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TRENDS AND CHALLENGES IN BIOBANKING

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ABSTRACT

The last twenty years have seen the emergence of the phenomena of biobanks, which are now regarded as essential research infrastructure in most countries around the world. However, the very nature of biobanks, as long-term repositories of sample and data that are used for many different research purposes continues to challenge many of the legal requirements for medical research, both in the UK and Australia. This chapter will provide an overview of biobanking and discuss some of the legal challenges that these activities raise by discussing and comparing the UK and Australian legal landscapes.

INTRODUCTION

At the end of last century, if you searched for the term 'biobank' it would be difficult to find anywhere. Twenty years later, 'biobank' has become the standard term in English for collections of samples and data that are systematically organised and curated so that they can be used for many different research purposes by many researchers over time.[1] Biobanks are now considered intrinsic to the research process and are regarded as essential infrastructure for hospitals and research institutions in most countries around the world. There are dozens of biobanks in Australia alone and thousands internationally, including some nation-wide repositories that have required considerable investment. The next stage of development in the field of biobanking has seen biobanks being brought together in organised networks through the establishment of national registries and standardised processes for the collection and curation of samples.[2] However, the development of biobanking as a field has not been without some challenges to existing norms, best practice and established legal requirements.

There are a number of key legal challenges that have emerged such as the nature of the consent that should be obtained, the protection of privacy, property rights in tissue and information, and how to enable access to researchers and commercial entities that have been raised by biobanking activities. Over time, other issues have emerged in line with evolving technologies and changing social attitudes such as if, and how, incidental findings should be returned to participants as well as concerns about the long-term sustainability of biobanks. As the costs of genome sequencing have fallen, biobanks have often enriched their collections by adding genetic samples, which has intensified issues about the return of results. The purpose of this chapter is to discuss these key issues that have dominated legal and ethical debates in biobanking over the last twenty years and to demonstrate how these concerns have evolved over time. We will focus on UK (and European law when it is relevant) and Australian law to bring out some of these issues and illustrate the complexity of the law in these jurisdictions, but also the similarities between them.

WHAT ARE BIOBANKS?

There are many different types of biobanks, from collections of pathology samples obtained as part of routine care through to large population biobanks designed specifically to be a national research resource. This is related to the research use, for example large-scale biobanks are more suitable for prospective and longitudinal molecular

[1] European Commission and Directorate-General for Research and Innovation, *Biobanks for Europe: A Challenge for Governance* (EUR-OP, 2012) 13.

[2] An example of this is BBMRI-ERIC, which co-ordinates the activities of biobanks across Europe, though the development of national nodes to make samples more accessible to researchers wherever they are located around the world.

epidemiology research projects, compared with smaller biobanks of samples collected for specific research projects.[3] Other biobanks have been established to enable a specific area of medical research, such as the UK Research Council-funded Stem Cell Bank, where purity and provenance of the material requires additional consideration.[4] A significant change over the past twenty years has been the acceptance of biobanks as research infrastructure requiring the development of new governance structures and procedures. As part of this process, international infrastructure has been developed that is designed to link smaller clinical research collections and biobanks under larger platforms, to streamline access and enhance statistical power.[5] A number of different types of biobanks have been identified based on sample collection size and their research uses.[6]

Population-based Biobanks

Population-based biobanks generally seek samples from healthy participants who represent a geographic area, country or particular ethnic group, to identify biomarkers for disease susceptibility specific to that population through prospective molecular epidemiology research methods. They may store bio-specimens such as germline-DNA isolated from venous blood, together with information such as physical, behavioural and socio-economic data. In Europe, large-scale biobanks include the UK Biobank,[7] and the Estonian Biobank.[8] There has been no equivalent investment in Australia.

Disease-specific Biobanks

Disease-oriented biobanks capture more diverse biological materials, usually during the course of clinical care. In Australia and elsewhere, the largest disease-orientated biobanks are cancer repositories, a good example being the Australian Prostate Cancer BioResource, which holds over 150,000 bio-specimens.[9] More recently, with the advent of technology that allows disease-specific stem cell lines to be created directly from a patient's cells, large initiatives such as the European Bank for Induced Pluriponent Stem Cells have been established.[10]

Case-control Biobanks

Case-control biobanks involve the collection of samples and information from people who have a particular disease and from a control group of matched healthy people, of the same age and sex. These offer an alternative to resource-intensive population-based biobanks. Examples in Australia include biobanks relating to juvenile arthritis,[11] Alzheimer's disease[12] and schizophrenia.[13]

Tissue Banks

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[3] Martin Asslaber and Kurt Zatloukal, 'Biobanks: Transnational, European and Global Networks' (2007) 6(3) *Briefings In Functional Genomics & Proteomics* 193; Peter HJ Riegman et al, 'Biobanking for Better Healthcare' (2008) 2(3) *Molecular Oncology* 213.

[4] Glyn Stacey and Charles Hunt, 'The UK Stem Cell Bank: A UK Government-Funded, International Resource Center for Stem Cell Research' (2006) 1(1) *Regenerative Medicine* 139.

[5] For example, the Oxford Radcliffe Biobank brought together existing collections within the University of Oxford and the Oxford Radcliffe Hospitals NHS Trust.

[6] European Commission and Directorate-General for Research and Innovation, above n 1, 13.

[7] http://www.ukbiobank.ac.uk/

[8] http://www.geenivaramu.ee/en/

[9] https://www.apcbioresource.org.au/

[10] Paula A De Sousa et al, 'Hot Start to European Pluripotent Stem Cell Banking' 35(7) *Trends in Biotechnology* 573.

[11] http://www.rch.org.au/rheumatology/research/Juvenile_Arthritis_Biobank/

[12] https://aibl.csiro.au/

[13] http://www.schizophreniaresearch.org.au/bank/

Tissue banks comprise very heterogeneous specimen collections, usually cryopreserved in hospital pathology departments after sampling by routine invasive medical procedures. They are likely to be associated with detailed patient data on underlying disease, and, subject to patient consent, may be further annotated with disease progression and outcomes. Other tissue banks, such as the Australian Brain Bank Network, have been established to accept post mortem tissue to advance fundamental understanding of brain and mind disorders.[14]

Clinical Trials and Biobanking

Biobanking can maximise the resources invested in clinical trials by ensuring that the wide-ranging samples and data collected during trials are retained and made available for subsequent research, particularly in the identification of disease-related biomarkers. An Australian example is the ASPREE Healthy Ageing Biobank, embedded in the ASPREE trial of aspirin for healthy older people.[15]

Other Types of Biobanks

Blood spots collected through routine national neonatal screening ("Guthrie cards") can comprise biobanks for subsequent research. The best known is the Swedish PKU Biobank, which contains several million Guthrie cards. In the cord blood context, public and private biobanks exist. In the cord blood context, there are networks of national public cord blood banks that for several decades have been providing matched transplants for treatment of blood disorders and some cancers.[16] More recently, private biobanks have been offering to store cord blood for future use. The Future Health Biobank is a useful example; a private operator, its activities traverse 75 countries and now extend beyond banking of cord blood to umbilical cord tissue, dental pulp and adipose tissue.[17] In Australia as elsewhere, banking of cord blood and other tissues is increasingly popular amongst parents seeking to secure improved health options for their child, although questions have been raised concerning the usefulness of private storage.[18] The ability to create and bank mini-organs, so called organoids, directly from a patient's own cells for use in drug development and precision medicine is also an emerging area that is attracting interest from biotech and pharmaceutical companies.[19]

THE LEGAL FRAMEWORK FOR BIOBANKING

The law that applies to biobanking activities is complex as biobanking involves many different kinds of samples and data, being used for both clinical and research purposes, as well as involving collaborations where samples and data are collected, used and transferred to different countries crossing multiple national borders. Like most countries, the UK and Australia do not have specific legislation for biobanks but instead rely on more generic law to regulate this area. Both countries have maintained a distinction in legislation between human material (samples) and information relating to individuals (data) that determines the appropriate regulatory framework for each. This separation creates a fragmented and complicated legal framework for the regulation of biobanks, which can be contrasted with other European countries that have created their own national biobank legislation, such as Estonia and its *Human Genes Research Act*. At the international level, a number of specific guidelines have been developed to enable greater

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[14] http://www.austbrainbank.org.au/roles.html

[15] This Biobank is notable for its collection methods, which include four specially-equipped mobile 'biobus' vehicles for sample collection in rural and regional areas. See https://aspree.org/aus/sub-studies/ive-been-everywhere-the-aspree-biobus-story/.

[16] An example is the Australian National Network of Umbilical Cord Blood Banks and Cord Blood Collection Centres, http://www.abmdr.org.au/auscord/

[17] Futurehealthbiobank.com

[18] http://www.smh.com.au/technology/technology-news/parents-pay-to-store-their-babies-cord-blood-but-few-ever-use-it-20140308-34efi.html, accessed 10 Aug 2017.

[19] Sarah Boers et al, 'Organoid Biobanking: Identifying the Ethics' (2016) 17(7) *EMBO Reports* 938.

harmonisation, such as the OECD Guidelines on Human Biobanks and Genetic Research 2009[20] and the HUGO statement on Human Genetic Databases 2002.[21] In both the UK and Australia, national policies and ethical guidelines have been developed to help researchers, health practitioners and research institutions navigate this complicated landscape which is heavily dependent upon a combination of national authorities and research ethics committees to oversee biobanking activities.

Legislation in the UK and Australia

Australia and the UK both feature different federated structures: Australia has both Commonwealth and state laws; while in the UK, European law has been integrated into national law and enables the UK to operate within the European Union (EU), a single common market of European countries. Having been a member of the EU since its inception, the UK's legal system has been shaped and modified by European law and a desire to facilitate the free movement of goods and people across Europe. However, there are still considerable differences between the UK and other member states, primarily because the UK, like Australia, is a common law jurisdiction but also because the adoption of European legal requirements has not been uniform across all the member states.

In the EU, the primary sources of legislation relevant to biobanking are the Directive 2004/23/EC setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48 (hereafter 'Tissue Directive'), which regulates human tissue; and the Council Regulation (EC) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L119/1 (hereafter the 'General Data Protection Regulation' or GDPR). European Directives enable European member states to implement data protection requirements into national law in ways that allowed for differences between the jurisdictions.[22] The new GDPR, by contrast, should be directly transposed into the national laws of EU Member States, in principle producing harmonisation of European data protection legislation. However, the GDPR does allow for some national variations (derogations) in certain circumstances[23] so it is likely that some differences between member states will persist after 2018. As a member state of the EU, the UK is responsible for implementing these Directives (and now the GDPR) into national law. The UK has implemented the EU Directives via the *Data Protection Act 1998* (UK), and the *Human Tissue Act 2004* (UK).

In Australia, at a Commonwealth level, the Privacy Principles derived from the *Privacy Act 1998* (Cth) regulate the manner in which biobanks manage and disseminate health information. This is in combination with state-based regulation of health information, such as the *Health Records Act 2001* (Vic). In addition, states have enacted legislation regulating the use of human tissue for research.[24] This creates a complex web of legislation that is dependent upon the demarcation of powers between the Commonwealth and the states. The purpose of implementing EU law in the UK and other member states is to achieve harmonisation, enabling co-operation and integration, with common legal principles and requirements. In contrast, within Australia, the law demarcates and

[20] OECD, 'OECD Guidelines on Human Biobanks and Genetic Research Databases' (2009) <http://www.oecd.org/sti/biotech/44054609.pdf>.
[21] Human Genome Organisation (HUGO), Ethics Committee, 'Statement on Human Genomic Databases, December 2002' (2003) 14(3–4) *Journal International De Bioethique = International Journal of Bioethics* 207.
[22] Yves Poullet, 'EU Data Protection Policy. The Directive 95/46/EC: Ten Years After' (2006) 22(3) *Computer Law & Security Review* 206.
[23] Information Commissioner's Office, *National Derogations* (17 January 2017) <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/national-derogations/>.
[24] Following the Australian Law Reform Commission's 1977 report, 'Human Tissue Transplants' (ALRC 7), Human Tissue legislation was enacted in all Australian jurisdictions, see: *Human Tissue Act 1983* (NSW); *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).

articulates the different powers and responsibilities between the Commonwealth and the states, which may make harmonisation more elusive.

Regulatory Bodies

The responsibilities of the regulatory bodies that apply to biobanking in the UK and Australia are determined by whether they regulate data, human tissue or medical research. This distinction applies in both jurisdictions and can be problematic if there are different legal requirements for research that apply to these different entities and are required by the different regulatory bodies. As a means of reconciling this, a separate oversight system has evolved for medical research, of which licensing and research ethics committees play a significant role in both Australia and the UK. The challenge for research ethics committees is that they are designed to review research projects rather than infrastructure such as biobanks.

Within the legal framework for biobanking in the UK, a number of organisations have a governance role to ensure biobanks' compliance with ethical and legal requirements. Some bodies are statutorily created to administer legislation. The *Human Tissue Act 2004* (UK) implements the EU Tissue Directive and regulates the removal, storage, use and disposal of human tissue for Scheduled Purposes (including for research purposes), via the statutory body the Human Tissue Authority (HTA).[25] The Act requires that all establishments that have any dealings with human material must be licensed. The HTA is the regulator for human tissue and organs and is responsible for licensing collections of samples[26] and administering Codes of Practice as guidance for professionals and researchers, as well as guidance for the public.[27] Although non-compliance with these Codes is not in itself an offence under the Act, it could influence licensing decisions made by the HTA, which are mandatory.

In addition to the HTA the Information Commissioner's Office[28] is responsible for developing guidelines for the use of data and applying fines for any breaches. The Health Research Authority (HRA) oversees research ethics committees across the UK but there is no single body that oversees biobanking activities. To address this issue biobanks have been given powers to be accountable to the HRA about research that is carried out on the individual biobank, through regulations passed by the Secretary of State. The Medical Research Council has also recently funded the UK Tissue Directory and Coordination Centre to establish an online Directory of biobanks and participate in European projects as BBMRI.uk and to be the National Node for the UK as part of BBMRI-ERIC.[29] While this is not a regulatory body as such, by developing harmonisation activities, this helps to develop best practice across the UK.

Unlike the EU, in Australia no Commonwealth legislation regulates health and medical research. Consequently, there are no national licensing requirements for regulating health and medical research, aside from research using human embryos.[30] Instead, the preferred approach has been to use the independent statutory agency the National Health and Medical Research Council (NHMRC)[31] that issues guidelines on matters relating to public health research and medical research. An example is the 'National Statement on Ethical Conduct in Human Research' (2007) (updated May 2015, hereafter 'National Statement', developed by the NHMRC, the Australian Research Council (ARC) and Universities Australia), which requires researchers to describe how their research data will be collected, used, stored

[25] https://www.hta.gov.uk/

[26] Excluding gametes and embryos, which is the remit of the Human Fertilisation and Embryology Authority (http://www.hfea.gov.uk/)

[27] For example: Human Tissue Authority, 'Code of Practice 1: Consent (Version 14.0)' (July 2014) <https://www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf>.

[28] https://ico.org.uk/

[29] http://www.ukcrc.org/research-infrastructure/ukcrc-tissue-directory-and-coordination-centre/

[30] This is regulated by the *Research Involving Human Embryos Act 2002* (Cth).

[31] The NHMRC was established by the *National Health and Medical Research Council Act 1992* (Cth) s 5B(1).

and disclosed[32] and sets out the obligations of researchers and custodians with regard to data usage.[33] While the National Statement is not binding of itself (except in relation to NHMRC and ARC funded projects), the requirements it sets out regarding Human Research Ethics Committee (HREC) approval processes have been incorporated into the *Privacy Act 1988* (Cth).[34] There have been proposals for reform of the Australian legal framework for human tissue and genetic information, and the role of the NHMRC, most significantly by the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC).[35]

The absence of specific and uniform biobanking legislation in the UK and Australia has implications for the interoperability of biobanks, which may otherwise benefit from the sharing of research resources across organisational and geographical boundaries. Biobank participants may also have different experiences of donating their human tissue depending on the project and its jurisdiction. In a bid to harmonise approaches across Australian states, the NHMRC has established the National Certification Scheme,[36] which certifies the ethics review processes of institutions in Australia thus making them eligible for the National Mutual Acceptance Scheme (NMA).[37] In order for ethics reviews of human research to be accepted under NMA, the HREC conducting the review must be under the authority of an institution certified under the NHMRC National Certification Scheme, and also be a Certified Reviewing HREC under the NMA scheme.[38] Within Europe, a number of collaborative projects have been established with the aim of harmonising and standardising biobanking across Europe, to help improve harmonisation efforts in lieu of European-wide biobanking legislation.[39]

THE LEGAL CHALLENGES

From Tissue to Data

The basis of any biobank is its tissue collection, but increasingly biobanks link medical data to samples and will develop new datasets of potential biomarkers and 'omics' information that is derived from, and then linked, to the samples of biobank participants. These data can sometimes be of greater research use than the original tissue and will be covered by data protection legislation rather than the law that applies to human tissue. The foundation of

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[32] The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee, 'National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015)' 3.2.1 <https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf>.

[33] Ibid 3.2.3-3.2.8.

[34] National Health and Medical Research Council, *How NHMRC develops its guidelines* (21 October 2009) <https://www.nhmrc.gov.au/guidelines-publications/how-nhmrc-develops-its-guidelines>; Australian Law Reform Commission, 'For Your Information: Australian Privacy Law and Practice (ALRC Report 108)' (12 August 2008) <http://www.alrc.gov.au/publications/report-108>.

[35] Australian Law Reform Commission, 'Essentially Yours: The Protection of Human Genetic Information in Australia' (96, 2003) <http://www.alrc.gov.au/publications/report-96>.

[36] National Health and Medical Research Council, 'National Certification Scheme: Institutions with Certified Ethics Review Processes' (2017) <https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/institutions-certified-ethics-review-processes>.

[37] The scope of the National Mutual Acceptance Scheme was extended in December 2015 beyond clinical trials to include all human research.

[38] In 2013, the Victorian, South Australian and Queensland Departments of Health, and the New South Wales Ministry of Health signed a Memorandum of Understanding (MOU) for the National Mutual Acceptance (NMA) of ethics and scientific review of clinical trials conducted in each of the participating jurisdiction's public health organisations. In December 2015, the scope of NMA was expanded beyond clinical trials to include all human research. In August 2016, the Australian Capital Territory joined the NMA. In order for ethics reviews of human research to be accepted under NMA, the HREC conducting the review must be certified under the NHMRC National Certification Scheme, and also be a Certified Reviewing HREC under the NMA scheme. See National Health and Medical Research Council, above n 36.

[39] Examples include BioSHaRE-EU and BBMRI-ERIC EU (Biobanking and BioMolecular resources Research Infrastructure). Internationally, examples include P3G Public Population Project in Genomics and Society and the International Cancer Genome Consortium (ICGC).

most data protection legislation is on the 'identifiability' of data and greater protections pertain to data that can identify an individual, with anonymous data falling outside data protection regimes. Legal frameworks in both Australia and the EU distinguish between identifiable and de-identified information. Unless completely anonymised, health data that are collected, linked and shared will be 'sensitive' personal information for the purpose of UK and Australian privacy laws. In contrast, the law that applies to human tissue does not generally make a distinction between different types of tissue, though there maybe exemptions for certain types of body products such as hair and nails. The difficulty is that human tissue samples contain genetic information that is assumed to constitute sensitive personal information for the purpose of data protection and privacy law. It is at this point that there is the convergence of two different areas of law that can have significant implications for biobanks.

Since it has been proven that it is not possible to fully anonymise genetic information,[40] participant consent is generally required to lawfully authorise the processing of this information for research purposes. In addition, many jurisdictions have developed research exemptions that enable researchers to process sensitive and personal health information without consent, subject to specific criteria. However, the variability of criteria for lawful use between jurisdictions means it can be difficult to know what is expected of researchers and biobank managers.

In the EU, the GDPR, which comes into force in May 2018, will regulate the use of health information in biobanks. Health data will constitute 'special categories of personal data' which will have to be processed fairly and lawfully for research according to the principles set out in Article 9. However, biobanks may be exempt from a number of GDPR provisions, in particular under exemptions provided to permit the processing of personal data for purposes of scientific research. Such provisions allow personal data to be stored for longer periods than would otherwise be permitted, provided that: i) they will be processed solely for scientific research purposes in accordance with GDPR Article 89(1), and ii) the data will be subject to implementation of technical and organisational measures required by the GDPR. The Regulation also retains a presumption of "compatibility of use for research purposes", which allows personal data collected for purposes other than scientific research to be repurposed for research as long as there is a valid legal ground for the original processing in EU or member state law. Although the purpose of the GDPR is to harmonise the level of protection of the rights and freedoms of individuals with regard to the processing of their data across the EU, there are a number of derogations that may allow for distinctive approaches to information regulation between member states. For example, each state can set a minimum age for consent to use of data at between 13 to 16 years of age. The extent and impact of national variations for biobanking will be seen over time. [41]

In Australia, the Commonwealth *Privacy Act 1988* and associated state and territory privacy legislation is of utmost importance for the regulation of biobanks. The Australian Privacy Principles (APPs) apply to the manner in which biobanks manage and disseminate health information. Where there is state privacy legislation, the state-based privacy principles are to be interpreted, as far as possible, in a manner consistent with the APPs. The APPs apply to the use or disclosure of health information for 'permitted health situations' (which includes public interest research) under section 16B(3) of the *Privacy Act 1988* (Cth).[42] The legal framework in Australia is further complicated by different regimes for public and private entities, and statutory[43] and common law confidentiality provisions may result in legal barriers to data sharing across multiple institutions in multiple jurisdictions. The Commonwealth provisions apply to Commonwealth agencies as well as private entities. Under Australia's federal arrangements, the *Privacy Act* does not apply to most state, territory and local government bodies, including public hospitals and other

[40] Erika Check Hayden, 'The Genome Hacker' (2013) 497(7448) *Nature* 172.
[41] Information Commissioner's Office, above n 23.
[42] S 16B(3) requires that for information to be used or disclosed, it must be necessary for research relevant to public health or public safety; it must be impracticable for the organisation to obtain the person's consent; and the use or disclosure must be conducted in accordance with guidelines approved under s 95A of the *Privacy Act*: See Annex 1.
[43] *Health Services Act 1988* (Vic) s 141.

health service providers; nor private sector health service providers working under contract for a state, territory or local government agency. In all such cases, the applicable practices and protections must be found in the relevant state or territory privacy legislation, although in many cases these apply similar principles to those in the federal law. It is noteworthy that some small business operators (annual turnover less than $3 million – but not those providing health services) also have considerable exemptions from the Commonwealth *Privacy Act*.[44]

Consent

Biobanks challenge the conventional ethical models of consent that have been used in medical research. The ethical standard that is required by many research ethics committees is that of an explicit and informed consent. In a biobank, samples and data will be used for many research applications that often cannot be anticipated at the time of collection when individuals are first asked to give consent.[45] Informed consent has been adopted for medical research to enable research participants to exercise their autonomy and make decisions about the risks and benefits of participation. With biobank research, it is impossible to fulfil the conditions of traditional informed consent as outlined in many ethical and legal documents.[46] It is very difficult to inform research participants of "all future uses of their information and samples over many years at the time of collection, nor can they be given an assessment of all the potential privacy risks of participation in the research",[47] particularly in relation to rapid advances in technology employed in medical research. Broad consent to future uses is "a practical solution with specific consent for the taking of a sample and information and its storage"[48] that has been adopted by many biobanks.

This has spurred a debate as to how informed participants really are, when they give broad consent and whether the relevant ethical standards are being met. [49] Broad consent has been described as 'consent for governance' by others, as judgments about appropriate uses of data and samples often fall to researchers, advisory boards, or research ethics committees, who must make decisions on behalf of research participants.[50] Other models have been proposed such as tiered consent,[51] authorisation instead of informed consent,[52] and open consent [53] and dynamic consent,[54] which takes advantage of digital technologies and provides a mechanism to communicate with research participants on an ongoing basis. New forms of governance models, using adaptive governance mechanisms that

[44] *Privacy Act 1988* (Cth) s 6D.
[45] Timothy Caulfield and Jane Kaye, 'Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas' (2009) 10(2) *Medical Law International* 85; MFA Otlowski, 'Tackling Legal Challenges Posed by Population Biobanks: Reconceptualising Consent Requirements' (2012) 20(2) *Medical Law Review* 191; Don Chalmers et al, 'Marking Shifts in Human Research Ethics in the Development of Biobanking' (2015) 8(1) *Public Health Ethics* 63.
[46] Paula Boddington et al, 'Consent Forms in Genomics: The Difference between Law and Practice' [2011] (5) *European Journal of Health Law* 491.
[47] LM Beskow et al, 'Informed Consent for Population-Based Research Involving Genetics' (2001) 286(18) *JAMA* 2315.
[48] Christine Grady et al, 'Broad Consent for Research with Biological Samples: Workshop Conclusions' (2015) 15(9) *American Journal of Bioethics* 34; Otlowski, above n 27.
[49] Jane Kaye, 'The Tension Between Data Sharing and the Protection of Privacy in Genomics Research' (2012) 13(1) *Annual Review of Genomics and Human Genetics* 415.
[50] Jane Kaye, 'Biobanking Networks: What Are the Governance Challenges' in Jane Kaye and Mark Stranger (eds), *Principles and Practice in Biobank Governance* (Routledge, 2009) 201.
[51] Susanne B Haga and Laura M Beskow, 'Ethical, Legal, and Social Implications of Biobanks for Genetics Research' (2008) 60 *Advances in Genetics* 505; Leslie E Wolf and Bernard Lo, 'Untapped Potential: IRB Guidance for the Ethical Research Use of Stored Biological Materials' [2004] (4) *IRB: Ethics & Human Research* 1.
[52] Vilhjálmur Árnason, 'Coding and Consent: Moral Challenges of the Database Project in Iceland' (2004) 18(1) *Bioethics* 27.
[53] Jeantine E Lunshof et al, 'From Genetic Privacy to Open Consent' (2008) 9(5) *Nature Reviews Genetics* 406.
[54] Jane Kaye et al, 'Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks' (2015) 23(2) *European Journal Of Human Genetics: EJHG* 141.

give voice to group concerns rather than just those of individuals, have also been proposed to address some of the deficiencies of the individual consent model.[55]

While broad consent has become the ethical standard for medical research, many generic legal instruments have provisions that allow exemptions from consent for the use of samples and data for medical research purposes. In Australia there may be circumstances in which it is possible to use human tissue samples obtained in the clinical context for research purposes, without consent from the individual from which they were derived. Researchers can rely on the research exemption in the *Privacy Act 1988* (Cth)[56] and have the HREC approve a waiver[57] to provide a legal basis for the lawful use of samples for research without consent. This exemption would require the information in the sample to be de-identified to the point where it is no longer 'about an identified individual', or an 'individual who is reasonably identifiable'.[58] This is difficult if a biobank contains genetic information, as it is not possible to fully anonymise sequence data, which has been demonstrated to be easily traceable to the individual from whom it was derived.

The NHMRC has issued Guidelines on the conditions that a HREC must be satisfied on before waiving the requirement for consent.[59] These conditions make it less likely that the research exemption and waiver would be granted for the establishment of new biobanks, where consent is likely to be easily obtainable, compared to biobanks based on existing collections, in which case it may not be practicable to contact participants to obtain consent to secondary research uses of their samples.[60] The exemption must be consistent with federal and state legislation regarding human tissue, the scope of which currently exclude tissue obtained during the course of therapeutic treatment, and privacy laws relating to health information which will contain exemptions for research use. Such fragmentation is likely to create obstacles for researchers wishing to access samples and tissue held in multiple institutions across multiple jurisdictions, as they will likely have to negotiate multiple HREC approvals.

Within the UK there are a number of exemptions for medical research that exist in both data protection and human tissue legislation. Under the GDPR, biobanks will be exempt for some of the fair processing provisions that apply to health data. This means that personal data can be stored for longer periods than would otherwise be permitted[61] and personal data collected for purposes other than scientific research can be used for research if there is a legal

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[55] Kieran C O'Doherty et al, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks' (2011) 73 *Social Science & Medicine* 367; David E Winickoff and Richard N Winickoff, 'The Charitable Trust as a Model for Genomic Biobanks' [2003] (12) *New England Journal of Medicine* 1180.

[56] 'Permitted health situations' under s 16B(3).

[57] *Privacy Act 1988* (Cth) s 95.

[58] Ibid*; Privacy Commissioner v Telstra Corporation Limited* [2017] FCAFC 4.

[59] National Health and Medical Research Council, *Guidelines Under Section 95 of the Privacy Act 1988* (4 March 2014) 2.3.6 <https://www.nhmrc.gov.au/guidelines-publications/pr1>.

a) involvement in the research carries no more than low risk to participants;
b) the benefits from the research justify any risks of harm associated with not seeking consent;
c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
e) there is sufficient protection of their privacy;
f) there is an adequate plan to protect the confidentiality of the data;
g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;
i) the waiver is not prohibited by state, federal, or international law.

[60] Margaret Otlowski, Dianne Nicol and Mark Stranger, 'Biobanks Information Paper' (2009) 20(1) *Journal of Law, Information and Science* 97.

[61] Art 89(1).

basis for doing so. The *Human Tissue Act* also allows the secondary use of tissue as long as it is anonymised, the use is consistent with the original consent, and approval by a research ethics committee has been obtained.[62] Therefore, it is not necessarily the legal framework that requires consent, but it is an ethical requirement that comes from guidance and is enforced by research ethics committees.

Privacy

Biobanks raise a number of privacy concerns, including fear of misuse of personal information, stigmatisation of groups and unjustified intrusion into private life.[63] Participant consent, confidentiality processes such as anonymisation and pseudonymisation, and accountable data governance and data access procedures operate within a legal framework to protect privacy interests and mitigate participants' loss of control over their information and samples when participating in biobanks.[64] While technical solutions that help biobanks uphold individuals' privacy interests are evolving over time, increased understanding of the limitations of such technologies has confirmed that it is virtually impossible to fully anonymise genetic information.[65] In addition, the now accepted shared nature of genetic information means that issues of relational privacy are brought to the fore (discussed below). As our understanding of genomics and health data evolves, the adequacy of data protection and privacy legislation to protect privacy interests is called into question and the importance of appropriate individual consent and governance procedures is magnified.

The push to link established biobanks with other existing databases,[66] and increasing pressure from funding bodies to make such databases open access,[67] further challenge the protection of the privacy of individual biobank participants. Original consent processes for collection of samples and health information are unlikely to have been developed with a view to subsequent data linkage. While integrating biobank collections can be viewed as a productive use of valuable data and a means of maximising limited funding resources in the sector, it demands careful consideration of governance systems and procedures, to ensure that issues of privacy and consent are worked through appropriately.[68] Large-scale population biobanks have also invested huge resources in IT infrastructure, to maximise the power of large-scale data collection through data integration, and as a technique for mining and analysing data. Biobanks will often contract with bioinformatics companies to analyse the genomic data contained within donors' samples, with cloud computing being the only platforms that have the computing power and storage facilities to support large-scale genomic analysis.

Dove has defined genomic cloud computing as "a scalable service where genetic sequence information is stored and processed virtually (i.e., in the 'cloud') usually via networked, large-scale data centers accessible remotely through various clients and platforms over the Internet."[69] In these systems, data are stored and their analyses conducted 'in the cloud' rather than on local information management systems, creating benefits in terms of efficiency, cost and

[62] *Human Tissue Act 2004* (UK) sch 1 para 6; pt 1 (f); pt 1 (9)(i-ii).
[63] Graeme Laurie et al, 'Managing Access to Biobanks: How Can We Reconcile Individual Privacy and Public Interests in Genetic Research?' (2010) 10(4) *Part of the Special Issue: Privacy and Biobanking* 315, 316.
[64] Ibid.
[65] Hayden, above n 40.
[66] Nuffield Council on Bioethics, 'The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues' (February 2015) <http://nuffieldbioethics.org/project/biological-health-data>; Catherine A McCarty et al, 'The EMERGE Network: A Consortium of Biorepositories Linked to Electronic Medical Records Data for Conducting Genomic Studies' (2011) 4(1) *BMC Medical Genomics* 13.
[67] Nuffield Council on Bioethics, above n 66, 32.
[68] Kaye, above n 49.
[69] Edward S Dove et al, 'Genomic Cloud Computing: Legal and Ethical Points to Consider' (2015) 23(10) *European Journal of Human Genetics* 1271, 1272.

real-time collaboration.[70] The advantages of cloud-based biobank data management tools have been described in the context of disaster recovery, and their superior accessibility.[71] There are, however, also increased risks to biomedical data in the cloud: reliability, security, data control and confidentiality may be problematic; further, national privacy and data protection laws may be a poor fit for complex transnational, decentralised flows of data.[72] There are also privacy concerns in relation to companies that may be for profit, providing services to biobanks that are located in other jurisdictions with different laws and are established for public benefit purposes.

In the absence of international legal standards on biomedical cloud computing it is incumbent upon biobanks to examine carefully the terms of contractual agreements with providers of cloud computing services and satisfy themselves that data security and privacy will be adequately maintained. Elements for particular consideration include: the provider's awareness of relevant data privacy and protection schemes, the location of data storage, procedures around data transfer and access, physical and digital security protections and independent audit. Data access committees also have an important role to play in the governance of cloud-based biobanks.[73] Large-scale cooperative research efforts have led to investment in tools and infrastructure to standardise and harmonise data collection and governance and provide guidance for biobanks. Groups active in this space include the Public Population Project in Genomics (P3G); the International Society for Biological and Environmental Repositories (ISBER); and the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI).

Technological advancement and increasingly affordable genomic sequencing has also led to an increased understanding of the familial nature of genomic information, which has reinvigorated relational privacy debates. This has implications for biobanks that intend to make available genotype information derived from samples, because such information will likely have relevance to the family members of the participant from which the sample is derived. This raises questions concerning the ethical imperative to disclose clinically relevant health information on biological relatives that is discovered by using a biobank. Whether or not this fact is communicated at the time of consent may vary, especially if the biobank has been formed on the basis of existing samples collections for which informed consent has not been obtained.

Over the past five years there has been a growing academic and policy debate about the feedback of results from genomic sequencing to individuals and whether this would apply to biobanks. Discussion has moved from whether to how to feedback clinically relevant results, with a general acceptance that some genetic markers ought to be communicated to research participants where possible, for example BRCA1.[74] Legal approaches to such feedback have been varied, with few countries recognising a legal duty of researchers or biobanks to return such results to participants.[75] In the UK it is well established that there is no legislative duty to return such results, instead placing the onus on biobanks to articulate their approach to feedback of results within their policy documents.

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[70] Ibid 1273.

[71] Shonali Paul, Aditi Gade and Sumani Mallipeddi, 'The State of Cloud-Based Biospecimen and Biobank Data Management Tools' (2017) 15(2) *Biopreservation and Biobanking* 169, 171, 172.

[72] Fruzsina Molnár-Gábor et al, 'Computing Patient Data in the Cloud: Practical and Legal Considerations for Genetics and Genomics Research in Europe and Internationally' (2017) 9 *Genome Medicine* 58.

[73] Dove et al, above n 69, 1275, 1276.

[74] Sarah S Kalia et al, 'Recommendations for Reporting of Secondary Findings in Clinical Exome and Genome Sequencing, 2016 Update (ACMG SF v2.0): A Policy Statement of the American College of Medical Genetics and Genomics' (2017) 19(2) *Genetics in Medicine* 249.

[75] Elizabeth R Pike, Karen H Rothenberg and Benjamin E Berkman, 'Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomic Research' (2014) 102 *Georgetown Law Journal* 795; Carolyn Johnston and Jane Kaye, 'Does the UK Biobank Have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12(3) *Medical Law Review* 239.

Alternatively, it is notable that the Commonwealth privacy law creates a framework for feedback, and in certain circumstances the consent of the individual participant may even be overridden. The National Statement[76] sets out a range of guidance on the information that researchers must provide to people who are being asked to consent to the collection of genetic material. Researchers must prepare an ethically defensible plan to disclose or withhold genetic information that may be important to the health of participants and their relatives including that "if the research discloses that a family member may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the approval of an HREC, be offered by a clinician to the family member, even if the research participant does not consent to this" (para 3.5.8(g)). In the event of disclosure, the plan "should either provide access to genetic and clinical advice or counselling, or clearly recommend to participants that they seek these services."[77] However, there appears to be sufficient leeway in this guidance for biobanks to determine that they will withhold important genetic findings from a person or their family member. Thus while the NHMRC guidelines represent "a world first…comprehensive attempt to deal with this complex issue",[78] in practice privacy concerns may prevent disclosure of biobank results to genetic relatives without participant consent, and participants may decline to be informed about important findings.

Ownership and Access

When a sample is given for purely research purposes, the question arises as to whether the donor of the sample has any continuing interest in that sample. This process is embroiled in ethical and legal debate as to whether there is 'property' in the human body and if so, who has the 'right' to this 'property'. In Australia, the common law recognises proprietary rights in samples preserved by hospitals and other organisations. *Doodeward v Spence*[79] is still authority for the position that no property exists in bodies and body parts, subject to an exception in the cases of preserved samples of tissue held, generally, in hospitals and clinical laboratories (extending more recently to laboratory samples that have been commercially developed, such as cell lines).[80] For a sample to be considered property in accordance with this rule, the person or organisation using the tissue must have lawful authority to do so, and the organisation must apply some work or skill to the preservation of the sample.[81] Subsequent cases in the UK and in Australian state Supreme Courts have adhered to[82] and extended[83] this rule.

Generally Australian courts have recognised that institutions holding samples in their lawful possession do have a proprietary interest in them, but that this may not extend to outright ownership. Others, such as donors and their representatives may have co-existing proprietary rights.[84] However the extent to which this line of cases may be applied to biobanking has been questioned; as Skene notes, "we do not know if the same principles will be applied

[76] The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee, above n 32, 41.
[77] Ibid 42.
[78] Don Chalmers, 'Biobanking and Privacy Laws in Australia' (2015) 43(4) *Journal of Law, Medicine & Ethics* 703, 711.
[79] *Doodeward v Spence* (1908) 6 CLR 406.
[80] William J Curran, 'Scientific and Commercial Development of Human Cell Lines — Issues of Property, Ethics, and Conflict of Interest' (1991) 324 *New England Journal of Medicine* 990, 998.
[81] *Doodeward v Spence* (1908) 6 CLR 406 414.This statement was cited with approval in *Pecar v National Australia Trustees Ltd (The Estate of Ivan Urlich deceased)* Unreported, Supreme Court of NSW, Bryson J, 27 November 1996 4.
[82] *R v Kelly* [1998] All ER (D) 215.
[83] *Yearworth v North Bristol NHS Trust* [2010] 1 QB 1; *Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 118; *Roblin v The Public Trustee for the Australian Capital Territory* [2015] ACTSC 100.
[84] *Roche v Douglas* [2000] WASC 146; *Pecar v National Australia Trustees Ltd (The Estate of Ivan Urlich deceased)* Unreported, Supreme Court of NSW, Bryson J, 27 November 1996; Loane Skene, 'Proprietary Interests in Human Bodily Material: Yearworth, Recent Australian Cases on Stored Semen and Their Implications' (2012) 20(2) *Medical Law Review* 227, 239–40.

to other stored bodily material, such as cord blood and autologous blood banks, or even organs for transplant and tissue in biobanks and other research repositories."[85]

Developments in data sharing, cross-jurisdictional transfer and cloud-based computing may complicate the issue of who 'owns' biobank samples. In Australia a distinction is made between the type of organisation running the biobank – public or private. Consequently, if samples are collected in one institution, then transferred to another institution that falls into a different organisational category, it is possible that legislative boundaries will have been crossed in terms of the applicable privacy laws. Crossing boundaries may make it difficult to determine who owns the rights to the samples and research outputs, as well as making compliance more challenging. While there is no legislative distinction between public/private entities in the UK, the purposes for which a biobank is run; public benefit research, commercialisation, clinical translation etc., will determine the biobanks' legislative framework.

The high costs associated with developing and maintaining biobanks has placed pressure on organisers to both seek private and philanthropic funding to establish and sustain the biobank, to commercialise their resources and the outputs of their work,[86] and make the samples available internationally and open access. The commercialisation of medical research is often promoted by public funding bodies[87] to enhance the research sustainability of research undertakings, but there are serious risks inherent in the process. Biobanks initially established with public funding may require the re-consent of participants if potential commercial access to data was not originally part of the 'broad consent' process.[88] The existing complexity around who owns samples is exacerbated with the involvement of third parties, who may be contracted by the biobank to provide a service such as genotyping the tissue samples for genetic research. There is a considerable tension for biobanks as they try to meet the requirements for open access and international access with a need to conform to privacy law and the protection of the privacy of participants. There is also strong evidence that the public sharply distrusts the notion of sharing biobank data with third parties, and in particular with commercial entities,[89] which may undermine efforts to diversify funding across the industry.[90]

Conclusion

The emergence of biobanks as essential research infrastructure for medical research has happened over the past twenty years and has required the development of new ethical norms and careful consideration of how the law might apply. During this time, there have been considerable advances in technology, such as bioinformatics, cloud computing and IT in general, as well as genome sequencing and the ability to modify different tissue and cells for different kinds of analysis and treatment purposes. Biobanks have had to accommodate these innovations and keep their collections responsive to changing research priorities and strategies, as well as changing social expectations as to the reporting of incidental findings to biobank participants and personal rights over samples and data. This raises challenges of sustainability and how biobanks can remain nimble in the face of considerable change. This has been a complex terrain to navigate and biobank professionals have been very successful in forging new standards and

[85]Skene, above n 84. See also Australian Law Reform Commission, above n 35, 20.15.
[86] Timothy Caulfield et al, 'A Review of the Key Issues Associated with the Commercialization of Biobanks' (2014) 1(1) *Journal of Law and the Biosciences* 94, 94.
[87] See, for instance, Australia's Medical Research Future Fund, http://www.health.gov.au/internet/main/publishing.nsf/Content/mrff (accessed 10 August 2017).
[88] Caulfield et al, above n 86, 104.
[89] Christine Critchley, Dianne Nicol and Margaret Otlowski, 'The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research' (2015) 18(3) *Public Health Genomics* 160; Dr Mairi Levitt and Sue Weldon, 'A Well Placed Trust?: Public Perceptions of the Governance of DNA Databases' (2005) 15(4) *Critical Public Health* 311.
[90] Timothy Caulfield, Pascal Borry and Herbert Gottweis, 'Industry Involvement in Publicly Funded Biobanks' (2014) 15(4) *Nature Reviews Genetics* 220, 220.

norms for biobanking, both nationally and internationally, which have distinguished biobanks as a new form of research infrastructure very distinct from research projects.

Biobanking activities have been regulated under general law and the role of Research Ethics Committees (RECs) and guidelines have been important in the regulation of this new field. The legal frameworks in Australia and the UK have some similarities and differences that provide a useful basis for comparison as they stem from the same legal foundations but have developed diverse mechanisms to regulate biobanks and their activities. The complex federal systems of law that apply in both jurisdictions have implications for research and for biobanks. The purpose of implementing EU law in the UK and other member states is to achieve harmonisation to enable co-operation and integration, with common legal principles and requirements. In contrast, within Australia, the law demarcates and articulates the different powers and responsibilities between the Commonwealth and the States with the intention of achieving the same effect. This complexity effects researchers seeking to understand what they should do to be lawful, and makes the introduction of new activities and innovation such as biobanks difficult to navigate. The way that data and samples are regulated through different legal regimes is an example of the additional complexity that the law creates, even though in medical research practice samples and the data they contain are often regarded and treated the same. In addition, the crucial role of RECs in the regulation of biobanks can result in biobanks operating in silos, and the complexity of legal regimes can mean that sharing samples and data across boundaries (both jurisdictional and institutional) can be fraught with difficulties that have the potential to hinder the overall value of a biobank resource. Indeed, there is growing acceptance that the merits of biobanking will only be fully realised if resources can "link up and learn from each other, ideally on a global scale".[91]

To address legal complexity and concerns about the ethical and social challenges raised by biobanks, including consent, privacy, ownership and access, more newly-established biobanks have taken responsibility for developing their own governance frameworks, which operate within external legal frameworks such as those described above.[92] A governance framework will articulate and oversee how the biobank is being managed, by whom, and for what purposes; to provide transparency and accountability of biobank practices. The biobank's access rules may also be articulated, including whether the biobank facilitates commercial access. For biobanks that are government initiatives for public interest research, data access procedures are necessary to maximise 'bona fide' research that is in the interests of the public, the participant and the scientific community using the resource.

Overall, a key challenge for biobank governance frameworks will be to balance the public interest in medical research with the private interests of its participants and the privacy risks associated with such participation, to inspire and maintain participation and public trust. These interests are not necessarily exclusive, and more recent academic and policy debate argues that there is a public interest in protecting the privacy interests of individuals who take part in research.[93] Using consent as the legal basis for biobanking may avoid some of the jurisdictional and institutional obstacles that are created by relying on research exemptions to use samples and data for research. Consent can also serve to address limitations associated with the inability to completely anonymise genetic data, while at the same time respecting the autonomy of patients and developing a relationship of trust between the individuals about whom data are collected, and those responsible for safeguarding the data. Technological

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[91] Graeme Laurie, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 *Human Genetics* 347, 349; Mark Walport and Paul Brest, 'Sharing Research Data to Improve Public Health' 377(9765) *Lancet* 537; A Cambon-Thomsen, E Rial Sebbag and BM Knoppers, 'Trends in Ethical and Legal Frameworks for the Use of Human Biobanks' (2007) 30(2) *European Respiratory Journal* 373.

[92] For example UK Biobank, 'UK Biobank Ethics and Governance Framework (Version 3.0)' (October 2007) <https://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf>.

[93] Nuffield Council on Bioethics, above n 66.

developments have made possible novel approaches to obtaining consent, which can help biobanks reach the highest ethical and legal standards. Fully exploring the potential of existing sample collections, which may not have begun as 'biobanks' and for which consent has not been obtained or is difficult to trace, in a lawful and ethical manner is one of the most pertinent challenges for the future. Without innovation, in governance as well as scientific and technological advances, biobanks will be unable to deliver on their full promise to advance medical research.