples, along with their medicinal applications.

This section will investigate the two types of patents in Australia, how they are granted, and the relevant case law governing patenting in the genetic technology field. It will look to international examples of positive and negative experiences and consider the issues that arise in the development of gene technology patents.

5.4.1 Patents in Australia

Australia grants two types of patents, *standard* and *innovation*, although innovation patents are due to be phased out by August 2021.

⁹² *Patents Act 1990* (Cth) s 13.

⁹³ Debra Harry, 'Bio colonialism and Indigenous knowledge in United nations Discourse' (2011), *Griffith Law Review*, 20(1), 702,702, see also International Center for Technology Assessment, the Indigenous Peoples Council on Biocolonialism, Greenpeace and the Council for Responsible Genetics, 'Brief for Amici Curiae in Support of the Plaintiffs', Submission in Association for Molecular Pathology, et al. v. Myriad Genetics, 569 U.S. 576,12,15, (2013),10 September 2009, 19.

Invention or innovation?

Standard patents grant 20 years' (up to 25 for pharmaceutical substances) protection for an invention. In order for an invention to be patentable it must be novel and inventive when compared to the prior art base.⁹⁴

On the other hand, innovation patents last for up to eight years and are designed to protect inventions that do not quite meet the threshold of 'inventive' but are nevertheless 'innovative'. Standard patents allow for innovative concepts and processes, and incremental advancements on existing technology.⁹⁵

Manner of manufacture

Both standard and innovation patents require that the invention is a 'manner of manufacture' within the meaning of section 6 of the *Statute of Monopolies* enacted in England in 1623. So, what is a 'manner of manufacture' that is appropriate for patent protection?

The meaning of manner of manufacture was first explained in the decision of *National Research Development Corporation v Commissioner of Patents (NRDC)*,⁹⁶ a 1959 Australian case which upheld the validity of a patent for the use of previously unknown property of a known chemical to effect a new purpose. This case, discussed by the Australian Law Reform Commission in *Genes and Ingenuity*, considered that the manner of manufacture "must belong to the 'useful arts' rather than the 'fine arts'; it must provide a material advantage; and its value to the country must be in the field of economic endeavour".⁹⁷

For patents related to cosmetic processes or changes to the appearance of the human body, they will be allowed if they have a commercial application and satisfy the proper subject matter, for example a particular composition in a process for improving the strength and elasticity of keratinous materials such as hair and nails.⁹⁸

In *Anaesthetic Supply Pty Ltd v Rescare Ltd* the Federal Court considered whether a method of medical treatment constitutes a 'manner of manufacture', and if so, should it otherwise be excluded as 'generally inconvenient' to patent.⁹⁹ The Australian Law Reform Commission in *Genes and Ingenuity* summarise Lockhart J's view that there is "no reason in principle why a method of medical treatment should not be considered to be a manner of manufacture and thus patentable".¹⁰⁰ As such, methods of medical treatment are considered a 'manner of manufacture'.

⁹⁴ *Patents Act 1990* (Cth) s 18(1A)(b).

⁹⁵ IP Australia, 'Types of Patents', *Understanding Patents* (Website, 26 April 2020) <<https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents>>.

⁹⁶ *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

⁹⁷ *Ibid*; ALRC, *Genes and Ingenuity*, (n 25), 6.23.

⁹⁸ *Bernhard Joos v Commissioner of Patents* (1972) 126 CLR 611.

⁹⁹ ALRC, *Genes and Ingenuity*, (n 25), [7.31].

¹⁰⁰ ALRC, *Genes and Ingenuity*, (n 25), [7.31]; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 19.

Patenting biological materials

Patents of biological materials however have controversially been allowed since the 1980 US Case of *Diamond v Chakrabaty*.¹⁰¹ Australia followed the ruling in *Diamond v Chakrabaty* in the case of *Grain Pool of Western Australia v Commonwealth of Australia*.¹⁰² This case involved the patenting of bacteria, not human genetic material, but it opened up the pathway to patent living things that were inventions rather than just products of nature.

Moving towards human genetic information, in 2015 the High Court in *D'Arcy v Myriad Genetics* handed down a landmark 7-0 judgement that determined patents which sought to claim naturally occurring nucleotides, whether or not the isolate contained other components and sequences, was not subject to patentability.¹⁰³

The monopoly created by patents allows companies to receive returns on their investment. However, there is a distinction between inventions that are created, and naturally occurring products. Australia takes a strict approach when it comes to patentable biotechnology with human genomic information. Legislation states that human beings, and the biological processes for their generation are not patentable inventions.¹⁰⁴

5.4.2 Where does Australia stand with gene patenting?

IP Australia's Patent Office Manual of Practice and Procedure states two key questions to determine the patentability of claims directed to nucleic acids or genetic information:

1. What is the substance of the claim?; and
2. Is the substance of the claim "made"?¹⁰⁵

The case of *D'Arcy v Myriad Genetics* concerned a patent claim by the respondents Myriad Genetics, who were successful in detecting and isolating the BRCA1 gene from its naturally occurring cellular environment. Once isolated, the mutations and components of the gene could be studied, to assist in the diagnosis of, and determine susceptibility to, breast and ovarian cancer.¹⁰⁶ In this case, D'Arcy argued the genes involved naturally occurring nucleic acids that were merely isolated, and failed to meet the 'manner of manufacture' test required for an 'invention' in s 18(1)(a) of the *Patents Act 1990* (Cth). In their judgement, Gageler and Nettle JJ observed that Myriad's claim was a

¹⁰¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁰² Matthew Rimmer, 'The Empire of Cancer: Gene Patents and Cancer Voices' [2013] 22(2) *Journal of Law, Information and Science*, 18, 3.2, *Grain Pool of Western Australia v Commonwealth of Australia* (2000) 202 CLR 479, [28]-[32].

¹⁰³ *D'Arcy v Myriad Genetics Inc* [2015] HCA 35, Matthew Rimmer, 'Gene Genie: The Judicial Revolution in Biotech IP', (2016) 26(2), *Australasian Biotechnology*, 60.

¹⁰⁴ *Patents Act 1990* (Cth) s 18(2).

¹⁰⁵ IP Australia, *Australian Patent Office Manual of Practice and Procedure* (01 August 2017) [2.9.2.6].

¹⁰⁶ Matthew Rimmer, 'The Empire of Cancer: Gene Patents and Cancer Voices' (2013), 22(2) *Journal of Law, Information and Science*, 18,18; "William Bartlett, '*D'Arcy v Myriad Genetics Inc* [2015] HCA 35: The plurality's new factorial approach to patentability rearticulates the question asked in *NRDC*' (2015), 25(1), *Journal of Law, Information and Science*, 120,121.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

claim for a monopoly over such isolated fragments of naturally occurring DNA as comprise the BRCA1 gene as are found upon examination to contain the (naturally occurring) specified mutations and polymorphisms.¹⁰⁷

Furthermore, Gordon J, in a lone judgement went further to state

...the question in this appeal is whether an isolated nucleic acid which has one or more specific mutations or polymorphisms in the BRCA1 gene is a proper subject for the grant of a patent under s 18(1)(a) of the Patents Act 1990 (Cth) ("the Act"). The answer is no.¹⁰⁸

In summary, the substance of the claim was isolated naturally occurring information that reproduced genomic DNA information. As this is a reproduction and naturally occurring, it could not be "made" and therefore could not be granted a patent.

The *Myriad* case focused predominantly on the concept of patents over genetic information, rather than gene patenting generally and did not make findings with respect to patents directed at methods of production or diagnosis. However, if a claim is directed towards a method or process that makes use of a nucleic acid molecule, such as a method of diagnosis and its practical application, then the substance of the claim will be the process.¹⁰⁹ This was discussed in the case of *Meat & Livestock Australia Limited v Cargill, Inc*¹¹⁰ where the patent involved the identification of genetic markers that correlated with favourable traits in livestock, and their application. This case differed to *Myriad* in that *Myriad*

centred on the patentability of claims defining isolated naturally occurring gene sequences *per se* rather than methods of using gene sequences.¹¹¹

In determining if the substance of the claim has been "made", examiners will compare the state of affairs prior to and after the application of the invention.¹¹² In the case of *Myriad*, because the application was for isolate nucleic acid that was the same as it was in the natural DNA, nothing was "made". Therefore "acts of isolation, purification or synthesis are not enough to confer patentability".¹¹³ This leaves open claims for diagnostic methods and processes.

5.4.3 Patents over diagnostic methods

The Federal Court of Australia has recently handed down a decision in *Sequenom, Inc. v Ariosa Diagnostics, Inc.* [2019] FCA 1011 that affirmed a patent for diagnostic methods that involve practical application of natural phenomena. The patent in dispute was

¹⁰⁷ *D'Arcy v Myriad Genetics Inc* [2015] HCA 35, 168.

¹⁰⁸ *Ibid*, 178.

¹⁰⁹ IP Australia, *Australian Patent Office Manual of Practice and Procedure* (01 August 2017) [2.9.2.6].

¹¹⁰ *Meat & Livestock Australia Limited v Cargill, Inc* [2018] FCA 51.

¹¹¹ 'Australia remains a gene-patent friendly jurisdiction', *Shelston IP* (Blog Post, 18 February 2018) <<http://www.shelstonip.com/news/australia-remains-gene-patent-friendly-jurisdiction/>>.

¹¹² IP Australia, *Australian Patent Office Manual of Practice and Procedure* (01 August 2017) [2.9.2.6].

¹¹³ *Ibid*.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample.¹¹⁴

The method in question which goes back to the substance of the claim, is that the invention:¹¹⁵

Applies and follows on from, but is different to, the identification of a natural phenomenon, namely the presence of cffDNA in maternal blood.... the invention builds on, uses, practically applies and reduces to practice a discovered substance found in nature, namely, cffDNA in maternal blood, to provide a new, inventive, useful, artificial method of detection of cffDNA, and where the method is of economic significance.

The result here is that if naturally occurring genomic information is identified in a naturally occurring state, then it cannot be patented. However, if a company invents a new and innovative method for identifying DNA or aspects of DNA, then that method or diagnosis can be patented.

5.4.4 Patents and Morality Debates

In the United States case of *Myriad Genetics*, there was submissions of amicus curiae, meaning “friend of the court”. A “friend of the court” is not a party to the case yet may have expertise or special interest in presenting submissions bearing to the questions on issue. One submission of amicus curiae was submitted by George Kimbrell in support of Plaintiff-Appellees. The arguments in this brief focused on the issue that products of nature are not patentable subject matter.¹¹⁶ Kimbrell claimed that the information dictated by the gene is identical whether inside or outside the body, privatisation of this genetic heritage of an individual (and gene patents of people in general) create a system that:

reduces people as nothing more than “treasure troves” to be mined for private economic gain, violating the fundamental rights of indigenous peoples and patients.¹¹⁷

In their brief, the Indigenous Peoples Council on Biocolonialism argued that patents on Indigenous peoples’ gene facilitate the exploitation of Indigenous people and violate international law. The submission states the cultural importance of genes as:¹¹⁸

fundamentally storehouses of information that has been passed down to each person from his or her ancestors, and that will be passed down to his or her children. For Indigenous groups, their genetic materials hold traditional and spiritual significance.

¹¹⁴ *Sequenom, Inc. v Ariosa Diagnostics, Inc.* [2019] FCA 1011, 294.

¹¹⁵ *Ibid* 485.

¹¹⁶ International Center for Technology Assessment, the Indigenous Peoples Council on Biocolonialism, Greenpeace and the Council for Responsible Genetics, ‘Brief for Amici Curiae in Support of the Plaintiffs’, Submission in Association for Molecular Pathology, et al. v. Myriad Genetics, 569 U.S. 576,12,15, (2013),10 September 2009,5.

¹¹⁷ *Ibid* 11.

¹¹⁸ *Ibid* 24-25.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Similar concerns were also raised in consultation with the Advisory Group in relation to blood in research and in repatriation. This demonstrates the importance that blood holds for Indigenous peoples and the attachment to it. Patents derived from the Indigenous genomic information are clearly culturally sensitive and require free, prior informed consent and consultation.

5.4.5 Patents over existing Aboriginal and Torres Strait Islander knowledge systems and practices

Companies have sought and successfully patented Aboriginal and Torres Strait Islander knowledge systems in Australia, sometimes with consent, although often without.

A non-consultative or non-consensual patent over Aboriginal and Torres Strait Islander knowledge systems and processes not only prohibits Aboriginal and Torres Strait Islander peoples from utilising their existing traditions in a commercial context, but also demonstrates a disregard or lack of understanding of Aboriginal and Torres Strait Islander knowledge systems by virtue of patents requiring an inventive step.

There are cases however where Aboriginal and Torres Strait Islander communities have successfully patented their knowledge systems with a commercial application. This raises the question, should patent law be supplemented with recognition of bioethical principles of informed consent and benefit sharing?

5.4.6 International Examples

Looking towards legislative safeguards, New Zealand has a morality exclusion that states: “An invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to... Morality”.¹¹⁹ When considering these exceptions, the Patent Commissioner may also seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate.¹²⁰ This kind of discretion, whilst not a guaranteed safeguard, can certainly reduce issues or concerns around exploitation of Māori intellectual and cultural property, and provides a voice at the table to consider issues as and if they arise, rather than an afterthought.

In addition to the morality exclusion, in New Zealand, patents cannot be claimed over:

Human beings, and biological processes for their generation, an invention of a method of; treatment of human beings by surgery or therapy or diagnosis practised on human beings, is not a patentable invention; or a plant variety.¹²¹

This results in a high moral standard of patent ineligibility in the healthcare sector in New Zealand.

Internationally, there have been cases of biopiracy. There is concern that such risks exist in Australia. For example, there are concerns over the possibility of colonisation of genes by government entities and health organisations. In 1984 the Hagahai people from Papua New

¹¹⁹ *Patents Act 2013* (NZ) s 15(1).

¹²⁰ *Ibid*, s15((3).

¹²¹ *Ibid*, s16.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Guinea made contact with the outside world to request medical help. American anthropologist, Carol Jenkins, assisted and took blood samples for diagnosis and provided the Hagahai with medicine. Jenkins observed rare genetic characteristics in these diagnostic samples that were resistant to certain types of leukemia. Looking to capitalise on this, the US National Institute of Health patented the donor's gene line. As a result, the US Government owned the DNA of a non-US Citizen. The patents were removed in response to the public outrage however, this was a discretionary reaction. What concerns Indigenous people is that there is no legal recourse for them to require removal from the patent register in circumstances where gene material is patented without their consent.

5.4.7 Conclusion

Legislative and common law safeguards against the commercialisation of genetic information in Australia appear to form a strong barrier against potential misuse of Aboriginal and Torres Strait Islander health related genomic information. Concerns may arise however if "new" processes are invented for detecting Indigenous genomic material. If these processes are patentable, this could lead to monopolies in which delivery of treatment is determined by commercial return rather than equity and human rights to health care. This could expand the already widened health gap or shut out Aboriginal and Torres Strait Islander peoples who cannot afford such treatment. Australia may seek to resolve these issues by adopting a similar morality exclusion or discretion like New Zealand, through legislative reform, or the introduction of patent guidelines for health researchers involved in the commercialisation stemming from Aboriginal and Torres Strait Islander genomic references.

5.5 Consumer law and consumption of health services

Medical professionals are bound by the *Competition and Consumer Act 2010*, and the Australian Consumer Law found in schedule 2 of the Act. When doctors working in private practice treat Aboriginal and Torres Strait Islander patients, they have certain obligations under this law. This includes when the doctors take samples from patients for diagnostic purposes using genomic science.

Note: this Act will apply where the "consumer" (the patient) is receiving medical services from a doctor. For example, when they visit their GP or a specialist to receive medical care. It may not apply in all circumstances that involve the use or handling of Indigenous genomic samples or data.

5.5.1 Misleading or deceptive conduct or representations

Doctors must not make false or misleading representations or statements.¹²² The prohibition on false or misleading representations includes representations that:

- services are of a particular standard, quality, value or grade,
- purport to be a testimonial of any person relating to the service, or
- the services have sponsorship, approval, or benefits

Doctors are also prohibited from engaging in misleading or deceptive conduct, or in conduct likely to mislead or deceive.¹²³ This means that doctors must never mislead their patients, for example, about the nature of the procedures recommended or the possible outcomes. Conduct can be misleading, even when there has not been an actual misrepresentation made. While there is not a general duty of disclosure, case law has certainly recognised that silence in circumstances where matters ought reasonably to be disclosed can amount to misleading conduct.¹²⁴

5.5.2 Unconscionable Conduct

Doctors must not engage in unconscionable conduct.¹²⁵ If unconscionable conduct is alleged, certain factors will be considered. See **Figure 7** below for a list of speculative questions that will be used to decide whether conduct has been unconscionable.¹²⁶

¹²² *Competition and Consumer Act 2010* (Cth), Schedule 2 The Australian Consumer Law, s29.

¹²³ *Ibid*, s 18.

¹²⁴ *Black CJ Demagogue Pty Ltd v Ramensky* (1992) 39 FCR 31, 3.

¹²⁵ *Competition and Consumer Act 2010* (Cth), Schedule 2 The Australian Consumer Law, s21.

¹²⁶ *Ibid* s 22.

Was the conduct unconscionable?

Was the patient at some kind of disadvantage? E.g. was there a language barrier? Did they understand what the procedure was they were consent to?

Was the patient able to understand any documents they were shown that related to the procedure? E.g the consent form?

Did the doctor exert undue influence on the patient? I.e. did the doctor pressure the patient into it?

Did the doctor deliver medical services to the patient with care and skill consistent with the level of care and skill they use when providing service to other patients?

Did the doctor disclose all relevant risks of the procedure to the patient?

Figure 7: Was the conduct unconscionable? Factors to consider

The Australian Consumer law clearly has application to Aboriginal and Torres Strait Islander genomics. In discussion with the Advisory Group, it is increasingly common for genomic samples to be taken in a clinical setting for a diagnostic purpose. This sample, and the data, may then be retained and used for research at a later date. In these circumstances, the Australian Consumer Law applies at the moment of collection – when the Aboriginal or Torres Strait Islander patient is in their appointment with their doctor. In those circumstances the doctor must ensure that the delivery of their medical services is in line with the conscionability standards detailed above, and must disclose all reasonable relevant information.

5.5.3 State and territory consumer protections

In addition to the national law above, states and territories each have their own fair-trading legislation, that may also apply to health service delivery. Their additional obligations do not contribute a great deal to regulating the delivery health services. Nevertheless, see **Figure 8** figure for a summary of the relevant acts.

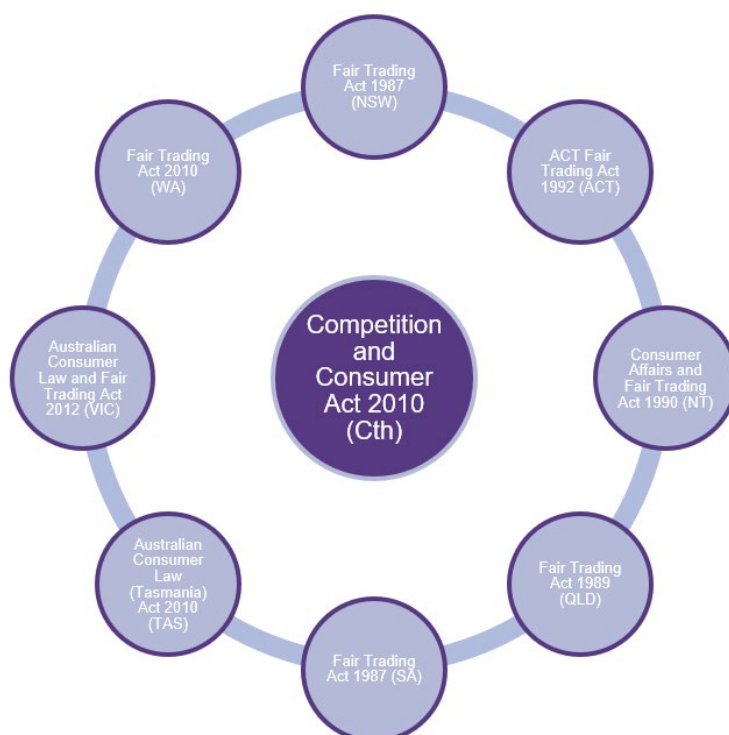


Figure 8: Summary of Fair Trading Laws

5.6 Who controls access to existing genetic material?

Note: The *Gene Technology Act 2000* (Cth) regulates certain dealings with certain genetically modified organisms (GMOs) through a licensing system. The Act specifically excludes human genes from the definition of genetically modified organisms, meaning that the Act has no application in the context of the regulation and control of Indigenous genomic material

For the most part, access to genetic material will be controlled by whoever holds title over the physical property, and whoever owns the intellectual property in the data. However, the use and handling of samples and data is governed by several legislative regimes.

Access to existing genetic data is primarily regulated through Federal and state privacy laws. See more in **Section 5.2**.

The states and territories also have legislation which regulates tissue procurement and supply, which could be relevant to control of access to the physical samples. Below is a table of the relevant legislation.

Table 6: State and territory regimes for human tissue procurement

State or Territory	Act or Regulation
New South Wales	<i>Human Tissue Act 1983</i>
Victoria	<i>Human Tissue Act 1982; Human Tissue (prescribed Institutions) Regulation 2006</i>
Queensland	<i>Transplantation and Anatomy Act 1979</i>
South Australia	<i>Transplantation and Anatomy Act 1983</i>
Western Australia	<i>Human Tissue and Transplant Act 1982</i>
Tasmania	<i>Human Tissue Act 1985</i>
Northern Territory	<i>Transplantation and Anatomy Act 1979</i>
Australian Capital Territory	<i>Transplantation and Anatomy Act 1978</i>

The Acts set the parameters for obtaining consent to take samples, when samples can be taken in the absence of consent or from a deceased person, and regulation of businesses authorised to handle or supply samples. There are some prohibitions on the trading of tissue. They are generally structured so that there is a general prohibition on the sale of tissue, that prohibition is subject to certain exceptions, for example, if the tissue has been subject to processing and has been made for use for therapeutic, medical or scientific purposes.¹²⁷

5.6.1 Access of law enforcement to data

One of the key recommendations of the Australian Law Reform Commission's 2003 report was that

a new criminal offence should be created to prohibit an individual or a corporation from submitting another person's sample for genetic testing or conducting such testing, knowing (or recklessly indifferent to the fact) that this is done without the consent of the person concerned or other lawful authority.¹²⁸

It does not appear that this amendment was ever made.

The Commonwealth has a DNA database – the National Criminal Investigation DNA Database (NCIDD) for law enforcement purposes. The Commonwealth also has a Disaster Victim Identification database (DVI Database).¹²⁹ Both systems are operated by the

¹²⁷ See for example *Transplantation and Anatomy Act 1983* (SA) s35.

¹²⁸ *ALRC Essentially Yours* (n 40) 35.

¹²⁹ Part 1D of the *Crimes Act 1914* (Cth).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Australian Criminal Intelligence Commission.¹³⁰ The NCIDD has more than 1.2 million DNA profiles and is available 24 hours 7 days a week to all Australian police agencies. The samples were collected by Australian police from crime scenes, convicted offenders, suspects, volunteers, items belonging to missing persons, and unknown deceased persons.¹³¹

Several people we spoke to also expressed concern that the police could compel a researcher to give them access to samples or data within their possession. The *Crimes Act (Cth)* has some provision for warrants, but they are also governed by individual state and territory legislation. This does seem to be a possibility, given that the terms as drafted (though they vary from state to state) were not drafted to exclude searches that include genomic data.

See **Table 7** for a summary of the relevant state legislation.

Table 7: Legislation relevant to access by law enforcement to data

State or Territory	Legislation
New South Wales	<i>Law Enforcement (Powers and Responsibilities) Act 2002</i>
Victoria	<i>Crimes Act 1958; Magistrates Court Act 1989; Terrorism (Community Protection) Act 2003</i>
Queensland	<i>Police Powers and Responsibilities Act 2000</i>
South Australia	<i>Summary Offences Act 1953; Criminal Assets Confiscation Act 2005; Criminal Investigation (Extraterritorial Offences) Act 1984</i>
Western Australia	<i>Criminal Investigation Act 2006; Misuse of Drugs Act 1981; Criminal Property Confiscation Act 2000; Firearms Act 1973; Weapons Act 1999</i>
Tasmania	<i>Search Warrants Act 1997</i>
Northern Territory	<i>Police Administration Act 1978</i>
Australian Capital Territory	<i>Crimes Act 1900</i>

¹³⁰ Australian Criminal Intelligence Commission, *Biometric and forensic services* (2019) <<https://www.acic.gov.au/our-services/biometric-matching>> viewed 22 April 2020.

¹³¹ Ibid.



5.6.2 Can researchers access Aboriginal and Torres Strait Islander samples in museum collections?

Genomic researchers may consider the possibility of accessing genomic samples kept in museum collections. Museums can vary in their legal structure. They can be privately owned, a state government entity, or a Commonwealth government entity.

Whatever their particular legal structure, museum collection items, including items that contain the genetic material of Aboriginal or Torres Strait Islander peoples, are generally the legal property of that museum. However, this might not always be the case, and particular items might not be owned by the museum outright. For example, legal title to a collection item might be held by someone else, who has agreed to let the museum take custody of the item. At any rate, any researcher wanting to access collection items must negotiate with the museum. Museums are likely to have their own internal policies and procedures for handling such requests.

Australia has a complicated framework of cultural heritage laws. However, the cultural heritage laws that do exist, focus mostly on cultural heritage sites, or access movable or intangible cultural heritage via access to cultural heritage places. Generally, they have no direct application to items already within a museum collection.

Nevertheless, there are sections within cultural heritage legislation, that could relate directly or indirectly to cultural heritage held in museum collection. See Table 8 below.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Table 8: Summary of relevant cultural heritage law provisions

Laws	Relevant Provisions
Federal	
<i>Environment Protection and Biodiversity Conservation Act 1999</i>	Addresses environmental heritage only
Queensland	
<i>Aboriginal Cultural Heritage Act 2003</i>	<p>Section 15 of the Act transfers ownership of all Aboriginal human remains back to the people with the traditional or familial link to those remains. Where the human remains are currently held by a state entity (e.g. a state-owned museum) the traditional owners may consent to the museum retaining custody of the remains, or may choose to have them repatriated (s16).</p> <p>Where the person holding the remains is not a state government entity, they must take all reasonable steps to turn these remains over to the state's chief executive as soon as possible (s17).</p>
<i>Torres Strait Islander Cultural Heritage Act 2003</i>	Identical provisions as those above, though relating to remains of Torres Strait Islander peoples (s15-17)
<i>Queensland Heritage Act 1992</i>	n/a
Northern Territory	
<i>Heritage Act 2011</i>	<p>Human remains falls into the definition of Aboriginal or Macassan objects (s8(2) & s9). Being an Aboriginal or Macassan object, they are automatically designated as heritage objects within the Act (s18).</p> <p>The territory's Chief Executive Officer must give approval if any heritage object is to be removed from the state, but if it is an Aboriginal or Macassan archaeological object the CEO can only approve the request if the traditional owners consent (s89)</p>

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Laws	Relevant Provisions
<i>Aboriginal Sacred Sites Act 1989</i>	n/a
Western Australia	
<i>Aboriginal Heritage Act 1972</i>	The Act does not apply to collections held by the Museum. Instead the Western Australia Museum is governed by the <i>Museum Act 1969</i> (s6(2a)).
<i>Museum Act 1969</i>	n/a
<i>Heritage of Western Australia Act 1990</i>	n/a
South Australia	
<i>Aboriginal Heritage Act 1988</i>	<p>One of the functions of the Minister is to protect and preserve Aboriginal sites, objects and remains (s5(1)).</p> <p>The Aboriginal Heritage Committee advises the Minister on measures that should be taken for the protection or preservation of Aboriginal sites, objects or remains (s8(1)(a)(ii)).</p> <p>There are also Recognised Aboriginal Representative Bodies for specified areas, sites, objects and remains (s19B).</p> <p>The extent to which this Act applies to museum collections is unclear. There is a provision that requires anyone in ownership or possession of an Aboriginal object that is part of a public or private collection to take reasonable measures to protect that that object (s28).</p> <p>There is another provision that could possibly be applied to museums: Section 35 states that, unless otherwise authorised by the Act, a person must not, in contravention of Aboriginal tradition, divulge information relating to an Aboriginal site, object or remains. Perhaps this could be applied to argue that genetic information derived from Aboriginal human remains cannot be divulged contrary to Aboriginal tradition?</p>
<i>Heritage Places Act 1993</i>	Act specifically relates to non-Aboriginal heritage places



Laws	Relevant Provisions
New South Wales	
<i>National Parks and Wildlife Act 1974</i>	<p>The Act defines Aboriginal objects to include Aboriginal human remains, and so generally deals with them together in the terms of the Act.</p> <p>There is no general prohibition on the ownership of Aboriginal human remains.</p> <p>The Australian Museum Trust is to have custody of any Aboriginal objects (including Aboriginal human remains) that are in the possession of the Crown (s88).</p> <p>The majority of the Act is concerned with permit requirements for access Aboriginal places and sites that could contain Aboriginal human remains and the development of conservation agreements</p> <p>The functions of the Chief Executive include the promotion of such educational activities, and undertaking of such scientific research, in respect of Aboriginal objects and places, as the Chief Executive thinks fit (s8(4)).</p> <p>There is an Aboriginal Cultural Heritage Advisory Committee that is to advise the Minister and Chief Executive of any matter relating to the identification, assessment and management of Aboriginal cultural heritage.</p>
<i>Australian Museum Trust Act 1975</i>	Is exclusively about the establishment and governance of the Australian Museum
<i>Heritage Act 1977</i>	Act does not relate to Aboriginal cultural heritage
Victoria	
<i>Aboriginal Heritage Act 2006</i>	<p>The Act has detailed provisions on Aboriginal ancestral remains (meaning the whole or part of the bodily remains of an Aboriginal person). However, this definition excludes:</p> <ul style="list-style-type: none">• An object made from human hair or any other bodily material, and• Any human tissue lawfully removed from an Aboriginal person or otherwise dealt with by the <i>Human Tissue Act</i>

Laws	Relevant Provisions
	<p>1982 (VIC) or similar law related to the removal of human tissue</p> <p>Aboriginal ancestral human remains are included as part of Aboriginal cultural heritage, but not as Aboriginal objects.</p> <p>The Act recognises that as far as practicable, Aboriginal cultural heritage (including Aboriginal ancestral remains) should be owned by and returned to traditional owners of the area from which the Aboriginal cultural heritage is reasonably believed to have originated (s12(1)(a)).</p> <p>Within 2 years of the commencement of the Act, a public entity (e.g. state-owned museum) or university, must notify the Aboriginal Heritage Council of any Aboriginal ancestral remains that are in its possession (s14(1)).</p> <p>The public entity or university must take all reasonable steps to transfer the Aboriginal ancestral remains into the custody of the Council (s14(3)).</p> <p>The Council must consult with any Aboriginal person or body they believe may have an interest in the Aboriginal ancestral remains, and determine the appropriate course of action in relation to the remains (s18(2)(b)).</p> <p>Options available to them include:</p> <ul style="list-style-type: none">• Transfer of remains to any relevant traditional owners of the remains or any relevant registered Aboriginal party entitled and willing to take custody of the remains• Transfer to the Museums Board for safekeeping• Otherwise deal with the remains as appropriate (s20) <p>If the remains are transferred to the Museums Board, they will be lodged at the Museum of Victoria (s26(2)).</p>
<i>Museums Act 1983</i>	n/a
<i>Heritage Act 2017</i>	n/a

Tasmania

Laws	Relevant Provisions
<i>Aboriginal Heritage Act 1975</i>	Aboriginal human remains are included in the definition of relic. None of the sections specifically relate to Aboriginal human remains in public or private collections, but Section 13 does read that where a relic becomes part of the property of the Crown, the Director of National Parks and Wildlife may cause such scientific or other investigations of the relic, having regard to the advice of the Aboriginal Heritage Council, he considers necessary or desirable. It is unclear whether this includes objects in a state-owned collection.
<i>Historic Cultural Heritage Act 1995</i>	n/a

Australian Capital Territory

Heritage Act 2004 The Act does not refer to Aboriginal human remains.

The question about whether researchers can access museum collections to get Aboriginal or Torres Strait Islander genetic samples is quite complex. The law varies a great deal across the different state and territory jurisdictions. Many of the state Acts do not provide any specific guidance on that question, and the ones that do apply, do so only indirectly. For example, Victoria has a very detailed framework for the repatriation of Aboriginal ancestral remains. This will indirectly limit researcher access to Aboriginal human remains that could be sampled. However, it does not include objects made from human hair or other bodily material, which could also be a source for genetic material.

It is also worth underlining, that apart from the question of whether or not public or private collections are permitted to negotiate with researchers on providing access to genetic samples for research projects, the larger gap is that there is no legal framework that requires the decision be referred to and considered by the relevant community. This is not surprising given that these Acts were not written with Aboriginal and Torres Strait Islander genomics in mind. The provisions that do apply, do so incidentally; they are not intended to provide guidance in this area.

There is another Act, the *Protection of Moveable Cultural Heritage* that is relevant to address, although, as will be seen, it does not provide a great deal of legal guidance either.

The Protection of Moveable Cultural Heritage

The *Protection of Movable Cultural Heritage Act 1986* and the *Protection of Moveable Cultural Heritage Regulations 2018* regulates how movable cultural heritage is exported or imported into Australia. This is relevant when Aboriginal human remains, or objects containing human hair or tissue may be exported. However, it does not apply where sampling occurs within Australia, and the data is exported.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

The following is a quick overview of the process that would apply.

What objects are protected under the Act and Regulations?

Objects of Australian Aboriginal and Torres Strait Islander heritage are protected under this Act, when they fall into one of these categories:¹³²

- it is of cultural significance to Aboriginal or Torres Strait Islander peoples; or
- was made by Aboriginal and Torres Strait Islander peoples (and is not an object created specifically for sale); and
- is a Class A or Class B object.

Class A objects include:¹³³

- sacred and secret ritual objects;
- bark and log coffins used as traditional burial objects;
- human remains;
- rock art; and
- dendroglyphs.

Class B objects must meet the criteria above and be at least 30 years old and not adequately represented in Aboriginal or Torres Strait Islander community collections, or public collections in Australia.¹³⁴ This kinds of objects include:

- objects relating to famous and important Aboriginal or Torres Strait Islander people, or to other persons significant in Aboriginal or Torres Strait Islander history;
- objects made on missions or reserves;
- objects relating to the development of Aboriginal or Torres Strait Islander protest movements; and
- original documents, photographs, drawing, sound recording, film and video recordings and any similar records relating to objects included in this category.

There is a separate category for objects of decorative art. It does not include all forms of decorative art, but instead sets parameters based on date and value. For example, Aboriginal or Torres Strait Islander decorative art from pre-1901 valued at least \$AUD25,000 is considered a Class A object. Aboriginal or Torres Strait Islander ochre paintings that are on bark, composition board, wood, cardboard, stone or other similar supports, valued at least \$AUS20,000 are Class B objects.¹³⁵

What are the protections?

Class A objects cannot be exported without a certificate.¹³⁶

¹³² *Protection of Moveable Cultural Heritage Regulations 2018*, (Cth) Schedule 1, Part 1.

¹³³ *Ibid* r 1.3.

¹³⁴ *Ibid* r 1.4.

¹³⁵ *Protection of Moveable Cultural Heritage Regulations 2018*, (Cth), Schedule 1, Part 5.

¹³⁶ *Protection of Movable Cultural Heritage Act 1986* (Cth) s8(2)(a).



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Class B objects cannot be exported without a permit or certificate.¹³⁷

Certificates of exemption only apply where a person intends to import an Australia protected object for a temporary purpose, or when they will subsequently export the object.¹³⁸

Class B objects require a permit granted by the Minister to export. In making their decision, the Minister will consider whether the loss of that object would significantly diminish the cultural heritage of Australia.¹³⁹ A collecting institution (a museum) may apply to the Minister for a Class B permit on an item accessioned into their collection.¹⁴⁰ In first instance, the Minister will refer the application to the National Cultural Heritage Committee, that includes four representatives from different collecting institutions.¹⁴¹ In addition, the National Cultural Heritage Committee must include an Aboriginal or Torres Strait Islander person nominated by the Minister.¹⁴²

While Aboriginal human remains fall into the Class A category, there may be Aboriginal cultural objects that contain human hair or tissue, that may fall into Category B and could potentially be exported overseas by an Australian Museum, for example, in a travelling exhibition.

This section provided an overview of the application of heritage laws to genomic research, particularly situations in which researchers may access samples from museum collections. The gap analysis in **Section 6** will go into more detail about the extent to which these laws address the ethical and cultural issues associated with researchers accessing museum collections.

5.7 Health records laws

The My Health Record system operates under the *My Health Records Act 2012* and a number of subordinate rules and regulations. A key legislative change in 2015/2016 was that the system was to automatically create records for individuals unless they chose not to have one.¹⁴³

The System Operator will retain the records, from the date of collection until:

- 30 years after the death of the healthcare recipient; or
- if the System Operator does not know the data of death of the healthcare recipient, 130 years after the healthcare recipient's date of birth; or
- the healthcare recipient cancels their registration.¹⁴⁴

¹³⁷ Ibid s8(2)(b).

¹³⁸ Ibid s12(1).

¹³⁹ Ibid s10 (1),(6).

¹⁴⁰ Ibid s10A(1).

¹⁴¹ Ibid s17(1).

¹⁴² Ibid s17(1A).

¹⁴³ *My Health Records (National Application) Rules 2017* (Cth) s5; *My Health Records Act 2012* (Cth) Part 2, Schedule 1.

¹⁴⁴ *My Health Records Act 2012* (Cth) s17(2).



Indigenous Health Genomics: The Legal, Ethical and Social Issues

The *My Health Records Act* contains a privacy framework in-line with the *Privacy Act*.¹⁴⁵ Key amendments by the *My Health Records Amendment (Strengthening Privacy) Bill 2018* were intended to strengthen the privacy provisions around healthcare recipient's My Health Records. The new laws:

- allowed people to permanently delete their records (and any backups);¹⁴⁶
- prohibited by law access to My Health Records by anyone for insurance or employment purposes;¹⁴⁷ and
- required that law enforcement and other government agencies produce a court order to access information in a My Health Record¹⁴⁸

The *My Health Records Act* also sets out the functions of the System Operator, which includes, in accordance with the guidance and direction of the Data Governance Board, the preparation and provision for research or public health purposes of:

- de-identified data (no consent required); and
- health information (with the consent of the healthcare recipient).¹⁴⁹

From the commencement of the amendments, a copyright exception applies to health records, sound recordings and cinematograph films, subject to copyright.¹⁵⁰ This exception allows providers to use the record, sound recording or film in a way that would otherwise be a copyright infringement, if the act they are doing is:

- for the collection, use or disclosure of health information under the My Health Records system;
- in circumstances permitted by the *Privacy Act* in relation to health; or
- for any purpose relating to healthcare or the communication or management of health information prescribed by the regulation.¹⁵¹

This exception does not apply to health records, sound recordings or cinematograph films created before the commencement date of the provisions.¹⁵²

The Australian Digital Health Agency was established in 2015/2016 to strengthen digital health governance arrangements and performs many of the System Operator Duties.¹⁵³

The result of these provisions is that for many Aboriginal and Torres Strait Islander peoples, unless they have opted-out of the My Health Record system, will already have My Health Record. This record may well include genomic information. This genomic information may be

¹⁴⁵ Ibid s72.

¹⁴⁶ Ibid s17(5).

¹⁴⁷ Ibid s70A(1).

¹⁴⁸ Ibid s69A(1)&(5).

¹⁴⁹ Ibid s15.

¹⁵⁰ Ibid s45A & s45B; *Copyright Act* (Cth) s104C & s44BB.

¹⁵¹ *Copyright Act* (Cth) s104C & s44BB.

¹⁵² *My Health Records Act 2012* (Cth) s45A & s45B.

¹⁵³ Australian Government *Australian Digital Health Agency* (2020) <<https://www.digitalhealth.gov.au/about-the-agency>> viewed 27 April 2020.

available (in deidentified form) for research or public health purposes, and may be made available to law enforcement if they have a court order.

5.8 Managing research agreements

Many research projects will involve a framework of agreements between the parties, including:

- agreements between the research institution and a funder (e.g. a university research program funded by a government grant);
- the individual researcher, and their employer, the research institution (e.g. employee or contractor agreement);
- the Aboriginal or Torres Strait Islander donors and the research team (if research team engages donor and community directly);
- the data source provider (e.g. a biobank) and the research team (if the research team uses data from an existing source); and
- the Aboriginal or Torres Strait Islander donors and the data source provider.

See **Figure 9** illustrating the research agreement network.

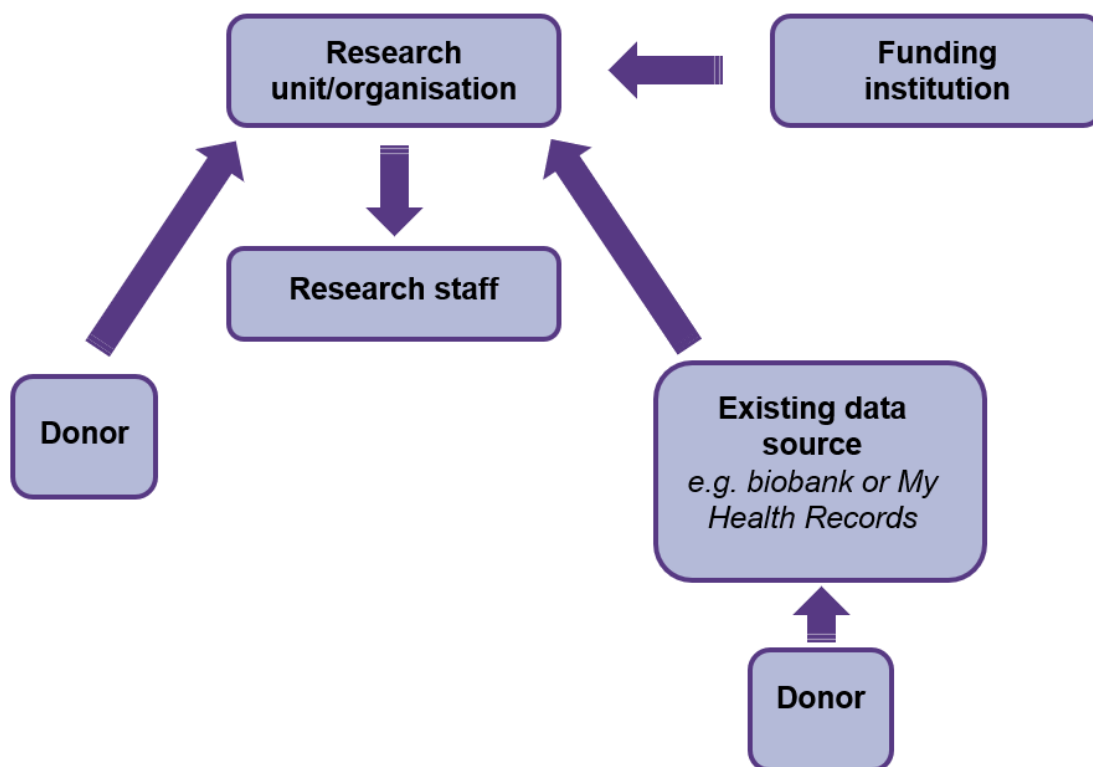


Figure 9: Research agreement network

The formality of the agreements may vary. Some may be written, some may be oral. The completeness of the consultation and consent process may also vary. For example, a research team may follow a best practice framework when engaging Aboriginal and Torres Strait Islander communities directly, and may form written agreements with the individuals

Indigenous Health Genomics: The Legal, Ethical and Social Issues

and community. Alternatively, the research team may access data from My Health Records, in circumstances where the donor may or may not be aware that their de-identified information is being shared for research purposes.

The parties' legal obligations will depend on the terms of the agreements. The principle of privity of contract means that generally only the parties to the agreement will be bound by the agreement.¹⁵⁴ So, for example, an employment agreement between researcher and university will legally bind the researcher and the university only. However, in practical terms, the terms of existing agreements will impact the parties' ability to commit themselves in subsequent agreements. For example, a funding institution may require that the results of a research project will be published online. This will impact the research organisation's ability to agree with the donor that results will only be published online after approval of the donor community following a review.

A question that frequently arose in discussion with the Advisory Group was the legal rights and responsibilities of the donor's successors and next of kin. Following the privity of contract principle, as general rule a person's successors or next of kin won't have any rights under a research agreement unless there has been some provision made in the research agreement. For example, a donor may name a personal representative to be contacted for any further consent after the donor has passed away.

There are some exceptions where family members or next of kin may have some on-going rights in relation to the tissue and data of a deceased donor. These exceptions are produced by specific applications of legislation. Below are several examples.

Example 1 Access to Health Records: the *Health Records and Information Privacy Act 2002* (NSW) allows an authorised representative to make decision on behalf of an individual who lacks capacity by reason of age, injury, illness, or physical or mental impairment.¹⁵⁵ An authorised representative has to be:

- an attorney for the individual under an enduring power of attorney;
- a guardian within the meaning of the *Guardianship Act 1987*;
- a person having responsibility for the individual if the individual is a child; or
- a person who is otherwise empowered under law to exercise any functions as an agent of or in the best interests of the individual.¹⁵⁶

However, note that under this Act "authorised representative" is defined by law, not by the community or the donor (unless the donor elected an enduring power of attorney). Even still, the Act only allows authorised persons to do certain things, for example, request access to health information about the individual.

¹⁵⁴ A common law principle. Leading case law authorities are *Trident General Insurance Co Limited v McNiece Bros Pty Ltd* (1988) 165 CLR 107 per Brennan J [9]-[10] & *Coulls v Bagot's Executor & trustee Co Ltd* (1967) 119 CLR 460 per Barwick CJ [31]-[32].

¹⁵⁵ *Health Records and Information Privacy Act 2002* (NSW) s7.

¹⁵⁶ *Ibid* s8.



Example 2 authority to authorise organ donation: Under the *Human Tissue Act 1982* (VIC) a senior available next of kin (spouse, parent or sibling) may have authority to consent to the removal of tissue from the body of a deceased person for the purpose of transplant or the use of the tissue for other therapeutic, medical or scientific purposes.¹⁵⁷ In the absence of consent from the senior available next of kin, a hospital may still remove the tissue if the donor had consented to the removal prior to their death, or the hospital is unable to ascertain the existence or whereabouts of the next of kin of the deceased person.¹⁵⁸ Nevertheless, if the donor, during their lifetime expressed in writing an objection to removal of tissue, or during their last illness orally expressed, in the presence of 2 witnesses, an objection to the removal of tissue, then the hospital is not permitted to remove the tissue, whether or not a next of kin can be found.¹⁵⁹

Even in the absence of an objection and an available next of kin, a hospital requires evidence of the donor's consent during their lifetime, either in writing or witnessed by two people, if expressed orally.¹⁶⁰

So in fact, under these rules, if the individual consents, prior to their death to, donate tissue for medical or scientific practices after their decease, that's an end to the matter. These rules do not require further additional consent from family.

Note: Remember that the definition of 'personal information' under the *Privacy Act* excludes deceased persons. Therefore, none of the individual rights recognized by the Australian Privacy Principles pass to the deceased's next of kin or family, when they pass away.

5.9 Documenting consents

5.9.1 Documenting consents in the doctor/patient relationship

In our discussions with the Advisory Group, it appeared that Aboriginal and Torres Strait Islander genomic samples, were most frequently obtained in a clinical setting (e.g where an individual visits their doctor or specialist). The patient may consent to a diagnostic test, and they may additionally consent to their sample or data being retained and used for research purposes at a later date.

Section 5.3 outlines the legal obligations of medical professionals when administering treatment to Aboriginal and Torres Strait Islander peoples, including when consulting and consenting to take a genomic sample.

This section looks specifically at the record keeping requirements of that process.

¹⁵⁷ *Human Tissue Act 1982* (VIC), s26(1).

¹⁵⁸ *Ibid* s26(1).

¹⁵⁹ *Ibid* s26(3).

¹⁶⁰ *Human Tissue Act 1982* (VIC), s26(1)(c).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

The states and territories have human tissue legislation which generally requires consent from individuals for removal of tissue (including blood) to be in writing following an explanation of the nature and effect of the removal.¹⁶¹

In practical terms, adequate record keeping is an indirect requirement of the doctor's legal obligations to their patients: records are the most effective way of demonstrating what was discussed and what was consented to. Detailed records are also necessary for doctors to follow through on-going obligations to the patient and for future reference by other doctors and researchers.

It is likely that most medical services will have medical record keeping policies and procedures that the staff will be required to follow as part of their duties as set out in their employment contract.

The My Health Records provisions are discussed in detail in **Section 5.7** Health records laws. They may be relevant in this context if the Aboriginal or Torres Strait Islander patient is registered for a My Health Record. In which case, their consent to their diagnostic test, and their results, would likely be recorded there, and therefore readily accessible by healthcare providers with access to My Health Records.

The clinical setting is not the only context in which Aboriginal and Torres Strait Islander samples are obtained by researchers. They may be from existing collections in museums or universities, or through commercial enterprise, for example, sites such as Ancestry.com.

5.9.2 Documenting consents when samples are obtained from existing collections

In the case of researchers accessing samples from museums or university collections, this would be a transaction between the museum/university and the research institution. Unless required by an ethics review framework or other policy, neither the individual nor the community would be represented. The legal obligations of museums when providing researcher access to genetic material within their collection is discussed in **Section 5.6.2**.

That said, many museums and universities are looking toward policy and best practice guidelines. With these policies and guidelines in place they can be given legal effect through contracts such as consent release forms or collaboration agreements. Funding agreements also have the power to make best practice compliance a contractual obligation on the researcher. This best practice policy may include specific requirements about consultation and community consent requirements. In which case, the museum would have a legal duty to obtain (and document) consent. But it is important to remember that contractual rights, are individual – the legal obligations only bind the parties who agreed to the terms. It is not a general legal duty.

¹⁶¹ *Human Tissue Act 1983* (NSW) s19.

5.9.3 Documenting consents when samples are obtained by private companies

When an Aboriginal or Torres Strait Islander person agrees to provide a sample to a private company, such as Ancestry.com, the legal view is that this a private arrangement between the individual and the company. Most likely these kind of companies will have a pro-forma agreement template that this individual signs, documenting their consent. It is likely that the consent will be broad and will include secondary uses.

5.10 Right of access to medical benefits & health outcomes

The right of access to medical benefits and the right to not be discriminated against based on your genes are linked in several ways. If Aboriginal and Torres Strait Islander people do not receive the medical outcomes made possible by precision medicine, this amounts to discrimination. Whether the cause of the lack of access was due to (a) lack of procedures to collect data in a culturally appropriate way; or (b) lack of culturally appropriate ways to deliver health outcomes the result is discrimination. See **Figure 10** below that demonstrates this two-stage barrier to delivery of health outcomes.

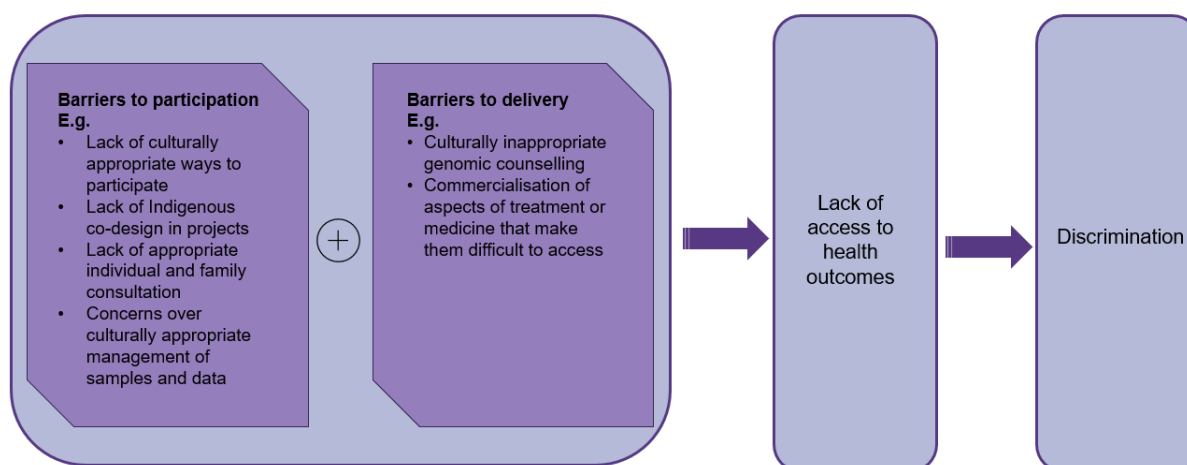


Figure 10: Barriers to delivery of health outcomes amounts to discrimination

If Aboriginal and Torres Strait Islander peoples are wary of participating in genomic studies based on a fear they will be discriminated against, this will mean they remain under-represented in genomic science, which again means lack of access to health outcomes and ultimately discrimination.

For the reasons explained above, laws against discrimination are the most relevant to Aboriginal and Torres Strait Islander peoples' rights to health outcomes.

The Federal Parliament's power to make laws that bind the states and territories is based on s51 of the Australian Constitution. None of the s51 powers specifically states 'anti-discrimination' and so the authority to make laws in this area has been based on a number of other powers including s51(xxix) external affairs powers.¹⁶² This High Court as interpreted

¹⁶² ALRC *Essentially Yours* (n 40) 291.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

s51(xxix) to mean that Federal parliament can make such laws as are required to comply with international obligations.¹⁶³ However, until enacted into Australian legislation, international law is not legally binding in Australia. For this reason this section will look specifically at Australian law, while **Section 9** will look at international law relevant to equity in access to health outcomes, and prevention of discrimination.

At the Commonwealth level Australia has the *Racial Discrimination Act 1975*. Complaints of racial discrimination can be made to the Australian Human Rights Commission.¹⁶⁴

In addition, states and territories have their own legal regimes. See the table below for a summary of the relevant state and territory acts.

Table 9: State and territory racial discrimination legislation

State	Relevant legislation	Complaints authority
New South Wales	<i>Anti-Discrimination Act 1977</i>	Anti-Discrimination, New South Wales
Victoria	<i>Racial and Religious Tolerance Act 2001; the Charter of Human Rights and Responsibilities; Equal Opportunity Act</i>	Victorian Equal Opportunity and Human Rights Commission
Queensland	<i>Human Rights Act 2019; Anti-Discrimination Act 1991</i>	Queensland Human Rights Commission
South Australia	<i>Equal Opportunity Act 1984; Racial Vilification Act 1996; racial victimisation provisions in Civil Liability Act 1936</i>	Equal Opportunity Commission
Western Australia	<i>Equal Opportunity Act 1984</i>	Equal Opportunity Commission
Tasmania	<i>Anti-Discrimination Act 1998</i>	Equal Opportunity Tasmania
Northern Territory	<i>Anti-Discrimination Act 1992</i>	Northern Territory Anti-Discrimination Commission
Australian Capital Territory	<i>Discrimination Act 1991; the Human Rights Act 2004</i>	ACT Human Rights Commission

Generally, discrimination may be unlawful when it meets these 4 criteria:

¹⁶³ *Commonwealth v Tasmania* (1983) 158 CLR 1.

¹⁶⁴ *Australian Human Rights Commission* (2020) <<https://www.humanrights.gov.au/our-work/aboriginal-and-torres-strait-islander-social-justice>> viewed 23 April 2020.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

- 1) It is based one of the grounds sets out in the legislation, in this case, racial discrimination;
- 2) **The discrimination must fall within an area of activity set out in the legislation** e.g. provision of goods and services, e.g. delivery of medical services;
- 3) **The discrimination must result in some harm or less favourable treatment**, whether by direct or indirect discrimination. In this context, harm can (and does) occur when Aboriginal and Torres Strait Islander peoples are prevented from accessing positive health outcomes. Harm is not just caused by missed opportunity but also by inappropriate medical treatment or misdiagnosis because data and treatments have a European bias; and
- 4) The discrimination must not fall within an exception, exemption or defence.¹⁶⁵

Australian law recognises two forms of discrimination¹⁶⁶:

- 1) **Direct discrimination:** Someone is treated less favourably based on that person's attribute. The reason behind this discrimination is irrelevant,¹⁶⁷ and
- 2) **Indirect discrimination:** also referred to as 'adverse impact' it focuses on the effect of the discriminator's actions.¹⁶⁸

5.10.1 Australian Human Rights Acts

In addition to anti-racial discrimination and equal opportunity acts, Victoria, Queensland and the Australian Capital Territory have some form of human rights legislation.

Section 27 of the Australian Capital Territory's *Human Rights Act 2004* specifically relates to Aboriginal and Torres Strait Islander peoples. It recognises Aboriginal and Torres Strait Islander peoples' rights to maintain, control, protect and develop their cultural heritage, languages and knowledge, and kinship ties.¹⁶⁹ It also recognises their right to have material and economic relationships with the land and waters and other resources with which they have a connection under traditional laws and customs.¹⁷⁰ This could potentially include genetic knowledge, especially given that a note on the Act reads that the primary source of the rights in that section, is the United Nations Declaration on the Rights of Indigenous Peoples art 25 and 31 (art 31 specifically refers to genetic resources).¹⁷¹

Queensland's *Human Rights Act 2019* also recognises Aboriginal and Torres Strait Islander peoples' right to enjoy, maintain, control, protect, and develop their kinship ties.¹⁷² Again, this could well apply to Aboriginal and Torres Strait Islander genomic information.

¹⁶⁵ *ALRC Essentially Yours* (n 40) 293.

¹⁶⁶ *Ibid*, 295.

¹⁶⁷ See for example the *Anti-Discrimination Act 1998* (Tas) s14.

¹⁶⁸ See for example *ibid*, s15.

¹⁶⁹ *Human Rights Act 2004* (QLD) s 27(2)(a).

¹⁷⁰ *Ibid* s 27(2)(b).

¹⁷¹ Declaration on the Rights of Indigenous Peoples, GA Res 61/295, UN GAOR, 61st sess, 107th plen mtg, UN Doc A/RES/61/295 (13 September 2007) art 31.

¹⁷² *Human Rights Act 2019* (QLD) S28(2)(c).



Victoria has a similar provision to the Queensland Act, although it only refers to maintenance of kinship ties which may not be quite as strong as the Queensland right.¹⁷³

5.11 Biobanks and genomic data storage areas

Australia has no biobank or genomic data storage specific legislation. This impacts the transparency and clarity of how Indigenous health related genomics information is stored and used, and ultimately the uptake on it by Aboriginal and Torres Strait Islander communities. The term 'biobank' is an umbrella term to describe 'any collection of biospecimens or human genetic information that can be used for research purposes'.¹⁷⁴ The *Essentially Yours* report also uses the terminology 'human genetic research databases'.¹⁷⁵

Some distinguishing features of biobanks is that they are often associated with the public interest and have established governance procedures that protect individual participants interests through human research ethics committees.¹⁷⁶ In Australia, they are generally smaller-scale multi-research facilities. Given a variety of characteristics and terminology, a consensus on a single definition unachievable.

The regulatory framework of biobanks and genomic data storage is a complex web of laws, policies, guidelines and codes of practice from a mix of state, national and international laws. Whether a facility is a biobank or for genomic data storage is not always straightforward. As these distinctions overlap, these questions must be addressed on a case by case basis.

In 2010, the National Health and Medical Research Council published the *Biobanks Information Paper*. This paper discusses in detail information pertaining to the establishment, management and governance of biobanks in Australia. There has been little follow up with guidelines or regulations to implement the recommendations in this sector, with Aboriginal and Torres Strait Islander participation remaining low.¹⁷⁷

5.11.1 Legal and policy framework

Legislation

Biobanks are subject to legislation regarding human tissue, privacy, intellectual property and anti-discrimination laws. Laws relating to contract, medical negligence and confidentiality, also apply.

At a Commonwealth level, the *Privacy Act* as discussed above at **5.2 Privacy and Personal Information**, in addition the relevant State based privacy legislation applies to the handling of the health information and sensitive information. Private biobanks that are corporations,

¹⁷³ *Charter of Human Rights and Responsibilities Act 2006* (Vic) s19(2)(c).

¹⁷⁴ NHMRC (National Health and Medical Research Council), *Biobanks Information Paper* (Report, February 2010) 8.

¹⁷⁵ *ALRC Essentially Yours* (n 40) 471.

¹⁷⁶ NHMRC (National Health and Medical Research Council), *Biobanks Information Paper* (Report, February 2010) 7.

¹⁷⁷ Imogen Elsum, et al, 'Inclusion of Indigenous Australians in biobanks: a step to reducing inequity in health care' (2019) 11 *Medical Journal of Australia* 7, 9.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

not Government owned fall under Commonwealth legislation and are subject to the *Corporations Act*.

The relevant Human Tissue Acts across the States govern the donation and use of human tissue from living and deceased individuals for both therapeutic and non-therapeutic purposes. The Acts deal with how tissue is donated and attained by organisations, expressly prohibiting the trading of human tissue except for therapeutic purposes, medical purposes or scientific purposes.¹⁷⁸ State and territory Human Tissue Acts do permit the donation of human tissues for research.¹⁷⁹

Policies and Guidelines

As with all human research, the *National Statement* (see below at 7.1) in particular *Chapter 3.2 Human biospecimens in laboratory based research* and *Chapter 3.3 Genomic Research* provide guidelines for biobanks to follow.¹⁸⁰ In addition, some States have their own standards and guidance on consent requirements. For example, the NSW Health Statewide Biobank Consent Toolkit is required to be used by the NSW Statewide Biobank and encouraged to be used by any NSW research biobank.¹⁸¹ This suggests that although operating within NSW, unless a State owned entity, privately run biobanks would be bound by Commonwealth legislation in addition to the *National Statement*.

International Guidelines

The United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Declaration on Human Genetic Data* requires that individuals and entities ensure the accuracy, reliability, quality and security of these data and the processing of biological samples with regard to ethical, legal and social implications.¹⁸²

Governance Frameworks

Internal governance frameworks are the best determinant of who owns data and material. The *National Statement* recommends that when multiple researchers collaborate on a project, or analysis of data, that they should agree on the

custodianship, storage, retention and destruction of those materials, as well as to rights of access, rights to analyse/use and re-use the data or information and the right to produce research outputs based upon them.¹⁸³

¹⁷⁸ *Human Tissue Act 1983* (NSW) s 34(1)(a)–(b) and cognate state and territory legislation.

¹⁷⁹ *Ibid*; *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); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

¹⁸⁰ *The National Statement* (no 44) Chpt 3.2.

¹⁸¹ NSW Health, 'Biobanking' <<https://www.medicalresearch.nsw.gov.au/biobanking/>> (Accessed 03 July 2020).

¹⁸² *International Declaration on Human Genetic Data*, 32 C/Res 22 UNESCO 39 (16 October 2003) Article 15.

¹⁸³ *The National Statement* (no 44) para 3.1.44.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

The NSW Statewide Biobank states that ownership of samples from legacy collections is decided by the Human Research Ethics Committee approval for a specific study.¹⁸⁴ Ownership will typically reside with the study investigators and the investigators will determine who can use them on a case-by-case basis.¹⁸⁵

Concluding remarks

Ownership of human tissue and genomic data from biobanks are subject to the specific agreements between donors, researchers, and the biobank itself. This places the onus on the institutions to set the frameworks of how benefits are shared and knowledge is obtained and used. A study published in 2019 found that biobanks in Australia lacked practices and policies to guide the inclusion and engagement of Aboriginal and Torres Strait Islander peoples in Biobanks.¹⁸⁶ Whilst the importance of Aboriginal and Torres Strait Islander representation was recognised, biobanks were 'remiss in how to achieve this'.¹⁸⁷ This is reflective of a broader lack of direction of Indigenous health genomic policy and specific biobank legislative framework. This however provides ample opportunity for the establishment of best practice guidelines that set a high standard for Aboriginal and Torres Strait Islander participation in biobanks.

6 Gap Analysis: Impact of the law on social and cultural issues

6.1 Do Aboriginal and Torres Strait Islander people own their genes?

Questions of ownership largely come back to the agreements entered into by the individual, community and researchers. Speaking broadly, proper consultation and prior informed consent should result in parties understanding who owns the information and who is entitled to results.

The data produced, absent a specific agreement that discusses ownership between parties, is most likely owned by the researchers, funding party or health organisation. As discussed in **Section 5.1** the party that applies changes through processing, analysing and documenting the results of a sample, will often have copyright over the material expression of the data. Whilst data may be, and should be shared with participants, pending an agreement to that effect, it is unlikely that ownership will rest with the individual.

¹⁸⁴ NSW Health Statewide Biobank, *NSW Health Statewide Biobank FAQ's for Researchers*, 4. Available at <https://biobank.health.nsw.gov.au/wp-content/uploads/2019/07/NSW-Health-Statewide-Biobank-FAQs-for-researchers-Feb-2017_FINAL.pdf>.

¹⁸⁵ Ibid.

¹⁸⁶ Imogen Elsum, Callum McEwan, Emma E Kowal, Yvonne Cadet-James, Margaret Kelaher and Lynn Woodward, 'Inclusion of Indigenous Australians in biobanks: a step to reducing inequity in health care' (2019) 11 *Medical Journal of Australia* 7,8.

¹⁸⁷ Ibid 8.



6.2 Do the privacy laws that regulate accessing and sharing genomic data provide enough protection for Indigenous genomics?

Privacy laws protect Indigenous genomics insofar as they relate to identified material. Based on the current approach by the Australian Privacy Principles, there are no specific guidelines that relate to Aboriginal and Torres Strait Islander genomic information. As such, privacy laws do not protect de-identified Aboriginal and Torres Strait Islander genomic information.

However, for identified material the protections afforded to individuals provide limited exceptions for the disclosure of identified material outside of the consent guidelines. Some exceptions in the Australian Privacy Principles that allow non-consensual use of data (e.g. via court order) leave gaps in the protection of Aboriginal and Torres Strait Islander genomic information. The Advisory Group spoke of these concerns. This shows not only the seriousness of the consent procedures, but also the distrust in the police system. This is part of a wider concern about potential misuse of genetic material by government through court order, with concerns arising around the use in native title applications or a possible register for Aboriginal and Torres Strait Islander peoples.

6.3 Are Aboriginal and Torres Strait Islander people getting fair access to health outcomes?

Fair access to health outcomes is based on a number of varying factors. In a research setting, fair access to health outcomes can take many years to eventuate, however, projects involving Aboriginal and Torres Strait Islander communities should consult and co-develop with communities, and as such, fair access to health outcomes would be defined by the community based on the situation. The Genomics Partnership Guidelines developed by the QIMR Berghofer, if followed can result in fair access to health outcomes for Aboriginal and Torres Strait Islander peoples. Overall, in a research setting, fair access to health outcomes are project specific, and not all projects are conducted ethically or characterised by co-development, prior informed consent and consultation.

However, based on research and consultations, in a clinical setting, it is likely that Aboriginal and Torres Strait Islander peoples are not getting fair access to health outcomes if they are not embedded as part of a project. Often in the case of rare disease or genetic disorders, Aboriginal and Torres Strait Islander families don't get the same clinical or support services that other families get, in both remote and non-remote communities. The issues are well known. Individuals or whole families can get diagnosed with a disease and they won't get proper clinical service because no one goes out of their way to ensure that they are adequately taken care of. For those that are in remote communities, there are often excuses around difficult logistics, however for many families, because Aboriginal and Torres Strait Islander communities are so relational, there is sometimes a suspicion around joining support groups where they do not know anyone. For the support groups in the cities, the groups may not have any issues finding individuals to join, whether they are Aboriginal or Torres Strait Islander or not. For Aboriginal and Torres Strait Islander patients though, the initial reluctance to join is taken by some support groups as a disinterest and so there will be no further attempts. Some support services fail to understand that Aboriginal and Torres Strait Islander groups are more community focused groups, rather than consumer groups

and so specialist clinics and support groups should go the extra mile as some Aboriginal or Torres Strait Islander patients might be shy.

The Advisory Group raised issues around genetic literacy in the clinical setting. Part of fair access to health outcomes, is understanding the condition one may have and improving their knowledge of the area so that they can inform their family if they possess similar predispositions. It was found in genetic counselling and community education, knowledge of rights and of conditions was lacking and of great need. Health outcomes should include knowledge of conditions and the rights that people have in regard to their genomic information, and at the present moment. Aboriginal and Torres Strait islander peoples are not receiving this.

6.4 Does the law promote (or impede) Aboriginal and Torres Strait Islander co-design and management of genomic projects?

Aboriginal and Torres Strait Islander peoples' genomes (the physical samples and the data derived from them) form part of their cultural heritage and part of their Indigenous Cultural and Intellectual Property (ICIP). To date, ICIP is not legally recognised in any Australian law.

Genomic science is outpacing legal reform – tomorrow's science is being regulated by yesterday's law. This is made more complicated by the fact that yesterday's law has a strong bias toward European ways of thinking about the body, the individual, and personal information. As outlined above, it does not recognise ICIP. Instead the current legal approach tends to focus on the balance between:

- 1) **Preserving the rights of the individual:** Legal regimes fixate on the informed consent of the individual. As result, many legal regimes make provision for proper disclosure and capacity to consent. For example, the Human Tissue legislation across the states have provisions setting age requirements for capacity to consent (e.g. if the patient is underage, then the parents must give consent). Again, in Privacy law, there is a complicated framework setting out scope of consent, and consent for primary and secondary uses; and
- 2) **Curtailling individual rights for the greater good:** The 'greater good' tends to be improved medical outcomes, law enforcement, and contribution to human knowledge generally. For example, the privacy law exceptions that allow access to data without the consent of the individual.

The greater good focuses on Australian society generally or even humanity as a whole. It does not recognise the cultural concerns of Aboriginal and Torres Strait Islander communities. The law has also followed the European bias that bodily samples, once separated from the body are mostly medical waste, and only the data is valuable.

There is nothing in the law that compels or motivates the genomics industry to promote Aboriginal and Torres Strait Islander co-design or management of projects. So as momentum behind genomic science builds, and the science is governed by law with strong European bias, this lack of impetus amounts to an impediment. As a result of the lack of legal requirement for Aboriginal and Torres Strait Islander co-design or management of

Indigenous Health Genomics: The Legal, Ethical and Social Issues

genomics projects, this area of science is mostly left to best practice policies and procedures developed in industry.

The exception to this may come in the state based Human Rights Acts in the ACT, Queensland and Victoria. The recognition of Aboriginal and Torres Strait Islander peoples' rights to control and manage kinship ties could extend to a right to be involved in the management of the genomic data those kinship ties follow. If that is the case, then denial of their right to manage those kinship ties and genomic information might amount to discrimination, and therefore be actionable through the state's complaints bodies.

6.5 How is community consultation impacted?

Many Aboriginal and Torres Strait Islander concerns about genomic study are unique from genomic study more generally. While the law addresses the rights of individuals to provide consent for genomic study, it generally does not take into account cultural well-being concerns and it does not recognise any links between cultural and mental health and physical health. There is also nothing in the law that considers cultural responsibilities or Aboriginal and Torres Strait Islander peoples on-going connection to their sample materials.

This raises the question: is there a legal requirement for project proponents to consult Aboriginal and Torres Strait Islander communities, so that these unique concerns become visible to projects? Unfortunately not. The focus on individual consent is to the exclusion of community concerns and terms that require proper disclosures to be made to a patient (for example, the human tissue legislation, or the ACL) does not include providing the individual time to return to their family to discuss the implications of the consent.

The impact of the law is that community is frequently not consulted. Community consultation provisions are largely left to policies and best practice guides.

6.6 Is the legal standard for consent enough to meet ethical and cultural needs?

As has already been referred to, all consultation and consent models are based on the individual. The law does not explicitly recognise community interest and rights in genomic research. In short, the law alone does not provide consent requirements that either requires consent from the community directly, or empowers Aboriginal and Torres Strait Islander individuals to connect with community and discuss their consent with them. For the most part, where legislation refers to standards of consent, it does not directly obstruct individuals from returning to community to discuss their consent. For example, if there is a research project collecting samples directly from Aboriginal and Torres Strait Islander individuals, there is nothing in the law preventing the individuals from discussing the project with their family before they decide to participate.

However, the counter example to that, would be the increasingly common practice of rolling clinical and research consent into a single step, when a doctor recommends a patient take a diagnostic test. If the doctor asks for consent to the test and retain the sample for research purposes all at once, then the patient has had no opportunity to think over the consent and discuss it with family. This will become more of an issue as the clinical/research divide continues to blur.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

There is a potential concern around the consent standards for the My Health Records. The My Health Records framework was discussed in detail in **Section 5.7 Health records laws**. As was seen there, there is actually quite a lot of potential access to data, most of it deidentified. However, the My Health Records laws allows for retention of the records for up to 30 years after the death of the individual, while Privacy Laws cease to apply on the death of the individual. There is therefore a potential period of time, after the death of the individual, when their health records would not be subject to privacy laws. Although, they would still need to be handled in accordance with the My Health Records legislation and its specific privacy provisions.

7 Policy

In the absence of specific laws to regulate Indigenous genomic projects, there are a number of key policies that attempt to deal with many of the social, ethical and cultural issues that arise in Aboriginal and Torres Strait Islander genomics. The *National Statement on Ethical Conduct in Human Research* and the *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Communities*, both published by the National Health and Medical Research Council, are key examples. Also, in the clinical setting, there are policies and guidelines have been developed.

While these policies and guidelines are not legislative, these documents are potentially legally enforceable. For example, through contract law, research agreements between a university and an Aboriginal or Torres Strait Islander community organisation can make compliance with policies a condition of the agreement.

Policies, protocols and guidelines also create industry norms. Below is an overview of the key policies, protocols and guidelines that apply to Aboriginal and Torres Strait Islander research, and therefore, apply to genomic research involving Aboriginal and Torres Strait Islander peoples and their genes.

7.1 *National Statement on Ethical Conduct in Human Research* (2007, updated 2018), National Health and Medical Research Council (NHMRC)

7.1.1 *What is it?*

The *National Statement on Ethical Conduct in Human Research* was first developed in 2007 jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

The *National Health and Medical Research Council Act 1992* (Cth) established the National Health and Medical Research Council whose role includes 'to foster consideration of ethical issues relating to health'.¹⁸⁸ The NHMRC Council is required to have one member with

¹⁸⁸ *National Health and Medical Research Council Act 1992* (Cth), s. 3(d).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

expertise in Aboriginal and Torres Strait Islander health needs, and also a member with expertise in human research ethics.¹⁸⁹

The *National Health and Medical Research Council Act 1992* provided that the CEO may issue human research guidelines.¹⁹⁰ The Act sets out the process for developing the guidelines with the Australian Health Ethics Committee (AHEC). There is a complaints process outlined in the Act.¹⁹¹

7.1.2 Who does it apply to?

The *National Statement* applies to:

- any researcher conducting research with human participants;
- any member of an ethical review body reviewing that research;
- those involved in research governance; and
- potential research participants.¹⁹²

In short, it is leading nationally applicable ethical standard setting document for research conducted with or about people, or their data or tissue.¹⁹³

Importantly, the *National Statement* emphasises not just the duties of researchers, but also the duties of institutions to the ethical conduct of research they fund, or are otherwise involved in.¹⁹⁴ This includes governments, industry, private individuals, organisation and networks of organisations.¹⁹⁵

It is intended to be read in conjunction with *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (Section 7.2)*; *Keeping research on track II (Section 7.3)* and *Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS) (Section 7.5)*.

7.1.3 Overview of provisions

The *National Statement* recognises the unique concerns of Aboriginal and Torres Strait Islander peoples and acknowledges that design and conduct of research involving Aboriginal or Torres Strait Islander peoples must adapt to the requirements of the context. Any research that involves Aboriginal or Torres Strait Islander peoples must be reviewed by a Human Research Ethics Committee, and will never fall into the 'low risk' or 'negligible risk' categories that might justify a lower level of ethical oversight.¹⁹⁶

The *National Statement* further requires that the Human Research Ethics Committee that reviews the research include assessment by, or advice from, people who have networks with Aboriginal and Torres Strait Islander peoples, knowledge of Aboriginal and Torres Strait

¹⁸⁹ Ibid s. 20(2)(d) and (g)(vii).

¹⁹⁰ Ibid s 10.

¹⁹¹ Ibid Part 8.

¹⁹² *The National Statement* (no 44) 1.

¹⁹³ Ibid 3.

¹⁹⁴ Ibid 4.

¹⁹⁵ Ibid 6.

¹⁹⁶ Ibid 78.

Islander research and people familiar with the cultural and practices of the relevant Aboriginal or Torres Strait Islander group.¹⁹⁷

7.2 Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders, National Health and Medical Research Council (NHMRC)

7.2.1 What is it?

The NHMRC has also published an ethics document entitled *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders*.¹⁹⁸ First published in 2003 and then updated in 2018, these Guidelines build on the provisions of the *National Statement (Section 7.1)* to address specific issues in relation to research that involves Aboriginal and Torres Strait Islander peoples.

7.2.2 Who does it apply to?

The Guidelines apply to researchers and ethics review bodies, as well as Aboriginal and Torres Strait Islander peoples and individual research participants and groups more generally.¹⁹⁹

7.2.3 Overview of provisions

The Guidelines recognise that it is important that research with Aboriginal and Torres Strait Islander peoples is led by the Aboriginal and Torres Strait Islander communities in which the research is taking place.²⁰⁰ The Guidelines recognise 6 core values:

- 1) **Spirit and integrity:** respectful behaviours and maintaining cultural continuity²⁰¹
- 2) **Cultural continuity:** maintaining bonds between people, their environment and their cultural knowledge²⁰²
- 3) **Equity:** demonstrating fairness and justice that enables Aboriginal and Torres Strait Islander people to be respected, to avoid discrimination and recognises culture, history and knowledge²⁰³.
- 4) **Reciprocity:** recognising the contributions of all project participants, ensuring equitable return of benefit²⁰⁴
- 5) **Respect:** This includes respecting difference, self-awareness about one's own beliefs and recognising and supporting everyone's contribution to a project. Importantly, this

¹⁹⁷ Ibid 78.

¹⁹⁸ National Health and Medical Research Council, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders*, (Australian Government, Canberra, 2018) available from <www.nhmrc.gov.au>.

¹⁹⁹ Ibid 2.

²⁰⁰ Ibid 2.

²⁰¹ Ibid 4.

²⁰² Ibid 4-5.

²⁰³ Ibid 67.

²⁰⁴ Ibid 7-8.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

includes engaging with Aboriginal and Torres Strait Islander communities and institutional structures when seeking ethics approval.²⁰⁵

- 6) **Responsibility:** negotiating and planning a research project with Aboriginal and Torres Strait Islander peoples that empower them to follow their cultural responsibilities to caring for country, kinship bonds, and caring for others.²⁰⁶

In applying these principles to specific projects, the Guidelines state that the manner of their implementation will be determined by the representative community/organisation that takes part in the research.²⁰⁷ Importantly, the Guidelines also note that Aboriginal and Torres Strait Islander peoples have the right to own and control their cultural and intellectual property. This includes more holistic forms of knowledge and cultural property that is recognised by Australia's intellectual property laws. Therefore, research agreements should make appropriate provision for on-going ownership and control of Aboriginal and Torres Strait Islander cultural and intellectual property.²⁰⁸

7.3 Keeping Research on Track II, National Health and Medical Research Council (NHMRC)

7.3.1 What is it?

Keeping Research on Track II is a companion document to the *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities* (Section 7.2).²⁰⁹

7.3.2 Who does it apply to?

The intended audience is primarily Aboriginal and Torres Strait Islander research participants and communities.²¹⁰

7.3.3 Overview of provisions

Keeping Research on Track II builds on the six core values set out in the Guidelines (Section 7.2.3) and sets out a rights based approach to participation in research including the right to self-determination, the right to free, prior informed consent, the right to have input into the research agenda, the right to seek advice and support to negotiate a written research agreement, and the right to make a complaint if something goes wrong. It then gives the audience an overview of the eight steps of a research project including:

- 1) building relationships;
- 2) developing the research idea;
- 3) developing the project and seeking agreement;
- 4) data collection;

²⁰⁵ Ibid 8-10.

²⁰⁶ Ibid 11-12.

²⁰⁷ Ibid 3.

²⁰⁸ Ibid, 17.

²⁰⁹ National Health and Medical Research Council, *Keeping Research on Track II*, (Australian Government, Canberra, August 2018) <<https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii>>.

²¹⁰ Ibid, 4.



- 5) analysing the data and making sense of the findings;
- 6) report writing;
- 7) sharing and translating the results into action; and
- 8) learning from experience.

The document recommends that the negotiated research agreement should cover copyright and intellectual property management as well as data collection, ownership, analysis and storage.²¹¹

7.4 Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research, National Health and Medical Research Council (NHMRC)

7.4.1 What is it?

Road Map 3 is a 10-year strategic plan to improve Australia's Aboriginal and Torres Strait Islander peoples' health through research. It is the third of its kind.

7.4.2 Who does it apply to?

NHMRC is Australia's leading expert body in health and medical research. They set industry standards for ethical research. Making their 10-year strategic plan to improve the conduct and management of research involving Aboriginal and Torres Strait Islander peoples, sets the bar for researchers, ethics review bodies, those involved in research governance and research participants.

7.4.3 Overview of provisions

The primary objective of Road Map 3 is to:

Guide NHMRC to improve health, social and wellbeing outcomes for Aboriginal and Torres Strait Islander peoples by ensuring research excellence and integrity – highlighting research priorities driven by Aboriginal and Torres Strait Islander communities.²¹²

This will be achieved through:

- strengthening the Aboriginal and Torres Strait Islander researcher workforce, by building capacity in the sector and supporting community-based researchers;
- engaging with Aboriginal and Torres Strait Islander communities, for example by supporting researchers to engage with communities and continually improving key protocol documents and guidelines; and

²¹¹ Ibid, 13.

²¹² National Health and Medical Research Council, *Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research* (Australian Government, Canberra, June 2018) 5.

- supporting research in high priority areas, while recognising that priorities will differ over time, and will differ between Aboriginal and Torres Strait Islander communities.²¹³

7.5 Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS), Australian Aboriginal Institute of Aboriginal and Torres Strait Islander Studies

7.5.1 What is it?

These Guidelines were prepared by AIATSIS. They are guidelines for ethical research involving Aboriginal or Torres Strait Islander participants, although they are not specific to health and medical research. Nevertheless, they are still relevant to the Indigenous genomics study space and set important principles and rights that Aboriginal and Torres Strait Islander people have in relation to all research that they are involved in, or that incorporates their knowledge.

7.5.2 Who does it apply to?

It applies to anyone conducting any kind of research involving Aboriginal or Torres Strait Islander peoples or their knowledge.

7.5.3 Overview of provisions

It recognises the inherent rights of Aboriginal and Torres Strait Islander peoples including their right to self-determination, full and fair participation in any process and the right to control and maintain their culture and heritage.²¹⁴

It goes on to set 14 research principles, grouped under the broad categories of:

- rights, respect and recognition;
- negotiation, consultation, agreement and mutual understanding;
- participation, collaboration and partnership;
- benefits, outcome and giving back;
- managing research: use, storage and access; and
- reporting and compliance.

7.6 Genomics Partnerships, QIMR Berghofer

QIMR Berghofer Medical Research Institute has published a document, *Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland*.²¹⁵ The Guidelines aim to provide researchers with practical advice before planning research with Aboriginal and Torres Strait Islander communities in Queensland. Using the NHMRC's 6 core values, the document sets out how to approach

²¹³ Ibid.

²¹⁴ AIATSIS, *Guidelines for Ethical Research and Indigenous Australian Studies*, 3.

²¹⁵ QIMR Berghofer Medical Research Institute, *Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland*, September 2019.

<<https://www.qimrberghofer.edu.au/wp-content/uploads/2019-Indigenous-Health-Genomics-Guide-v9-WEB-1.pdf>> accessed 30 April 2020.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

engagement with communities. Using a North American First Nations communities framework, the approach for partnership is based on co-designed research and incorporating Aboriginal and Torres Strait Islander research methodologies.

Sections 3 and 4 of the document cover sovereignty and research regulation. It is here that the document sets out the support documents for research projects which include letters of support, research agreements, and Memorandum of Understanding (MOUs). The document highlights the importance of intellectual property issues being covered in discussion and negotiated in agreements:

In circumstances where there is the possibility of commercially relevant intellectual property (IP) or financial gain from the research, this needs to be clearly communicated with the participants and the community. Discussions and agreements about compensation and ownership of IP need to be made early, even when a project is unlikely to yield these outcomes²¹⁶

7.7 Central Australian Academic Health Science Network

The Central Australian Academic Health Science Network (CAAHSN) is a partnership between health services, health/medical research organisations and educational institutions in Central Australia. Focussing on collaboration research projects which benefit the health of Central Australians, it was formally recognised as a Centre for Innovation in Regional Health in 2017.

7.8 Kimberley Land Council Policies

The Kimberley Land Council has developed protocols and policies that relate to traditional knowledge, intellectual property and conducting research in the Kimberley - The Kimberley Land Council's Intellectual Property and Traditional Knowledge Policy.

The Policy covers 'Aboriginal Cultural and Intellectual Property Rights' which includes rights to heritage, 'human genetic material' and 'genealogical information and kinship relationships'.²¹⁷ It also covers knowledge and documentation of Aboriginal people's heritage which would be collected during research projects.

The Policy promotes 9 principles, including:

- **mutual arrangements:** the researched community must not be disadvantaged by the project; and
- **formal agreement:** negotiation should result in a formal agreement, based on good faith and Free, Prior Informed Consent.²¹⁸

7.9 Strengths and Limitations of a Guidelines Approach

National Statement

²¹⁶ Ibid 12.

²¹⁷ Kimberley Land Council, *Intellectual Property and Traditional Knowledge Policy* (6 September 2011), Kimberley Land Council), ss 2.2.4 and 2.2.7 <<https://www.klc.org.au/research-facilitation>>.

²¹⁸ Ibid, 3.6 and 3.8.



A shortfall of these Guidelines is that not all HREC's have Aboriginal or Torres Strait Islander reviewers or there are too few Aboriginal and Torres Strait Islander ethics committees or positions to ensure that people are doing the right thing culturally.

Guidelines allow organisations to be flexible in their approach to Indigenous health related genomics. Different projects will have different interests and priorities, guidelines can allow the flexibility to ensure that these interests can be expressed in unique research agreements or governance frameworks within an organisation. Guidelines can assist in culture of best practice, reflects a rapidly changing field. In contrast, if legislation can be rigid and slow to adapt.

8 Best practice models: leading practices in Indigenous genomics

There are several genomics projects that exemplify culturally appropriate and respectful approaches to working with Aboriginal and Torres Strait Islander peoples and their data. This section looks at several of these examples. It is followed by an overview of several key areas for consideration when project planning, engaging with some of the most important ethical and cultural issues that should be incorporated into any research project.

8.1 Case studies

8.1.1 The Ochre Plan

The Ochre plan is an initiative of the Aboriginal Affairs Department within the NSW Government. The name is an acronym for Opportunity, Choice, Healing, Responsibility and Empowerment. It sets the government's approach to working with Aboriginal communities. It sets the government's intention to support Aboriginal communities to actively influence and fully participate in all aspects of the social, economic and cultural life.²¹⁹ It foregrounds genuinely shared decision making through partnerships.²²⁰

Particularly relevant in this context are the Plan's intentions in relation to local decision making. The NSW government recognises that Aboriginal communities are best placed to understand local needs and that inflexible 'one-size- fits-all' approaches are a roadblock to service delivery both for government and the private sector.²²¹

The local decision making model is currently being rolled out. It starts with a staged process of power-sharing. Local management committees will progressively be delegated greater powers and budgetary control.²²² This process will be augmented by capacity building for community leadership and skills and building capacity for existing Aboriginal peak bodies.²²³

²¹⁹ Aboriginal Affairs *The Ochre Plan* NSW Government 2013
<<https://www.aboriginalaffairs.nsw.gov.au/our-agency/staying-accountable/ochre/nsw-government-aboriginal-affairs-strategy>> 5.

²²⁰ Ibid 7.

²²¹ Ibid 22.

²²² Ibid 23.

²²³ Ibid 25.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Ultimately, this decision-making model, building capacity for localised decision making about service delivery, following a partnership model has the potential to shape the way genomics involving local Aboriginal people are planned and managed. It could further the goal of self-determination and co-design in research projects, and it could provide a framework for on-going management of samples and data.

8.1.2 Footprints in Time – The Longitudinal Study of Indigenous Children

Footprints in Time is a longitudinal study of Aboriginal and Torres Strait Islander children conducted by the Department of Social Services with the aim of gathering qualitative and quantitative data about how a child's early years affect their development.²²⁴ The study is guided by a steering committee chaired by Professor Mick Dodson AM. The study began in 2008 with over 1,945 interviews with parents and carers. The second round of interviews the following year (wave 2) interviewed over 1,200 of the original families, as well as further interviews with other families. 2020 marks the thirteenth wave of interviews.

For the most part the interviews are conducted by Department of Social Services Aboriginal and Torres Strait Islander Research Administration Officers, although some interviews are conducted by other National Office Indigenous and non-Indigenous staff from time to time.

The study has a broad scope and covers topic areas including:

- children's physical and mental health and social and cognitive development;
- parent's health, social and emotional wellbeing;
- family history and connection to country and culture; and
- community resources and community safety.

Importantly, the content for each wave of data each year is approved by the steering committee and ethics clearance for the content and methodology goes through the Human Research Ethics Committee of AIATSIS.

Only approved data users have access to the data which is on a secure network, the Australian Data Archive Dataverse. Access to the Dataverse requires the user to sign a Confidentiality Deed Poll and follow the *National Centre for Longitudinal Data Access and Use Guidelines* about using, storing and publishing the data.²²⁵

8.2 Best practice and project planning

Table 10 summarises some key questions that project proponents need to consider when planning a research project that incorporates genomic information or samples belonging to Aboriginal and Torres Strait Islander peoples.

²²⁴ 'Footprints in Time – The Longitudinal Study of Indigenous Children (LSIC)' Australian Government, Department of Social Services (Web Page) <<https://www.dss.gov.au/about-the-department/publications-articles/research-publications/longitudinal-data-initiatives/footprints-in-time-the-longitudinal-study-of-indigenous-children-lsic#3>>.

²²⁵ Australian Government, Department of Social Services, *National Centre for Longitudinal Data Dataverse* <<https://dataverse.ada.edu.au/dataverse/nclid>>.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Table 10: Key questions when project planning

Issue	Key Questions
Issue identification	<p>How do Aboriginal and Torres Strait Islander genomics issues vary from non-Indigenous genomics research? Are there any special issues?</p> <p>What does the community need/want?</p> <p>What work has already taken place?</p>
Project planning	<p>What are the relevant ethical and legal frameworks?</p> <p>Are there any gaps in the ethical or legal guidance? How will you consult with community to plan best practice to fill those gaps?</p> <p>What policies and procedures does the community already have in place?</p>
Consultation and consent	<p>How will you consult with community?</p> <p>What will be your approach to consulting with individuals and community?</p> <p>What information will you give to people about the research? How will you give it?</p> <p>Do you plan to commercialise the research, or any research outcomes? What if that changes?</p> <p>Will you hold community information sessions?</p> <p>Have you contacted any relevant Prescribe Bodies Corporate or Traditional Owner Corporations?</p> <p>Have you discussed the risks of research?</p> <p>How will you keep records of who you have spoken to and the concerns they have raised?</p> <p>What is your system for responding to concerns and adapting accordingly?</p> <p>How will you record consents?</p> <p>How will you keep in touch with research participants into the future?</p> <p>Will participants have access to their data? How?</p>

Issue

Managing risks and concerns

Key Questions

If you, or a project participant has concerns about how a project is being run, are there easily accessible procedures for raising these concerns?

9 International Indigenous Health Genomics

9.1 What are the international law instruments that give guidance for Australian law and policy on Indigenous genomics?

This section focuses specifically on Aboriginal and Torres Strait Islander human rights in the context of their own genomic material and kinship ties. There are additional international law instruments relating to Indigenous peoples genetic and biological knowledge more broadly, which include consideration of Indigenous plant and ecological knowledge. These areas of international law could also be relevant, as they provide guidance on equitable access and benefit sharing particularly in the context of commercialisation of knowledge. However, ecological knowledge and plant genetics really falls beyond the scope of this paper and so, at present, the focus remains on Aboriginal and Torres Strait Islander peoples' human genomics.

These international instruments are standard setting documents. While they are not directly legally binding on Australia until they are ratified into Australian law, they nevertheless provide an important reflection of international expectations. On the world stage, the terms of the United Nations Declaration on the Rights of Indigenous Peoples, for example, are well understood and there is the expectation that Australia should uphold these rights. These international laws also often provide important guidance for policy documents and best practice models that are implemented within Australia.

9.1.1 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

This resolution was adopted by the UN Assembly in 2007 and Australia became a party to it in 2009.

Article 31 of UNDRIP states that

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage traditional knowledge...as well as the manifestations of their sciences, technologies and cultures, including human and genetic resource...They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge and traditional cultural heritage²²⁶

This is an important statement recognising Aboriginal and Torres Islander peoples genetic material and knowledge as part of their cultural heritage. As such Aboriginal and Torres

²²⁶ Declaration on the Rights of Indigenous Peoples, GA Res 61/295, UN GAOR, 61st sess, 107th plen mtg, UN Doc A/RES/61/295 (13 September 2007) art 31.

Strait Islander people have a right to maintain on-going ownership and control of their genetic material and knowledge, to protect it, and to develop it. The inclusion of reference to intellectual property underlines that these rights include rights over the data derived from this genetic material and knowledge.

As was mentioned previously, this article has been somewhat incorporated into state legislation in the human rights acts introduced in the ACT, Queensland and Victoria. In fact both Queensland and the ACT adopt the language of UNDRIP when they refer to Aboriginal and Torres Strait Islanders rights to “*maintain, control protect and develop*” kinship ties, and the ACT specifically references UNDRIP in a note on the relevant provision.

9.1.2 Universal Declaration on the Human Genome and Human Rights

This declaration was adopted by the United Nations Educational, Scientific and Cultural Organisation (UNESCO) in 1997 and the UN General Assembly in 1998. This declaration makes specific prohibition against any form of genetic discrimination.²²⁷ Article 2 states that

(a) Everyone has the right to respect for their dignity and for their rights regardless of their genetic characteristics

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity²²⁸

Article 6 then goes on to read:

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms human dignity.²²⁹

In our discussions with the Advisory Group, a concern was raised several times that historically, scientific research generally, and genetic study in particular has been used as a tool for racism. Genetic difference was viewed through the lens of racism and used as justification for racist policy, law and behaviour. This Article makes clear that this must not happen again. Genetic difference and diversity must be respected without use of racist stereotypes.

9.1.3 International Declaration on Human Genetic Data

The International Declaration on Human Genetic Data was adopted by UNESCO in 2003 and written in response to the increasing number of genetic databanks. It does not make specific reference to Indigenous peoples but there are some key provisions that certainly apply to respectful, culturally appropriate collection of Aboriginal and Torres Strait Islander genomic data.

²²⁷ *Universal Declaration on the Human Genome and Human Rights*, C/Res 16, UNESCO 29th sess, (11 November 1997), Preamble.

²²⁸ *Ibid* art 2.

²²⁹ *Ibid* art 6.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Key provisions include:

- genetic data should only be collected for purposes consistent with the Universal Declaration on the Human Genome and Human Rights, and the international law of human rights, including UNDRIP;²³⁰
- genetic data should be collected, processed, used and stored in a transparent and ethically appropriate manner;²³¹
- informed disclosure includes disclosure of any potential risks and consequences, and the participant should be informed that they are free to withdraw consent without disadvantage;²³²
- human genetic data should not be used to discriminate or infringe human rights or human dignity;²³³
- prior, free, informed consent should not be obtained through financial inducement or personal gain, except as strictly allowed for through domestic legislation. In other words, financial pressure or exploitation negates free, prior, informed consent;²³⁴
- genetic counselling should be available when appropriate, and should be culturally adapted and consistent with the best interests of the person;²³⁵
- no one should be denied access to their own genetic data;²³⁶
- except in limited circumstances, data should not be used for a purpose outside the original consent, without further consent;²³⁷ and
- benefit sharing should include special assistance to the persons or groups that have taken part in the research.²³⁸

9.1.4 Universal Declaration on Bioethics and Human Rights

The Universal Declaration on Bioethics and Human Rights was adopted by UNESCO in 2005. It includes specific reference to the unique position of the world's Indigenous peoples. Specially, it recognises that "unethical scientific and technological conduct has had a particular impact on indigenous and local communities."²³⁹

Interestingly, it also stresses the need to reinforce international cooperation, while also taking into account the special needs of Indigenous communities.²⁴⁰ This could be referring to the dual goals of free, and easily accessible data, while also maintaining Indigenous data

²³⁰ *International Declaration on Human Genetic Data*, 32 C/Res 22 UNESCO 39 (16 October 2003) art 5.

²³¹ *Ibid* art 6(a)

²³² *Ibid* art 6(d).

²³³ *Ibid* art 7(a).

²³⁴ *Ibid* art 8(a).

²³⁵ *Ibid* art 11.

²³⁶ *Ibid* art 13.

²³⁷ *Ibid* art 16.

²³⁸ *Ibid* art 19 (a)-(i).

²³⁹ *Universal Declaration on Bioethics and Human Rights*, 32 C/Res 24, UNESCO 33rd session, (19 October 2005), Preamble.

²⁴⁰ *Ibid*.



sovereignty frameworks that empower Indigenous communities in the management of their data.

9.2 What case law in other jurisdictions?

The case law of other jurisdictions outside Australia provides further context for the ethical and cultural issues of the world's Indigenous people that have been impacted by the operation of law.

There are a number of international cases that have canvassed general issues relating to gene research and there are also cases which deal with Indigenous gene research that has gone wrong.

There are a number of cases that involved human genes. The cases deal with the key issues of whether human genes should be the subject of patents. The discussion focusses on what is a product of nature (that is, what is occurring naturally) and what is inventive. There is also some discussion of how public policy should be considered (if at all) in patent applications.

9.2.1 *Moore v Regents of the University of California (1990)*

This case discussed ownership over human tissue. John Moore took action against his doctor and others for using his cells from a spleen operation in potentially commercially valuable research without his permission. Moore alleged that he was not given information about the economic interests before he gave consent for the cells being extracted. This resulted in unauthorised use constituting conversion.²⁴¹

The result in this case, as described by Mortimer, was based on a narrow reading of precedent, in that there was no precedent for liability for conversion of human tissue. As such the applicant could not establish any rights.²⁴² As Moore did not intend to keep his spleen post-surgery, he could not claim a proprietary interest.²⁴³

This case resulted in the concept of property entering debates around the human body and body parts, and allowing scientists in the United States to patent and claim genetic information without the requirement of benefit sharing back with donors. Whilst this can be beneficial as some organisations may receive large volumes of body parts and it is not always guaranteed that there will be anything of value found, and organisations should claim intellectual property rights over the data as they have taken the effort to find it. On the other hand, individuals ought to retain an interest in their human tissue and the information encoded as it inherently is their DNA.

9.2.2 *The OncoMouse case*

The patentability of the Harvard Oncomouse, a mouse that had its genome genetically altered by a cancer-promoting gene (oncogene) was also the subject of dispute and ethical

²⁴¹ *Moore v. Regents of University of California*, 793 P.2d 479, 63 (Cal. 1990).

²⁴² Debra Mortimer, 'Proprietary Rights in Body Parts: The Relevance of Moore's Case in Australia,' (1993) 19(2) *Monash University Law Review* 217, 222-223.

²⁴³ *Moore v. Regents of University of California*, 793 P.2d 479, 63-64 (Cal. 1990).

Indigenous Health Genomics: The Legal, Ethical and Social Issues

questions around patentability. This case was very complex, both legally and ethically and raised two key issues for the patent system. Firstly, whether patents should be granted for animals or plant varieties, and secondly, how should moral implications be addressed e.g. suffering caused to animals.

Whilst a patent was granted in the United States, the European Patent Office (EPO) and Canada considered the case significantly (see below).²⁴⁴

European Patent Office (EPO)

The EPO applies the European Patent Convention which has exceptions for patents that 'would be contrary to "*ordre public*" or morality' and can exclude patents on "animal varieties or essentially biological processes for the production of...animals".²⁴⁵ The EPO found that the Oncomouse was not an animal variety and as such was not excluded. For the public morality exception, it developed a utilitarian approach that sought to assess the benefits in the use of mice for medical research and the negatives being the pain suffered by the mice. It found that as mice were often used in cancer research, then there was no moral disapproval.

Canada

Canada initially rejected the claims to the animals as they were not considered an invention. The rejection was because "microorganisms, or an oncogene-injected egg capable of maturing into an oncomouse, may be a mixture of ingredients and thus patentable under Canadian Law, the body of a mouse was not".²⁴⁶ It left the complex ethical and legal discussions around patentability of higher life forms to Parliament.

Conclusion

These cases show how morality and ethical questions are answered in the patent system by different jurisdictions. Whilst it only applies to animals, the Canadian reasoning is interesting because it allows the patenting of a process but not the end result.

9.2.3 Henrietta Lacks Immortal Cells

Whilst not a patent, commercial exploitation of genomic information has been occurring for many decades with the use of Henrietta Lacks' cells. A black American woman, Ms Lacks had her cells collected when she went into John Hopkins Hospital during treatment on her cervix in the 1950s. It turned out that she had a tumour which the doctors took cells from without her knowledge and consent. The scientists called the cells 'HeLa' and used the cells to develop cancer treatments and vaccines. The grandchildren of Ms Lacks are calling for guardianship of the cells, but the legal issues are not clear. Whilst there is no patent, this case raises important issues around the benefit that the HeLa cells have had for medicinal

²⁴⁴ World Intellectual Property Organization, 'Bioethics and Patent Law: The Case of the Oncomouse' (June 2006), *WIPO Magazine*) available online at <https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html> accessed 30 April 2020.

²⁴⁵ *Convention on the Grant of European Patents (European Patent Convention)* (2016) OJ EPO June 2016) Art 53(a), (b).

²⁴⁶ World Intellectual Property Organization, 'Bioethics and Patent Law: The Case of the Oncomouse' (June 2006), *WIPO Magazine*) citing *Harvard College v Canada (Commissioner of Patent)* (2002 SCC 76).



research and the rights of individuals and families to be compensated for commercial exploitation of their genomic information.

9.2.4 Myriad Genetics US

Analogous to the Australian case, it relates to an isolated gene BRCA1 that is linked to breast and ovarian cancer.²⁴⁷ The decision held, "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring". Therefore, the difference here is that in the United States, you can replicate genetic information in cDNA and it will be patent eligible, whereas in Australia, it will not be. This creates concerns if United States based companies seek to conduct research on Aboriginal and Torres Strait Islander peoples outside of Australian borders, as it is possible they will be able to patent their DNA.

9.2.5 Havasupai Tribe v Arizona Board of Regents

The Havasupai People from the Grand Canyon region of Arizona bought claims against the Arizona Board of Regents out of the misuse of their blood samples taken from members of the Havasupai Tribe in the early 1990's. Samples were taken with consent for use in diabetes research, however were used in studies for schizophrenia, population migration and inbreeding, all taboo in Havasupai society. Whilst the case settled out of court, the breach of trust led to a moratorium on genetic research within the Navajo Nation.

Background

The Havasupai people are a Federally recognise Native American Tribe living on their ancestral lands in a reservation at the base of the Grand Canyon, Arizona. Since the 1960's, the rates for type 2 diabetes have rapidly increased, forcing many Havasupai to have their lower limbs amputated or to leave the canyon for treatment. As it is a remote village, access to and from is incredibly difficult.

In 1989, tribal leaders approached John Martin, an anthropology professor from Arizona State University (ASU) with whom they had a long-standing relationship, to assist them in finding the cause.

Martin enlisted the help of genetics professor Therese Ann Markow from ASU, whilst not an expert on diabetes, she was the only human geneticist at ASU.²⁴⁸ Following a successful pilot program of the study, the Havasupai had written to Martin to confirm that the study on diabetes will go ahead. Unbeknownst to the Havasupai, Markow had obtained the funding for the schizophrenia research on the samples, without notifying the Havasupai.²⁴⁹

The initial blood sampling was undertaken in June 1990 using the funds from the schizophrenia research despite all donors believing it was for diabetes research. The consent forms used were general in nature and deliberately vague stating the project was to

²⁴⁷ *Association for Molecular Pathology, et al. v. Myriad Genetics*, 569 U.S. 576,12,15, (2013).

²⁴⁸ Kristof Van Assche, Serge Gutwirth and Sigrid Sterckx, 'Protecting Dignitary Interests of Biobank Research Participants: Lessons from *Havasupai Tribe v Arizona Board of Regents*, Law, Innovation and Technology', (2013), 5(1), 55, 57.

²⁴⁹ *Ibid*, 56.

Indigenous Health Genomics: The Legal, Ethical and Social Issues

'study causes of behavioural/medial disorders'.²⁵⁰ Approval from ASU for the schizophrenia and diabetes research were given 6 and 9 months, respectively after the projects had already began. The second round of blood sampling from July 1991- late 1994, was consented to orally, as it was advised by a Havasupai nurse as less confusing.

Following the conclusion of the diabetes study, Markow and her collaborators continued studying the samples for schizophrenia. Markow moved to the University of Arizona (UA) and took the samples with her despite the consent forms requesting that no information on the Havasupai would leave ASU.²⁵¹ In 1993, a paper was published by Markow and Martin that argued that the Havasupai had high levels of inbreeding.²⁵² The samples were also used for research in population migration studies attempting to trace the origin of the Havasupai through DNA comparison.²⁵³ Both of these studies were outside the scope of consent and in conflict with the lore and beliefs of Havasupai tribal members that they originated in the Grand Canyon. The Havasupai found out about the misuse of their genes in 2003 when tribal member, Carletta Tilousi, was invited by Martin to attend a PhD defence which involved use of the samples. It was during this defence that Tilousi raised questions about the procedures used to obtain the blood donors permission for the studies.²⁵⁴

Once the Havasupai found out about the misuse, they gave a "banishment order" to the ASU, its Professors and employees. The Havasupai intended to hold a press conference, however the ASU requested it to not go ahead pending an external investigation into the circumstances surrounding the collection of blood samples and other research data from members of the Havasupai Tribe and any and all subsequent uses of the samples or their derivatives and other data for research or other purposes".²⁵⁵ This report is known as the Hart Report. Following this report, there were unsuccessful settlement negotiations leading to the Havasupai initiating proceedings against Markow, ASU and the Arizona Board of Regents (ABOR), the governing body for Arizona's public university system.

Havasupai Legal Claims

The claims were filed by the Tribe on its own behalf and under the doctrine of *parens patriae* for the members of the Tribe involved in the diabetes project, and by one of the 52 participants who was involved in the blood draws.²⁵⁶ The Tribe claimed the following causes of action:²⁵⁷

- breach of fiduciary duty. In particular the tribe observed that there was a lack of informed consent, and there were inadequate procedures for vulnerable subjects

²⁵⁰ Ibid 55.

²⁵¹ Ibid 60.

²⁵² Theres Markow, John Martin, 'Inbreeding and developmental stability in a small human population', (1993), 20(4) *Annals of Human Biology*, 389, 394.

²⁵³ Kristof Van Assche, Serge Gutwirth and Sigrid Sterckx, 'Protecting Dignitary Interests of Biobank Research Participants: Lessons from *Havasupai Tribe v Arizona Board of Regents*, Law, Innovation and Technology', (2013), 5(1), 60.

²⁵⁴ *Havasupai Tribe v Arizona Board of Regents*, 204 P.3d, 1063, 5 (Ariz, Ct App 2008).

²⁵⁵ Ibid.

²⁵⁶ Ibid; *Parens Patriae* is legal principle that a Government may initiate a lawsuit on behalf of it's citizen.

²⁵⁷ Ibid.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

such as children, people with mental illness, and people whose main language was the tribal language;

- fraud, misrepresentation and fraudulent concealments;
- intentional or negligent infliction of emotional distress;
- conversion (tort law – person exercises dominion over goods which is in violation of the legal rights of the party who has a right to immediate possession of those goods);
- violation of civil rights; and
- negligence and gross negligence.

The Tribe's claims centred around the breach of "dignitary torts" that do not require proof of manifestation of injury.²⁵⁸ Rather the invasions of privacy that result from the misuse of health information can give rise to "deeply personal and subjective injury of the sort on which the Tribe based its settlement demand".²⁵⁹

Following a long procedural battle in the Court, the Court found that the substantive case would be heard unless the matter settled. The parties settled in 2010 with ABOR paying the plaintiffs \$USD700,000, returning all blood samples and research deriving from it. Secondly, the ABOR also initiated a five-year collaborative project with the Havasupai in the areas of education, clinical care and tourism.

What was also significant was that in 2002, the Navajo Nation passed a moratorium on genetic research within their borders. This moratorium raised several important issues around appropriate consent procedures, mistrust of medical researchers, unequal benefit sharing, community exploitation by researchers and adherence to cultural protocols.

Key take away points from the Havasupai case are:

- consent forms and clear understanding;
- need to implement cultural protocols as misuse of samples from an Indigenous perspective could not breach any university ethics guidelines;
- need to report back on all findings to donors;
- benefit sharing with the donor community; and
- the Tribe seeking a claim under *parens patriae* demonstrates the need for Community consent (see below).

Parens Patriae

In this case, the claim of *parens patriae* was bought by the Tribe on behalf of its citizens. This raises questions of law whether this could be implied in Australia for Prescribed Body Corporates, Land Councils or Regional Authorities in Australia.²⁶⁰ Historically, the doctrine of *parens patriae* has been used to order the protection and education of children, 'wards' or those incapable of exercising it themselves.²⁶¹ Its application in present day is "wide-ranging

²⁵⁸ *Havasupai Tribe v Arizona Board of Regents*, 204 P.3d, 1063, 48 (Ariz, Ct App 2008).

²⁵⁹ *Ibid.*

²⁶⁰ *Truth About Motorways Pty Ltd V Macquarie Infrastructure Investment Management Ltd* (2000) 169 ALR 616.

²⁶¹ Justice Paul Brereton, 'The Origins and Evolution of the *Parens Patriae* Jurisdiction' (Lecture, Sydney University, 5 May 2017) 1.



and far-reaching...as far as necessary for the protection and education of the child".²⁶² As such, it is a welfare and equitable based law, that could see expansion for claims by a State on behalf of citizens for misuse of DNA, or damages caused by overseas based entities operating in Australia or potentially by representative bodies of Aboriginal or Torres Strait Islander patients.

9.3 What International examples are there of best practice research methodologies?

9.3.1 *The Slim Initiative for Genomic Medicine in the Americas (SIGMA)*

The Slim Initiative for Genomic Medicine in the Americas is a collaboration project convened by the Carlos Slim Centre for Health Research established in 2010 from \$65m funding from the Carlos Jim Foundation. The Centre aims to ensure that Latin Americans benefit from genomics and promotes access to genomic medicine in Mexico and Latin America by support research programs that focus of local and regional health needs. The Centre launched SIGMA beginning the initial research by working closing with Mexican colleagues from range of research institutes led by the Mexican National Institute of Genomic Medicine.²⁶³ Scientists found a common genetic variant predisposing Latin American populations to the type 2 diabetes, including research that indicated that indigenous Mexicans, 10% of the population, have genetic risk factors.²⁶⁴ The project identified other genetic links to cancer and kidney disease.

In 2015, with a further contribution of \$74.1m for the Carlos Slim Foundation the Broad Institute developed the Type 2 Diabetes Genetic Knowledge Portal. The Portal is designed to assist more researchers to study type 2 diabetes.²⁶⁵

9.3.2 *Welcome Trust/NIH Human Heredity & Health in Africa (H3Africa) project (>\$50M)*

The Human Heredity and Health in Africa (H3Africa) consortium facilitates fundamental research into diseases on the African continent while also developing infrastructure, resources, training, and ethical guidelines to support a sustainable African research enterprise – led by African scientists, for the African people.²⁶⁶ The project empower African scientists to take the lead on projects that include population-based genomic studies of common, non-communicable disorders such as heart and renal disease, as well as communicable diseases such as tuberculosis. To safeguard for the future, a database has been established to securely archiving the genomic and phenotypic research data generated by the H3Africa projects. The H3 Archive collects data that meets its data submission

²⁶² Ibid 8.

²⁶³ Broad Institute website, <<https://www.broadinstitute.org/sigma>>, viewed 8 July 2020.

²⁶⁴ Peter Wade, *Degrees of Mixture, Degrees of Freedom: Multiculturalism, and Race in Latin America*, Duke University Press, 2017.

²⁶⁵ Type 2 Diabetes Knowledge Portal, <<http://www.type2diabetesgenetics.org/>>, viewed 8 July 2020.

²⁶⁶ H3 Africa, *Human Heredity & Health in Africa* <<https://h3africa.org/>>

Indigenous Health Genomics: The Legal, Ethical and Social Issues

criteria, and manages access to, and transfer of biospecimens, by having controlled access policies.²⁶⁷

Simons Foundation's Genome Diversity Project The Simons Foundation has developed the Simons Genome Diversity Project which holds complete genome sequence from more than one hundred diverse human populations.²⁶⁸ The SGDP is a public project containing open access files. The collection is more culturally diverse than other collections. The primary dataset contains data from over 260 genomes from more than 127 populations including 22 African Indigenous populations, 23 Native Americans and 27 Oceanians which includes Aboriginal and Torres Strait Islander peoples.

All genome sequence data are made freely available however accessors are asked to observe the Fort Lauderdale principles which entitle the data producers to make the first representation and publish the first genome-wide analysis of the data.

The data has been used to demonstrate that Aboriginal and Torres Strait Islander peoples do not derive substantial ancestry from an early dispersal of modern humans but instead have modern human ancestry from the same source as that in other non-Africans.²⁶⁹

9.3.3 *Te Mata Ira: Guidelines for Genomic Research with Māori*

In 2016, the *Te Mata Ira: Guidelines for Genomic Research with Māori* were established to provide a 'framework to address Māori ethical issues within the context of genetic or genomic research'.²⁷⁰ The Guidelines are founded upon mātauranga (Māori knowledge) and tikanga Māori (Māori protocols and practices).²⁷¹ Building upon the Te Ara Tika guidelines that identify Māori ethical issues relevant to all research, the Te Mata Ira provide specific guidance for the context of genomic research.²⁷² Te Mata Ira describes

the cultural foundation informing ethical approaches to genomics; to inform decision-making around ethical issues when conducting genomic research with Māori; and outline best practice approaches for addressing Māori ethical concerns.²⁷³

The Guidelines are useful for researchers, ethics committee members and those who engage in consultation or advice about genomic research with Māori in local, regional, national or international settings.²⁷⁴

The Guidelines identify the ways to protect the interests of Māori participants and groups that chose to participate in genetic or genomic research.²⁷⁵ They provide distinct

²⁶⁷ Ziyaad Parker et al, 'Building Infrastructure for African Human Genomic Data Management (2019) 18(1) *Data Science Journal* 47.

²⁶⁸ Simons Foundation website, <<https://www.simonsfoundation.org/simons-genome-diversity-project/>>, accessed 7 July 2020.

²⁶⁹ Swapan Mallick et al, 'The Simons genome diversity project: 300 genomes from 142 diverse populations' (2016) 538(7624) *Nature* 201. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5161557/>>

²⁷⁰ Maui Hudson et al, *Te Mata Ira: Guidelines for Genomic Research with Māori* (Te Mata Hautū Taketake – Māori & Indigenous Governance Centre, 2016), 1.

²⁷¹ Ibid 1.

²⁷² Ibid.

²⁷³ Ibid.

²⁷⁴ Ibid.

²⁷⁵ Ibid 3.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

opportunities to engage Māori communities in all stages of the research project and results.²⁷⁶ The Guidelines are broken into four sections. Section one is the cultural foundation that informs Māori understandings of genetics.²⁷⁷ Section two is the Te Mata Ira Framework for Genomic Research which covers the 'context and key issues that Māori have interests in discussing in relation to genomic research' including consultation, governance, research and consent.²⁷⁸ Section three includes guidance tables to provide specific advice on determining appropriate engagement, methodologies and identifying pathways for benefit sharing.²⁷⁹ Section four involved special ethical considerations such as incidental findings, data rights and interests (data sovereignty) and data linkage (governance and control over collation of data).²⁸⁰

The guidelines have a significant scope that not only informs researchers looking to work with Māori peoples of key Māori ethical concepts, but identifies the opportunities to engaging Māori communities. This empowers Māori communities with the knowledge of how they can assert their interests in project stages, and sets standards for researchers and organisations wishing to work in this area.

²⁷⁶ Ibid 4.

²⁷⁷ Ibid 6.

²⁷⁸ Ibid 19-25.

²⁷⁹ Ibid 28.

²⁸⁰ Ibid 36-37.



10 Conclusion: Opportunities for improvement

Genomics research is the future of health and medicine. Aboriginal and Torres Strait Islander peoples will need to be a part of it in order to have access to health solutions in the same way as other Australians. However, for Aboriginal and Torres Strait Islander peoples, there are significant ethical, social and cultural concerns that arise in light of the collection and use of Aboriginal and Torres Strait Islander genomic material, knowledge and data.

This paper analyses IP law and related laws to consider how they enable Aboriginal and Torres Strait Islander peoples to have control over their genes. We have been informed by the Aboriginal and Torres Strait Islander Advisory Group to provide insights on the emerging issues.

There is a large framework of laws, including IP laws, that govern the collection and use of Aboriginal and Torres Strait Islander health-related genomics information in the clinical and research setting. They focus on commercialisation and do not adequately address cultural issues.

Health access laws govern the equitable delivery of health services but there are barriers for Aboriginal and Torres Strait Islander peoples to participate in a genomic study in a culturally safe way. This compromises the integrity of the data by having it biased toward European or Asian genomic reference data. This then negatively impacts the delivery of health services to Aboriginal and Torres Strait Islander peoples – e.g. you get false positive and false negatives.

Through discussions with the Advisory Group and a gap analysis examining the shortfalls of legal protection in safeguarding the Aboriginal and Torres Strait Islander knowledge and heritage embodied by their genes, this paper has identified a number of key issues.

The first key issue is that of **ownership**. The legal view of gene ownership is grounded in western views of the body: once the patient consents to the removal of a sample, the sample ceases to be the property of the individual. The data then, for the most part, belongs to the organisation that has invested time and money in deriving a commercial use for the information. However, for many Aboriginal and Torres Strait Islander peoples, their samples are data for part of their cultural knowledge and heritage. It connects them to their culture and their land. Their genes are not just potential IP, but form part of their collectively owned ICIP. A much broader legal survey was necessary to analyse Australian law's protection (or lack thereof) of this ICIP.

In the absence of legal ownership over genes, **consent provisions** become the vanguard for control over the use of Aboriginal and Torres Strait Islander genes. Current legal standards of consent over the removal of samples and the use of data have gaps. For example, as precision medicine develops and blurs the lines between clinical and research uses, the scope of consent gets broader. This increased breadth will not always be apparent to patients when they consent to their diagnostic test. For example, will a patient be aware that when they give a blood sample to see if they have diabetes, that their de-identified results could eventually be used in medical research when researchers access My Health

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Records data? And does the 'opt-out' structure of the My Health Records meet the internationally recognised principle of free, prior, informed consent? Probably not.

For these reasons the clinical setting is probably the location of the greatest difficulty when it comes to consent; settings in which samples are now been taken, and will eventually go into research databases and biobanks. While there is potential for researchers to access historical collections of Aboriginal and Torres Strait Islander genomic information (e.g. in museums or historical university collections) these spaces seem to be much more familiar with cultural protocols. This means that even in the absence of legislative or general law requirements for free, prior, informed consent, these institutions are aware of the standard and able to give them legal effect through contract law (e.g. through research agreements and consultation and consent documentation). In fact, it is circumstances where consent is given 'on the run' that poses the greatest risk to cultural safety.

The quality of consent can also be influenced by the **return of benefit** discussions and arrangements. The consultation that precedes informed consent must include a discussion of the return of benefits. This includes discussion of the risk that benefits may be a long time coming, or may never accrue at all. Potential benefits must not be oversold as an inducement to participation.

Governance structures play an important role in ensuring the representation of Aboriginal and Torres Strait Islander concerns and in taking decision-making roles in the use and management of data. However, there are many opportunities to strengthen existing governance structures. Recurring concerns about lack of Aboriginal and Torres Strait Islander representation of advisory and ethics were raised. So too was over-reliance on just a few Aboriginal and Torres Strait Islander representatives, leading to over-burdening and burn out. Beyond ethics committees, there is also greater need for Aboriginal and Torres Strait Islander representation on project steering committees responsible for research involving Aboriginal and Torres Strait Islander genomic information.

Australia lacks infrastructure to manage immense amounts of genomic data, risking **data sovereignty** and security for Aboriginal and Torres Strait Islander genomic data. Storing data at great distances from its region of origin disconnects people from country, potentially causing cultural harm. In addition, the practicality of this remote storage means loss of control over the data (e.g. if data stored on overseas servers, that data is potentially subject to the laws of that jurisdiction). This lack of control will mean that cultural mourning protocols will not be followed, and there will be greater uncertainty about who controls that data after the donor dies.

There is also risk associated with third-party platforms and software. This risk is that the data may be re-used by the platform/software without donor consent. This re-use could either be legally permitted (e.g. by far reaching consent clauses in the software licence terms and conditions) or in breach of the licence agreements. Either way, there is significant risk of cultural harm.

Privacy and disclosure laws, although not proprietary laws, allow some measure of control over disclosure and use of health-related information. There are, however, several exceptions to the general principle that any use must be consented to by the individual.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Permitted non-consensual uses may include use of deidentified information (although, in genomics is anything really thoroughly de-identified? Particularly in smaller communities) and court-ordered access to identified information. The potential for police to access genomic information with a court order was a source of significant concern among the Advisory Group as this would be seen as a breach of the trust placed by donors in researchers by allowing them to access their genes.

Discrimination was also identified as significant issue. This could occur in the context of genetic discrimination – discrimination against Aboriginal and Torres Strait Islander peoples based on their genes. For example, research to detect a so-called “sports” or “alcoholic” gene. Or research without consent into culturally sensitive topics (e.g. the Havasupai case study). In addition, while recent legislative amendments preventing life insurance companies from accessing My Health Records were put in place, questions remain: what if a further amendment removes that prohibition? Could testing into genetic pre-disposition be used in disability claim?

Another risk of discrimination arises elsewhere: could a lack of opportunity for Aboriginal and Torres Strait Islander peoples to engage in genomic study in a culturally appropriate and safe way amount to discrimination by excluding them from positive health outcomes?

There are opportunities for **capacity building in the workforce** by better equipping medical service personnel to meet their duty of care and for the management of incidental findings. There is also potential for capacity building among community by providing better knowledge of their rights, and the responsibilities of the medical personnel to whom they disclose their genomic information.

The potential commercialisation of genes, particularly through **patents** is another significant concern. The proprietary ownership by non-Indigenous companies over Aboriginal and Torres Strait Islander genes and ICIP is completely at odds with all best practice models and standards of international law. While human genes are not currently eligible for patent protection in Australia, they may be in other jurisdictions. This becomes relevant were data may be stored (and therefore potentially accessible) in other jurisdictions. It is also possible that innovations derived from human genes *may* be patentable in Australia.

Finally, **secondary uses** of genetic materials, without consent represents a loss of control and sovereignty over Aboriginal and Torres Strait Islander genes. Unauthorised secondary uses may occur in a number of contexts including use of data through permitted uses under privacy law, or use of de-identified data obtained through My Health Records for medical research.

Unauthorised secondary uses of data stored in existing biobanks or other collections are also a potential concern. In some areas, the importance of cultural protocols are well understood, and the absence of legal protections have been remedied by the adoption of best practice models. The National Centre for Indigenous Genomics, for example, prioritises consultation and consent to ensure that there is no unauthorised use of any genomic sample in their collection. They apply the standard of free, prior, informed consent, and a donor (or their family or community) is free to withdraw consent at any time.



Indigenous Health Genomics: The Legal, Ethical and Social Issues

In other sectors, however, cultural protocols and the standard of free, prior, informed consent is less well understood. In those sectors, the absence of legal protections is far more apparent.

Genomic research is a dynamic and rapidly developing area of medical research. It has the potential to deliver significant positive medical outcomes. However, it operates in the context of scientific research that has historically been used to discriminate against Aboriginal and Torres Strait Islander peoples. In addition, common procedure, policy and law are all based on European views of the body, culture and heritage. This issues paper has outlined the primary ethical, social and cultural issues of Indigenous genomic research and analysed the current legal landscape to see how these concerns are addressed.

To complete the analysis, national and international case studies of best practice (and not best practice) have been used to demonstrate the risks and opportunities available for law and policy in this area. International comparative legal analysis serves the same function. The outcome has been the key issues outlined above. With a better understanding of these key issues we have a starting place for policy and law makers when working towards better health outcomes for Aboriginal and Torres Strait Islander peoples.



11 References

A Articles/Books/Reports

Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* ALRC Report 96 (2003)

<<https://www.alrc.gov.au/publication/essentially-yours-the-protection-of-human-genetic-information-in-australia-alrc-report-96/07-information-and-health-privacy-law/applying-the-privacy-act-to-genetic-information/>>

Australian Law Reform Commission, *Genes and Ingenuity: Gene patenting and human health*, ALRC Report 99 (2004)

Bartlett, William, 'D'Arcy v Myriad Genetics Inc [2015] HCA 35: The plurality's new factorial approach to patentability rearticulates the question asked in NRDC' (2015) 25(1) *Journal of Law, Information and Science*, 120

Ekstein, Lisa, Donald Chalmers, Christine Critchley, Ruthie Jeanneret, Rebekah McWhirter, Jane Nielsen, Margaret Otlowski, Dianne Nicol, 'Australia: regulating genomic data sharing to promote public trust', (2018) 137(8) *Human Genetics* 583-591

Elsum, Imogen, Callum McEwan, Emma E Kowal, Yvonne Cadet-James, Margaret Kelaher and Lynn Woodward, 'Inclusion of Indigenous Australians in biobanks: a step to reducing inequity in health care' (2019) 11 *Medical Journal of Australia* 7

Harry, Debra, 'Bio colonialism and Indigenous knowledge in United nations Discourse' (2011) 20(1) *Griffith Law Review*, 702

Janke, Dr Terri, *True Tracks: Indigenous Cultural and Intellectual Property Principles for putting Self-Determination into practice* (PhD Thesis, Australian National University, 2019) available at <<http://www.terrijanke.com.au/terri-janke-phd-true-tracks>>

Kowal, Emma, 'Genetic research in Indigenous health: significant progress, substantial challenges' (2012) 197(1) *The Medical Journal of Australia*, 19

Van Assche, Kristof, Serge Gutwirth and Sigrid Sterckx, 'Protecting Dignitary Interests of Biobank Research Participants: Lessons from *Havasupai Tribe v Arizona Board of Regents*' (2013) 5(1) *Law, Innovation and Technology* 5, 60

Markow Therese, John Martin, 'Inbreeding and developmental stability in a small human population', (1993) 20(4) *Annals of Human Biology* 389

Marshall, Virginia, Terri Janke and Anthony Watson, 'Community Economic Development in Patenting Traditional Knowledge: A Case Study of the Mudjala TK Project in the Kimberley Region of Western Australia' (2013) 8(6) *Indigenous Law Bulletin* 16

McWhirter, Rebekah, Carolyn Johnston, and Jo Burke, 'Disclosure of Genetic Results to At-risk Relatives without Consent: Issues for Health Care Professionals in Australia' (2019) 27(1) *Journal of Law and Medicine* 108

Mallick Swapman, Heng Li, Mark Lipson, Iain Mathieson, Melissa Gymrek, Fernando Racimo, Mengyao Zhao, Niru Chennagiri, Susanne Nordenfelt, Arti Tandon, Pontus Skoglund, Losif Lazaridis, Sriram Sankararaman, Qiaomei Fu, Nadin Rohland, Gabriel



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Renaud, Yaniv Erlich, Thomas Willems, Carla Gallo, Jeffrey P. Spence, Yun S. Song, Giovanni Poletti, Francois Balloux, George van Driem, Peter de Knijff, Irene Gallego Romero, Aashish R. Jha, Doron M. Behar, Claudio M. Bravi, Cristian Capelli, Tor Hervig, Andres Moreno-Estrada, Olga L. Posukh, Elena Balanovska, Oleg Balanovsky, Sena Karachanak Yankova, Hovhannes Sahakyan, Draga Toncheva, Levon Yepiskoposyan, Chris Tyler-Smith, Yali Xue, M. Syafiq Abdullah, Andres Ruiz-Linares, Cynthia M. Beall, Anna Di Rienzo, Choongwon Jeong, Elena B. Starikovskaya, Ene Metspalu, Jüri Parik, Richard Villems, Brenna M. Henn, Ugur Hodoglugil, Robert Mahley, Antti Sajantila, George Stamatoyannopoulos, Joseph T. S. Wee, Rita Khusainova, Elza Khusnutdinova, Sergey Litvinov, George Ayodo, David Comas, Michael Hammer, Toomas Kivisild, William Klitz, Cheryl Winkler, Damian Labuda, Michael Bamshad, Lynn B. Jorde, Sarah A. Tishkoff, W. Scott Watkins, Mait Metspalu, Stanislav Dryomov, Rem Sukernik, Lalji Singh, Kumarasamy Thangaraj, Svante Pääbo, Janet Kelso, Nick Patterson, and David Reich 'The Simons genome diversity project: 300 genomes from 142 diverse populations' (2016) 538(7624) *Nature* 201

Mortimer, Debra, 'Proprietary Rights in Body Parts: The Relevance of Moore's Case in Australia, (1993) 19(2) *Monash University Law Review* 217

National Health and Medical Research Council, *Keeping Research on Track II* (Australian Government, Canberra, August 2018) <<https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii>>

Rimmer, Mathew, 'The Genographic Project: Traditional Knowledge and Population Genetics' (2007) 11(2) *Australian Indigenous Law Reporter* 46

Rimmer, Matthew, 'The Empire of Cancer: Gene Patents and Cancer Voices' (2013) 22(2) *Journal of Law, Information and Science* 18

Rimmer, Matthew, 'Gene Genie: The Judicial Revolution in Biotech IP' (2016) 26(2) *Australasian Biotechnology* 60

Wade, Peter, *Degrees of Mixture, Degrees of Freedom: Genomics, Multiculturalism, and Race in Latin America* (Duke University Press, 2017)

B Cases

Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) 50 FCR 1

Association for Molecular Pathology, et al. v. Myriad Genetics, 569 U.S. 576 (2013)

Bernhard Joos v Commissioner of Patents (1972) 126 CLR 611

Black CJ Demagogue Pty Ltd v Ramensky (1992) 39 FCR 31

Breen v Williams (1996) 186 CLR 71

Commonwealth of Australia & Anor v Human Rights and Equal Opportunity Commission [1997] FCA 664 (18 July 2007)

Commonwealth v Tasmania (1983) 158 CLR 1



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Coulls v Bagot's Executor & trustee Co Ltd (1967) 119 CLR 460

D'Arcy v Myriad Genetics Inc (2015) 258 CLR 334; [2015] HCA 35 (7 October 2015)

Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd (2002) 192 ALR 433

Diamond v. Chakrabarty, 447 U.S. 303 (1980)

Grain Pool of Western Australia v Commonwealth of Australia (2000) 202 CLR 479

Havasupai Tribe v Arizona Board of Regents, 204 P.3d, 1063, 13 (Ariz, Ct App 2008)

Hunter and New England Area Health Service v A [2009] NSWSC 761 (6 August 2009)

Meat & Livestock Australia Limited v Cargill, Inc [2018] FCA 51 (9 February 2018)

Moore v. Regents of University of California, 793 P.2d 479, 63 (Cal. 1990)

National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252

Primary Health Care Ltd v Commissioner of Taxation [2010] FCA 419 (4 May 2010)

Privacy Commissioner v Telstra Corporation Limited [2017] FCAFC 4 (19 January 2017)

QFG & Anor v JM [1998] QCA 228 (19 August 1998)

Re MB [1997] 2 FCR 514

Rogers v Whitaker (1992) 175 CLR 479

Rosenberg v Percival [2001] HCA 18 (5 April 2001)

Secretary of the Department of Health and Community Services v JWB (Marion's Case) (1992) 175 CLR 218

Sequenom, Inc. v Ariosa Diagnostics, Inc. [2019] FCA 1011 (27 June 2019)

Telstra Corporation Limited and Privacy Commissioner [2015] AATA 991 (18 December 2015)

Trident General Insurance Co Limited v McNiece Bros Pty Ltd (1988) 165 CLR 107

Truth About Motorways Pty Ltd V Macquarie Infrastructure Investment Management Ltd (2000) 169 ALR 616

Wallace v Kam (2013) 250 CLR 375

White v Johnston (2015) 87 NSWLR 779



C Legislation

Anti-Discrimination Act 1977 (NSW)

Anti-Discrimination Act 1991 (Qld)

Anti-Discrimination Act 1992 (NT)

Anti-Discrimination Act 1998 (Tas)

Charter of Human Rights and Responsibilities Act 2006 (Vic)

Competition and Consumer Act 2010 (Cth)

Copyright Act 1968 (Cth)

Crimes Act 1914 (Cth)

Discrimination Act 1991 (ACT)

Equal Opportunity Act 1984 (SA)

Equal opportunity Act 1984 (WA)

Equal Opportunity Act 2010 (Vic)

Federal Court of Australia Act 1976 (Cth)

Health Care Complaints Act 1993 (NSW)

Health Practitioner Regulation (Adoption of National Law) Act 2009 (NSW)

Health Practitioner Regulation National Law 2009 (Qld)

Health Practitioner Regulation National Law 2009 (Vic)

Health Practitioner Regulation National Law Act 2010 (NT)

Health Practitioner Regulation National Law Act 2010 (Tas)

Health Practitioner Regulation National Law Act 2010 (ACT)

Health Practitioner Regulation National Law Act 2010 (SA)

Health Practitioner Regulation National Law Act 2010 (WA)

Health Records and Information Privacy Act 2002 (NSW)

Human Rights Act 2004 (ACT)

Human Rights Act 2019 (Qld)

Indigenous Health Genomics: The Legal, Ethical and Social Issues

Human Tissue Act 1982 (Vic)

Human Tissue Act 1983 (NSW)

Human Tissue Act 1985 (Tas)

Human Tissue and Transplant Act 1982 (WA)

Human Tissue Transplant Act 1979 (NT)

Mental Health Act 2007 (NSW)

My Health Records (National Application) Rules 2017 (Cth)

My Health Records Act 2012 (Cth)

National Health and Medical Research Council Act 1992 (Cth)

Patents Act 1990 (Cth)

Patents Act 2013 (NZ)

Privacy Act 1988 (Cth)

Protection of Movable Cultural Heritage Act 1986 (Cth)

Protection of Moveable Cultural Heritage Regulations 2018 (Cth)

Public Health Act 2010 (NSW)

Racial Discrimination Act 1975 (Cth)

Transplantation and Anatomy Act 1978 (ACT)

Transplantation and Anatomy Act 1979 (Qld)

Transplantation and Anatomy Act 1983 (SA)

Transplantation and Anatomy Act 1983 (SA)

D Treaties

International Covenant on Civil and Political Rights, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976)

International Convention on the Elimination of all forms of Racial Discrimination, opened for signature 21 December 1965, 660 UNTS 195 (entered into force 4 January 1969)

E Internet Materials



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Aboriginal Affairs, *The Ochre Plan*, NSW Government (2013)
<<https://www.aboriginalaffairs.nsw.gov.au/our-agency/staying-accountable/ochre/nsw-government-aboriginal-affairs-strategy>>

Australian Criminal Intelligence Commission, *Biometric and forensic services* (2019)
<<https://www.acic.gov.au/our-services/biometric-matching>>

Australian Government *Australian Digital Health Agency* (2020)
<<https://www.digitalhealth.gov.au/about-the-agency>>

Australian Human Rights Commission (2020) <<https://www.humanrights.gov.au/our-work/aboriginal-and-torres-strait-islander-social-justice>>

Brereton, Paul, 'The Origins and Evolution of the *Parens Patriae* Jurisdiction' (Lecture, Sydney University, 5 May 2017)

Broad Institute, *Carlos Slim Center for Health Research at the Broad Institute*,
<<https://www.broadinstitute.org/sigma>>

Burt, Jemima, 'Gumby Gumby trademark bid angers Indigenous people who want intellectual property rights reform', *ABC* (online, 9 April 2019)
<<https://www.abc.net.au/news/2019-04-09/gumby-gumby-trademark-bid-angers-indigenous-people/10975908>>

Fryer, 'Brooke No DNA test exists for Aboriginality: Scientists' on *NITV* (16 March 2019)
<<https://www.sbs.com.au/nitv/article/2019/03/16/no-dna-test-exists-aboriginality-scientists1>>

Parker, Ziyaad, Suresh Maslamoney, Ayton Meintjes, Gerrit Both, Sumir Panji, Scott Hazelhurst, Nicole Mulder, 'Building Infrastructure for African Human Genomic Data Management' (2019) 18(1) *Data Science Journal* 47
<https://datascience.codata.org/articles/10.5334/dsj-2019-047/>

H3Africa, *Human Heredity & Health in Africa* <<https://h3africa.org/>>

IP Australia, 'Types of Patents', *Understanding Patents* (Website, 26 April 2020)
<<https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents>>

National Centre for Indigenous Genomics *Annual Report 2018, 8*. (Australian National University, 2018) <<https://nciq.anu.edu.au/files/NCIG-2018-Annual-Report.pdf>>

National Centre for Indigenous Genomics, *About NCIG* <<https://nciq.anu.edu.au/>>

National Centre for Indigenous Genomics, *How the Galiwin'ku samples came to be held at ANU* (Case Study, 07 July 2020) <<https://nciq.anu.edu.au/nciq-collection>>

National Centre for Indigenous Genomics, *NCIG Collection* (Webpage, 05 July 2020)
<<https://nciq.anu.edu.au/nciq-collection>>

National Centre for Indigenous Genomics, *Public Lecture by Prof Simon Easteal* (YouTube, 16 June 2015) <<https://www.youtube.com/watch?v=UieBgf9AuPw>>

National Centre for Indigenous Genomics, *Repatriation: bringing home the Manggu* samples* (Case Study, 07 July 2020) <<https://nciq.anu.edu.au/nciq-collection>>



Indigenous Health Genomics: The Legal, Ethical and Social Issues

National Centre for Indigenous Genomics, Strategic Plan 2017-2021(Webpage, 06 July 2020) <<https://ncig.anu.edu.au/about/strategic-plan-2017-2021>>

National Geographic, *Genographic Project* <<https://genographic.nationalgeographic.com/>>

NSW Health Statewide Biobank, *NSW Health Statewide Biobank FAQ's for Researchers* (February 2019) <https://biobank.health.nsw.gov.au/wp-content/uploads/2019/07/NSW-Health-Statewide-Biobank-FAQs-for-researchers-Feb-2017_FINAL.pdf>

NSW Health, 'Biobanking' <<https://www.medicalresearch.nsw.gov.au/biobanking/>> (Accessed 03 July 2020)

Shelston IP, 'Australia remains a gene-patent friendly jurisdiction' on Shelton IP Blog (18 February 2018) <<http://www.shelstonip.com/news/australia-remains-gene-patent-friendly-jurisdiction/>>

Type 2 Diabetes Knowledge Portal, <<http://www.type2diabetesgenetics.org/>>, viewed 8 July 2020.

Wellington, Shahni, 'Indigenous Blood Samples return to Galiwin'ku after 50 years in medical storage', *National Indigenous Television Network (NITV)* (online, 13 November 2019) <<https://www.sbs.com.au/nitv/article/2019/11/18/indigenous-blood-samples-return-galiwinku-after-50-years-medical-storage>>

World Intellectual Property Organization, 'Bioethics and Patent Law: The Case of the Oncomouse' (June 2006), *WIPO Magazine* <https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html>

Zhang, Sarah, *How a Genealogy Website Led to the Alleged Golden State Killer* (27 April 2018) <<https://www.theatlantic.com/science/archive/2018/04/golden-state-killer-east-area-rape-dna-genealogy/559070/>>

F Guidelines and Codes of Conduct

Australian Government, Office of the Australian Information Commissioner, *Australia Privacy Principles Guidelines*, (at July 2019) <<https://www.oaic.gov.au/assets/privacy/app-guidelines/app-guidelines-july-2019.pdf>>

Australian Institute of Aboriginal and Torres Strait Islander Studies, *Guidelines for Ethical Research in Australian Indigenous Studies* (2012)

Hudson, Maui, Angela Beaton, Moe Milne, Waiora Port, Khyla Russell, Barry Smith, Valmaine Toki, Lynley Uerata and Phil Wilcox, *Te Mata Ira: Guidelines for Genomic Research with Māori* (Te Mata Hautū Taketake – Māori & Indigenous Governance Centre, October 2016)

IP Australia, *Australian Patent Office Manual of Practice and Procedure* (1 August 2017)

Kimberley Land Council, *Intellectual Property and Traditional Knowledge Policy* (6 September 2011), Kimberley Land Council) <<https://www.klc.org.au/research-facilitation>>



Indigenous Health Genomics: The Legal, Ethical and Social Issues

Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (17 March 2014)

National Health and Medical Research Council, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders*, (Australian Government, Canberra, 2018)

National Health and Medical Research Council, *Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research* (Australian Government, Canberra, June 2018)

Office of the Australian Information Commissioner, *Australian Privacy Principles Guidelines Privacy Act 1988*, (Australian Government)

QIMR Berghofer Medical Research Institute, *Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland*, September 2019, <<https://www.qimrberghofer.edu.au/wp-content/uploads/2019-Indigenous-Health-Genomics-Guide-v9-WEB-1.pdf>>

South Australian Aboriginal Health Research Accord, *South Australian Health & Medical Research Institute* (Web Page) <<https://www.sahmriresearch.org/our-research/themes/aboriginal-health/research-list/south-australian-aboriginal-health-research-accord>>

The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, *National Statement on Ethical Conduct in Human Research 2007* (Updated 2018), (Australian Government, Canberra, 2018)

G International Legal Instruments and Sources

Convention on the Grant of European Patents (European Patent Convention) (2016) OJ EPO June 2016)

International Declaration on Human Genetic Data, 32 C/Res 22 UNESCO 39 (16 October 2003)

Universal Declaration on Bioethics and Human Rights, 32 C/Res 24, UNESCO 33rd session, (19 October 2005)

Universal Declaration on the Human Genome and Human Rights, C/Res 16, UNESCO 29th sess, (11 November 1997)

Universal Declaration on the Rights of Indigenous Peoples, GA Res 61/295, UN GAOR, 61st sess, 107th plen mtg, UN Doc A/RES/61/295 (13 September 2007)

H Other

AU Patent Application no 2007205838, filed on 19 January 2007 (Withdrawn 27 October 2011)

AU Patent Application no 2008300612, filed on 15 September 2008 (Issued 6 May 2010)

Australian Government, Department of Social Services, *Footprints in Time – The Longitudinal Study of Indigenous Children (LSIC)* <<https://www.dss.gov.au/about-the->



Indigenous Health Genomics: The Legal, Ethical and Social Issues

[department/publications-articles/research-publications/longitudinal-data-initiatives/footprints-in-time-the-longitudinal-study-of-indigenous-children-lsic#3](https://www.data.gov.au/department/publications-articles/research-publications/longitudinal-data-initiatives/footprints-in-time-the-longitudinal-study-of-indigenous-children-lsic#3)>

Australian Government, Department of Social Services, *National Centre for Longitudinal Data Dataverse*, <<https://dataverse.ada.edu.au/dataverse/ncl>>

CCH Intelliconnect, *Australian Health & Medical Law Report* (online at 22 April 2020) *Source of Patient Rights* [27-130]

Consultation with National Centre for Indigenous Genomics, (Patrick Goulding and Laura Curtis, Teleconference, 15 April 2020).

International Center for Technology Assessment, the Indigenous Peoples Council on Biocolonialism, Greenpeace and the Council for Responsible Genetics, 'Brief for Amici Curiae in Support of the Plaintiffs', Submission in Association for Molecular Pathology, et al. v. Myriad Genetics, 569 U.S. 576, 12, 15, (2013) 10 September 2009

LexisNexis, *Halsbury Laws of Australia* (online at 24 April 2020) 280 Medicine, '2 Disciplinary Matters and Offences – Registration of Medical Practitioners, [280]

National Health and Medical Research Council, *Biobanks Information Paper* (Report, February 2010)

Simons Foundation, *Simons Genome Diversity Project* (12 April 2017) <<https://www.simonsfoundation.org/simons-genome-diversity-project/>>

