THE LAWS OF PRIVACY AND CONSENT AND LARGE-SCALE DNA BIOBANKING IN NEW ZEALAND

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ABSTRACT

Large-scale population genetic databases have become increasingly common around the world. However, these initiatives are financially and politically costly and fraught with ethical, legal and social implications that few have successfully overcome. The unique nature of biobanking challenges established research practice; in particular, the immutable status of traditional ethical standards is hotly debated amongst scholars.

This thesis examines current privacy and consent laws in New Zealand and the adequacy of these laws to protect the interests of biobank participants. This New Zealand-focused examination also takes into consideration the obligation of the Crown to protect Māori interests and discusses how these obligations may impact on any future policy involving the collection, storage and use of genetic material in biobanking.

I conclude that the current state of the law is piecemeal and inadequate in its protection of biobank participants. However, current guidelines are progressive in its flexibility towards modifying traditional consent norms to accommodate the uncertainty of future unspecified research. This thesis concludes by highlighting the need for more research in the area of Māori perspectives on biobanking and the importance of avoiding the pitfalls of genetic exceptionalism in any future reform that may takes place.

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INTRODUCTION

The establishment of population biobanks has in the past decade or so become a popular consideration of many within the international research community. Compared to traditional tissue banks that collect data for specific fields of research, a biobank is intended for access by a wide range of health researchers, some of who may be located across the world. Biobank research is intentionally broad and involves the collection and storage of vast amounts of genetic material and associated personal information for the purposes of future unspecified research. The way in which information may be used in the future is unknown and unforeseen and is limited only by research technology and the laws that govern its use.

A biobank in this instance is defined as a large-scale population-based repository that collects, stores and uses genetic material and its associated data for future unspecified research purposes. It does not conduct research itself but is designed for researchers as a ready platform to a vast amount of population-unique genetic material and other personal and medical data. New Zealand presently has a number of organised collections that store a variety of human tissue and other samples derived from the body, some linked with associated personal or medical data. These relatively small-scale collections of samples and data are typically held by individual clinicians or research groups and were established for a purpose such as medical training or research into a specific disease. These current collections may plausibly be used for further research not originally specified at the outset. While some of the issues raised in this thesis may have some relevance to these more traditional collections, it is acknowledged that these collections are distinct from the biobank proposed.

The aim of this thesis is to identify the privacy and consent issues that arise in biobanking and the adequacy of New Zealand’s laws in addressing them. This thesis is very limited in scope and represents only a starting point to a very complicated and sensitive area. However, it is hopefully one that sheds light on some of the complexities that arise in biobanking and inspires deeper discussion on future policy directions for New Zealand.

Chapter One examines the claim that genetic information is special and deserving of special protection in the law. A belief (or non-belief) of this special nature is foundational in the examination of genetics-related issues and the extent of protection genetic information deserves.

Chapter Two examines the concept of privacy and the balance between the privacy interests of biobank participants and how a biobank collects and stores health information. Current health information privacy legislation and guidelines are studied for its serviceability for developing policies around biobanking privacy. I conclude that the current privacy framework in New Zealand is not optimal for protecting patient privacy against the nuances of biobanking.

Chapter Three examines the law of informed consent in New Zealand and its relevance to biobanking. I discuss the capacity of the law to balance the public interests of health research while protecting biobank participants and explain the impracticality of the standard of informed consent in biobanking. I conclude that New Zealand’s combination of law, codes and other regulations show flexibility towards modifying informed consent to accommodate biobanking. However, I argue that more must be done in New Zealand to cement the standard so as to guarantee that the interests of human subjects remain upheld in this changing environment.

Finally, in Chapter Four, I explore the perspective of Māori towards genetic research and how cultural imperatives might influence this. New Zealand’s obligation to the protection of Māori under the Treaty of Waitangi means that the beliefs and values of Māori need to be carefully considered and incorporated into research practice. I present some potential issues that may arise in biobanking to highlight the complexities of cross-cultural tensions and the need for more research in this area.

For the purposes of this thesis, I refer to BiobankNZ as the hypothetical national biobank to which my discussions relate. BiobankNZ is based in New Zealand and is subject to the laws and regulations of New Zealand. BiobankNZ collects, stores and processes the DNA and corresponding health information of volunteer participants and serves as a national resource for health researchers.
THE UK BIOBANK AND THE ICELANDIC HEALTH SECTOR DATABASE

Throughout this thesis, I refer occasionally to the experiences of the United Kingdom and Iceland as examples of different approaches in biobanking that have been taken. Both countries embarked on the ambitious journey of establishing population-based biobanks with very different governance structures, policy frameworks and outcomes. This is a very brief introduction to both.²

The UK Biobank is a “self-governed” registered charitable body established jointly by a number of governmental and charities.³ It began recruiting volunteer participants in 2006 and, in 2010, achieved its aim of recruiting 500,000 participants aged between 40–69 years. In March 2012, the UK Biobank announced that it was ready for researchers to begin research on the biobank’s anonymized data. Within its vaults is a growing 20 terabytes of secure data containing ongoing personal, medical and lifestyle information of every participant.⁴ The UK Biobank is the first known population-based DNA biobank to be successful from conception to full operation⁵ and is subject to the oversight of an independent Ethics and Governance Council that ensures the biobank’s strict adherence to the UK Biobank Ethics and Governance Framework.⁶

In Iceland, the situation is very different and the biobank originally envisaged has never been fully realized. The Icelandic Healthcare Database (IHD) was established as part of a triad of databases that were to link together to create an elaborate “super” database that linked the personal, medical and genealogical information of Icelanders. On 17 December 1998, the Icelandic Parliament passed the Health Sector Database Act — specific legislation that permitted the establishment of database that would store the past, present and future health information of the Icelandic population.⁷ This database was to be linked with a separate bank that stored DNA samples and a third database that stored

⁴ “UK biobank opens to researchers” (30 March 2012) BBC News <www.bbc.co.uk>.
⁵ Other countries such as Estonia, Singapore and Iceland have, for a variety of reasons, halted plans to establish a biobank.
⁶ “UK Biobank Ethics and Governance Council” <www.egcukbiobank.org.uk>.
⁷ Act on Health Sector Database 1998 (Iceland)
genealogical information. Working as intended, the IHD was to become a research tool with comprehensive data from an entire population of approximately 270,000 Icelanders.

Unfortunately, the establishment of the Icelandic biobank was highly controversial for many reasons, including the fact that a single license was granted to a commercial enterprise for exclusive commercial use and the “opt-out” nature of participation. Ultimately, the bold move away from informed consent, the automatic inclusion of participants and no right of family members to opt-out on behalf of deceased family members resulted in a case brought to the Icelandic courts. In Gudmundsdottir, R. vs. The State of Iceland, the Supreme Court of Iceland found that there was an infringement of privacy because the information entered into medical records — and consequently, the database — is highly detailed and that data relating to the hereditary characteristics of the deceased might also apply to the daughter. This infringement of privacy was exacerbated by the fact that provisions for the encryption and transfer of data were indefinite and inadequate to protect the privacy interests of people. Ultimately, opposition prevailed and the Icelandic database has since failed to progress.

12 For a discussion on the main reasons for its termination, see: Gisli Pálsson “The rise and fall of a biobank: The case of Iceland” in Herbert Gottweis and Alan Peterson (eds) Biobanks: Governance in Comparative Perspective (Routledge, London, 2008) 41.
CHAPTER ONE: THE CLAIM OF GENETIC EXCEPTIONALISM

Our DNA and the genes that it codes for are seen as fundamental building blocks of all living beings. Many believe that our genes are the code from which human life is created and sustained and the key to “unravel the mysteries behind everything from evolution to disease origins”.\(^\text{13}\) However, this elevated status of human genes has been tempered by a realization that the human genome is complex and that the interplay between genes and environment is more complicated than was first appreciated.

A search of the literature on human genetic policy reveals very polarized schools of thought on the value and status of genetic information. On one hand, some believe that genetic information is immensely powerful in its ability to reveal the present and future health of a person and, as such, deserves special legislation to prevent abuse and exploitation of such information. On the other hand, others believe that genetic information is no different from other sensitive medical information and thus should not be treated as special in the law.

This chapter questions the claim that genetic information deserves special status in the law. The issues raised by biobanking are novel in that traditional standards upon which medical research was founded upon may no longer offer an easy answer. As such, it is crucial to determine how one should perceive genetic information against other types of health information before further issues can be considered. Failing to consider whether genetic exceptionalism is a valid argument is to overlook the importance and power of public perception in shaping and influencing policy.

I Is there a place for genetic exceptionalism?

Genetic exceptionalism may be defined “roughly as the claim that genetic information is sufficiently different from other kinds of health-related information that it deserves special protection or other exceptional measures”.\(^\text{14}\) The discussion of genetic exceptionalism in this instance is structured around one of two “international points of reference in the field of bioethics”,\(^\text{15}\) namely the United Nations Educational, Scientific

\(^{15}\) “International Declaration on Human Genetic Data” United Nations Educational, Scientific and Cultural Organization <www.unesco.org>
and Cultural Organization’s (UNESCO) International Declaration on Human Genetic Data (the “Declaration”).\textsuperscript{16} The Declaration was created and adopted in 2003 as a response to growing calls and concerns for guidelines at an international level around the use of human genetic data.

Article 4 of the Declaration states that:\textsuperscript{17}

\begin{itemize}
  \item[(a)] Human genetic data have a special status because:
  \begin{itemize}
    \item[(i)] they can be predictive of genetic predispositions concerning individuals;
    \item[(ii)] they may have significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;
    \item[(iii)] they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;
    \item[(iv)] they may have cultural significance for persons or groups.
  \end{itemize}
\end{itemize}

To summarise, Art. 4—which has been accused indirectly of genetic exceptionalism—\textsuperscript{18} implies that genetic information is special because of its predictive nature and the unknown or future potential it holds; its ability to impact more than just the individual concerned; and the potential cultural significance it has. As will be explained, this view that human genetic data have special status is disputed by many who believe that genetic exceptionalism is flawed and “an overly dramatic view of the significance of genetic information in our lives”.\textsuperscript{19}

\textbf{A Genetic information is “predictive”}

There are instances where a genetic test for the presence of a mutation gives accurate indication of future disease. However, this is not representative of the general predictability of genetic information for two main reasons: first, high penetrance, single gene disorders are rare; and second, genetic information is more indicative of degrees of probability rather than certainty. Furthermore, the claim that genetic information is unique because it is predictive runs counter to the existence of other types of predictive information that is not genetic in nature.

\begin{flushright}
\textsuperscript{16} Ibid. \\
\textsuperscript{17} Ibid. \\
\textsuperscript{18} Bartha Maria Knoppers and Madelaine Saginur “The Babel of genetic data terminology” (2005) Nature Biotechnology 925 at 925. \\
\textsuperscript{19} Thomas Murray, above n 14, at 71.
\end{flushright}
Scientists have found a number of instances where the presence of a genetic mutation is indicative of future manifestation of an illness. These mutations are typically high penetrance, single gene disorders (such as Huntington’s Disease and familial adenomatous polyposis)\(^\text{20}\) that result in a fifty-percent chance of the disease developing in gene carriers. However, these single gene disorders are relatively rare compared to the prevalence of other genetically linked multifactorial diseases such as cancer, diabetes or cardiovascular disease.\(^\text{21}\) Despite this, high penetrance, single gene disorders continue to dominate the image of genetics in the public mind and evoke a lot of fear in people for its perceived power.

The “predictive” nature of genetic information is arguably more probability than certainty. Genetic information has been likened to a “future diary” containing “uniquely powerful and uniquely personal” information.\(^\text{22}\) However, many scientists have argued that, with the exception of a very small number of disorders such as those described above, the “predictive” nature of genetic information is an ambitious term for something that is more a probability than certainty.\(^\text{23}\) Because only a proportion of people with a particular disease-related mutation go on to develop the disorder, many genes are really only pre-disposing and not a guarantee that the condition will develop. Furthermore, one’s estimated mortality depends on numerous other factors including environmental, biological and stochastic (referring to the play of chance within families and populations) factors.\(^\text{24}\) This probability of disease being dependent on a play of a number of factors is demonstrated in research that has found that estimates for a cumulative risk of breast cancer by age 70 within oncogene BRCA1 carriers have ranged from 36–87%.\(^\text{25}\)

\(^\text{20}\) Familial adenomatous polyposis (FAP) can have different inheritance patterns and genetic causes. In this instance, I am referring to FAP resulting from mutations in the APC gene that is inherited in an autosomal dominant pattern, meaning that only one copy is required for disease expression. See: “Familial adenomatous polyposis” (2011) Genetics Home Reference <ghr.nlm.nih.gov>.

\(^\text{21}\) In 2008, heart diseases, cancers and diabetes were the top 10 causes of death in high-income countries. See: World Health Organization The top 10 causes of death (World Health Organization Fact sheet No. 310, 2011)


\(^\text{23}\) Essentially Yours: The Protection of Human Genetic Information in Australia (report by the Australian Law Reform Commission, National Health and Medical Research Council (Australia) & Australian Health Ethics Committee 2003) at [3.29].


\(^\text{25}\) Ibid, at 131.
Thus, there is no doubt that carriers of certain genes may eventually develop a condition to which they have a genetic predisposition. However, this predisposition should not be mistaken as a guarantee of clinical illness. Mainstream media’s tendency to sensationalize news pieces with little deference to the nuances and complexities of research often leave the public with perceptions of risk that may inaccurately reflect scientific facts and uncertainties.

Finally, the claim that genetic information is “predictive” and therefore distinguishable from other types of medical information cannot be supported. Traditionally, physicians have accurately used the results of simple biological tests to predict disease risk. For example, a simple blood test for cholesterol levels and a blood pressure reading can reveal that a person is at increased risk of heart disease; similarly, a HIV-positive blood test result is indicative of a very strong likelihood of developing AIDS. Conventional physiological markers remain very important tools in disease risk assessment and it has been argued that there is little to suggest that genes will have any greater clinical value.

Thus, while it is accepted that testing positive for genetic mutations linked to high penetrance diseases like Huntington’s Disease indicate a near certainty of developing the disorder, this is the exception and not the norm. While tests for such unusual diseases have exceptionally high predictability, they should not be used as the reason to consider all genetic information “predictive” with little recognition of its probabilistic and uncertain nature. Indeed, a small number of genetic tests for high penetrance genes do have a high rate of predictability. However, the argument that its predictability justifies special protection over other types of health information is not compelling.

B Genetic information may have “significant impact on the family” and “on the whole group to which the person concerned belongs”
This concern about the nature of genetic information has two parts, namely that genetic information:

1) has the ability to divulge information about other family members because of the hereditary nature of genes; and

2) can encourage stigmatization or discrimination of certain groups of people with a predisposition for certain diseases.

27 Ibid.
First, genetic information does have the potential to cause distress to family members. Identification of certain “risk genes” in a person immediately divulges certain information about related family who may have inherited the same genes. For example, if a woman inherits a mutation in a BRCA1/BRCA2 gene, her risk for breast or ovarian cancer, as well as that of her female siblings and children, increases.\(^{28}\) Family members are suddenly faced with hard questions of genetic testing and whether test results should be disclosed to other family members who might be affected. In addition, where a patient with a BRCA1/BRCA2 mutation chooses not to disclose this to family, physicians are faced with the dilemma of whether breaching confidentiality outweighs the potential good that may be achieved by early testing and detection.\(^{29}\) Such tests raise significant issues of patient autonomy, confidentiality and privacy and have the potential to create the sort of family discord, psychological distress and stigmatization that was anticipated by the Declaration.

However, others such as Green and Botkin, have argued that other types of sensitive health information can also be revealing of an individual and other family members and be equally distressing.\(^{30}\) While genetic information may affect relatives because of its hereditary nature, other types of information may affect relatives and even friends, purely by association. For example, a woman discovering that she is infected with a sexually transmitted disease immediately creates implications for her spouse or partner and this raises similar issues about disclosure and confidentiality and potentially is very damaging for a relationship.\(^{31}\)

The ability of genetic information to impact groups becomes especially concerning when a predisposition is attached to a certain group or community. Here, they may face unjust stigmatization and discrimination for their perceived “weakness”. In New Zealand, a reported link between genes and behavior led to the “warrior gene” controversy and the claim that “anti-social” behaviours in Māori were genetic.\(^{32}\) While bad science and poor

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\(^{29}\) For a discussion of this, see: Adrian Burton “Should patient confidentiality come second to the prevention of disease in others?” (2009) 10(3) Lancet Oncol 210.

\(^{30}\) Michael J. Green and Jeffrey R. Botkin, above n 28, at 572

\(^{31}\) Ibid.

\(^{32}\) “Warrior gene prevalent in Māori: study” One News (New Zealand, 9 August 2006) <tvnz.co.nz/view/page/425826/810285>
media reporting were both blamed,\textsuperscript{33} this incident stirred deep mistrust towards scientists and highlighted the power of genetic research to impact groups in society.

There is undoubtedly a risk that certain groups might face discrimination from what genetic information might reveal. However, giving genetic information a special status in law to prevent this is not the solution. Granting the results of such tests special protection in the law fails to acknowledge that results of other tests might cause equal, if not greater, discrimination and harm. Rather than granting protection based on the “biological underpinnings” of a disease or how a result was obtained, protection should instead be based on the effect of a test result and its consequences.\textsuperscript{34} For example, whether something is “genetic” is less relevant than other issues such as whether a particular type of health information is likely to be stigmatizing, whether there is a cure or whether family members are likely to be affected. Taking this approach and avoiding genetic exceptionalism ensures that disease sufferers are offered equal protection in the law regardless of the cause of their disease.

\textbf{C Genetic information may have cultural significance for persons or groups}

The special significance of genetic information to certain persons or groups is perhaps the most relevant discussion in the argument for granting special protection over such information. This is especially important in New Zealand because of the Treaty of Waitangi and the promise by the Crown to protect and promote the interests of Māori.

Genetic information may indeed have special cultural significance for Māori because of traditional views towards what it represents and holds.\textsuperscript{35} However, this might be similar for other personal information. A paper on privacy reported that “Māori view their personal information as taonga\textsuperscript{36} and information about Māori represents “grandparents, parents, uncles and aunties, brothers and sisters, cousins and the rest of the whanau”.\textsuperscript{37} Making the decision to grant special protection over genetic information because of its

\textsuperscript{34} Michael J. Green and Jeffrey R. Botkin, above n 28, at 573
\textsuperscript{35} The perspective of Māori towards genetic research and how cultural imperatives might influence this is discussed in detail in Chapter Four.
\textsuperscript{36} “treasure”
\textsuperscript{37} \textit{The Privacy Act 1993 = Te Ture Matatukiri, Matatapu 1993} (Te Puni Kokiri/Ministry of Māori Development, 1994) at 7.
cultural significance but not over other personal information might make the wrong statement to some who feel that both classes of information deserve equal protection.

Rather than implementing further legislation to guarantee the importance of genetic information, it might be more valuable to commit to actively engaging Māori, finding out what they want and working to achieve this. A blunt (and impossible) demarcation between non-genetic and genetic information can cause more complications in the future. Taking a flexible approach may allow particularly significant aspects of genetic information to Māori (for example, issues of ownership and decision-making) to be specifically considered and addressed rather than providing and perpetuating the notion that genetic information should be given more protection purely because it is exceptional.

II Some problems with genetic exceptionalism

Genetic exceptionalism and special genetics legislation (such as the regulation of genetic testing and laws restricting use of genetic information) create a number of significant problems. First, legal protection for some diseases but not others on the basis of genetics can cause more harm than good; second, it perpetuates an inaccurate understanding of genetics and has been blamed for the confusion in biobanking terminology; and third, it is impractical when considered with the aspiration of personalized medicine.38

First, genetic legislation creates significant legal protection for some but not for others. This is because there is immense difficulty in distinguishing genetic information from non-genetic information and, in turn, those that qualify for special protection and those that do not. The struggle to define “genetic information” ultimately leads to problems of over- and under-inclusiveness and results in unsatisfactory legislation that fails to serve its purpose.39 The impossibility of finding a satisfactory working definition of genetic information is reflected in impractical legislation that either ends up not protecting enough or protecting too much. Restricting the definition of “genetic information” to only information derived from genetic tests immediately excludes a large number of genetic disorders that are observed through clinical observation and clinical history and for which there may or may not be tests.40 For example, a patient with a family history of

38 Personalized medicine refers roughly to a type of medical care that is individualized based on a person’s unique personal, clinical, genetic, and lifestyle information.
Huntington Disease (and who therefore has a fifty-percent risk of developing the disorder) who has not undergone genetic testing does not qualify for protection under the narrow definition. Similarly, a breast cancer patient with a BRCA gene mutation will qualify for special protection but not the majority of other breast cancer patients whose cause of disease has not yet been established. In the other extreme, if genetic information is defined too broadly, it will essentially include too much. Common diseases like heart disease, diabetes and epilepsy, regardless of how small the genetic contribution, would immediately qualify under the definition and be afforded similar protection to someone suffering from Huntington’s Disease. This would create situations where employers and insurance companies are unable to make reasonable decisions based on any illness or disease with a genetic predisposition. By insisting that genetic information deserves special protection through legislation, we risk creating unworkable laws that discriminate on the basis of genetic information—a term on its own that is troublingly difficult to define.

Proponents of genetic exceptionalism call for special genetics legislation in order to prevent admittedly very real consequences that may arise with improper use of genetic information. However, when considered closely, genetics legislation can create even more troubling consequences that can drive disparities between individuals and classes, purely by virtue of their genes. Ironically, the fear of societal divide on the basis of genetics is the fear that genetic exceptionalists justify their claims by. However, this is not to say that fears of inappropriate use of genetic information should be ignored for fear of creating worse consequences. Rather, as will be discussed in later chapters, there are mechanisms and frameworks that can be adopted to ensure fair protection of genetic and other equally sensitive medical information.

Second, the inaccurate understanding of genes perpetuated by the claim for genetic exceptionalism has been partially blamed for the problem of inconsistent terminology in biobanking. A “combination of privacy fears and the perception that genetic information is different” has resulted in the adoption “of a mind-numbing array of proposals employing different terminology to protect genetic data”.

This lack of broad consensus on terminology has been a major challenge in the establishment and governance of biobanks and has led us to a place where biobanks are using different terms for shades of the same thing: is a “reversibly anonymised” sample the same as a

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42 Bartha Maria Knoppers and Madelaine Saginur, above n 18, at 925.
“coded” or a “de-linked” sample? 43 This uncertainty in nomenclature at its most basic level leaves different parties in the same field uncertain about key terms relating to identifiability and thus how information ought to be stored and protected. This affects the inter-operability of biobanks and ultimately may impede crucial international collaboration.44

Finally, the vision of personalized medicine does not fit well with genetic exceptionalism. Having refuted the claims of genetic exceptionalism, it seems timely to recognize a significant aspect of this thesis—the viability of biobanking in New Zealand—and the hope that the landscape of medicine will evolve far enough to include personalized medicine. It is with hope that greater understanding of genetics will eventually mean that patient diagnoses and treatments will be tailored to their genetic make-up. However, if we were to grant special protection to genetic information, we create a logistical nightmare in which certain parts of a patient’s medical records has to given special protection. As highlighted by one practitioner, how will this be possible in an age when genetic information gets “smeared” across all aspects of health information? 45

Thus, it is important to recognize the difficulties that can arise in genetic legislation arising from a belief that genetic information is special and deserving of special protection. While recognizing the potential for abuse of genetic information (just like with other types of information), we must not throw the baby out with the bath water. Instead, we should give careful thought to future legislation to ensure that a balance between fair protection and practicality is reached. Lapsing into tendencies towards genetic exceptionalism can generate a lot of downstream effects that may be more harmful than beneficial.

III Genetic information as “health information” — New Zealand’s approach

Rule 3 of the Health Information Privacy Code (HIPC) relates to the collection of health information from individuals. It defines the steps that should be taken to ensure transparency by an agency towards an individual and is “intended to reinforce individual autonomy and people’s control over their health information”.46

43 This is discussed in Chapter Two on page 27.
44 Bartha Maria Knoppers and Madelaine Saginur, above n 18, at 925.
45 Essentially Yours: The Protection of Human Genetic Information in Australia, above n 23, at [3.53].
46 Health Information Privacy Code 1994 [HIPC], Commentary at 21.
Before any health information can be collected, rule 3 requires an agency to take “reasonable steps” to ensure that an individual is aware of several things: the fact that a collection is being carried out;\(^{47}\) the purpose of the collection;\(^{48}\) the intended recipients of the information;\(^{49}\) details of the agency collecting and holding the information;\(^{50}\) whether the collection is voluntary or mandatory (and if so, the legal authority);\(^{51}\) whether there are any consequences of not supplying the information requested;\(^{52}\) and the rights of access and correction of the individual.\(^{53}\) The rationale for this rule is to allow for a thorough explanation to “help [individuals] decide what information (if any) to make available”.\(^{54}\)

Most importantly, the commentary in the HIPC states that in carrying out genetic tests, agencies should “carefully consider whether they have fulfilled their obligations under rule 3”.\(^{55}\) While the HIPC does not explicitly state that genetic information is the equivalent to health information, any extra protection for information acquired from genetic tests is notably absent. A health agency need only meet the obligations under rule 3 regardless of whether the health information acquired is genetic in nature or not. While the commentary calls on an agency to consider the wider implications of any information acquired from genetic tests, this is only a recommendation and suggests flexibility for a different interpretation if the need ever arises. Through this approach, the Privacy Commissioner is essentially —until a reason otherwise arises— rejecting the claim of genetic exceptionalism and instead deems genetic information equally sensitive to other types of health information.

**IV Conclusion**

The approach taken by New Zealand appears consistent with the prevailing view that genetic information is not sufficiently distinct and special to deserve extra protection over other types of health information. As long as the media continue to stress the incredible

\(^{47}\) Ibid, r 3(1)(a).
\(^{48}\) Ibid, r 3(1)(b).
\(^{49}\) Ibid, r 3(1) (c).
\(^{50}\) Ibid, r 3(1) (d).
\(^{51}\) Ibid, r 3(1) (e).
\(^{52}\) Ibid, r 3(1) (f).
\(^{53}\) Ibid, r 3(1) (g).
\(^{54}\) Ibid, Commentary at 23.
\(^{55}\) Ibid, Commentary at 26.
possibilities of genetic advancements, there will always be fear of the unknown. However, the fact that New Zealand’s stance on genetic information protection remains un-codified allows for flexibility in the event a remarkable advancement justifies special genetic protection. For now though, genetic exceptionalism remains unproven — genetic information is not meaningfully different enough from other health information and the complications of perpetuating this notion far outweigh any benefits one might obtain from special protection.
CHAPTER TWO: PRIVACY IN BIOBANKING

This chapter examines the current laws in New Zealand and its serviceability for developing policies around biobanking privacy. An analysis of privacy in biobanking is important because inadequate protections in the law can lead to violations of a person’s right to privacy. However, laws that uphold privacy with little regard to other interests can have the unwanted effect of hindering research progress. What is desirable is a framework that adequately protects privacy rights in biobanking while remaining reasonably permissive towards health research that evolves with technology.

In the first half of this chapter, I provide a brief history of privacy in general and the international laws that have influenced New Zealand legislation. I then briefly discuss the hereditary nature of genetic information and its potential to infringe on the privacy of others.

In the next half, I examine the principles within the Health Information Privacy Code, the Code of Health and Disability Services and the Guidelines for the Use of Human Tissue for Future Unspecified Research. As instruments that were mostly drafted before the advent of large-scale biobanking, I assess these rules and guidelines as it relates to biobank data and explain the impact of these rules on biobank participants.

This chapter concludes that the current framework in New Zealand is not optimal for protecting patient privacy against the nuances of biobanking. The right to privacy recognized in New Zealand justifies a reconsideration of the current law and calls for discussion into reform in order to adequately protect participant privacy.

I A General Introduction to Privacy in New Zealand

Privacy may be defined in ordinary language as the state of seclusion or secrecy. In the law, the right to privacy was first introduced by Warren and Brandeis as “the right to enjoy life—the right to be let alone” that stemmed from fundamental rights to life, liberty and property. However, on closer inspection, one soon discovers a very broad and

complex notion—a concept described as “exasperatingly vague and evanescent”\textsuperscript{58} and incapable of a ready definition.\textsuperscript{59}

While a dictionary definition of privacy may provide some ideas on what privacy can be equated with, it fails to provide analysis to the multi-layered and multi-dimensional characteristics of privacy or give recognition to underlying principles from which these ideas stem. Attempts at defining privacy have had varying success and are generally centered around ideas of human dignity, limited access and an individual’s control over his\textsuperscript{60} personal information and its dissemination.\textsuperscript{61} Privacy has also been presented as a sub-category of two interconnected core values—personal autonomy and equality of respect—that together provide “a measure of individual solitude and reflection”.\textsuperscript{62}

Privacy is multi-dimensional and can apply in many senses. As described by Allen, physical privacy can be understood to be freedom from physical intrusion on one’s private space; informational privacy is the expectation to have facts about oneself protected from public disclosure; proprietary privacy relates to interests that one may have over parts or products of one’s body\textsuperscript{63} or identity; and decisional privacy relates to freedom in decision-making and the ability to keep one’s decision and decision-making process confidential.

Privacy can arise in a huge range of situations and is often “relative to cultural, historical and societal influences”.\textsuperscript{64} One man’s idea of an intrusion on privacy in one context can, in fact, be seen by another as a treasured form of shared community living in another. Similarly, the idea of privacy tends to carry different meanings for different disciplines.\textsuperscript{65} However, there is general consensus on the strong facilitative value of privacy in overall


\textsuperscript{59} Stephen Penk “Thinking about privacy” in Privacy law in Stephen Penk and Rosemary Tobin (eds) Privacy Law in New Zealand (Brookers, Wellington, 2010) 1 at 1.

\textsuperscript{60} The male pronoun is used throughout this thesis for consistency although it includes females as well.

\textsuperscript{61} See generally: Stephen Penk “Thinking about privacy”, above n 59, at 5–6.

\textsuperscript{62} Law Commission A Conceptual Approach to Privacy (NZLC MP19, 2007) at 5.

\textsuperscript{63} Moore v Regents of the University of California 793 P 2d 479 (Cal 1990). In Moore v. Regents of the University of California, the plaintiff, Moore, argued that in taking his tissue for unrevealed research and development purposes unrelated to his medical care, doctors at the University of California had appropriated his identity much like how an advertiser uses a person’s photograph without consent for commercial gain.

\textsuperscript{64} Stephen Penk, above n 59, at 2.

human development, existence and interaction.\textsuperscript{66} Indeed, it is also a term of deep emotional resonance and when an individual speaks of an invasion of privacy, they are speaking of a serious threat to their sense of well-being.\textsuperscript{67} Privacy has often been equated with, amongst other things, confidentiality,\textsuperscript{68} secrecy, anonymity and solitude.\textsuperscript{69} While criticized by some as highly individualistic, privacy can also enrich communities by the way it fosters individual qualities such as creativity, independence, autonomy and freedom of thought.\textsuperscript{70}

There are many theories that exist justifying the right to privacy.\textsuperscript{71} A justification for the right to privacy can be framed within the principle of personal autonomy and a person’s right to have his wishes respected. Privacy can refer to a person’s control over the types of people that may have different kinds of access to him. This “idea of having a domain or territory of sovereignty for the self and a right to protect it” refers to a person’s autonomy and is intrinsically linked to privacy.\textsuperscript{72} In other words, the significance and importance of respecting a self-governing agent and the dominion of a person over his body warrants the existence of some right to privacy.

When making decisions in health care research, a participant’s right to privacy demands that the scope of access be explained to, and subsequently authorized by, the participant. In biobanking, the converse is the more critical issue: can a person, in the interests of research, legitimately permit nearly unlimited access to his present and future health information and waive his right to privacy and control over information relating to him? Does the current law provide adequate protection or is more needed to protect the privacy interests of potential biobank participants?

\textsuperscript{66} Ibid.
\textsuperscript{68} Although courts in Hosking v Runting drew distinctions between privacy and confidentiality. See: Hosking v Runting [2004] NZCA 34, [2005] 1 NZLR 1 at [246].
\textsuperscript{69} Encyclopaedia of Bioethics (3rd ed, 2004) vol 4 Privacy at 2122.
\textsuperscript{70} Daniel J. Solove, above n 58, at 1146.
\textsuperscript{71} A number of other justifications have also been proposed including Judith Thomson”s view that the right to privacy is nothing more than a cluster of rights and consequentialist theorists justifying privacy as necessary for their instrumental ends. See generally: Tom L. Beauchamp and James F. Childress Principles of Biomedical Ethics (6th ed, Oxford University Press, New York) at 298.
\textsuperscript{72} SA Green “The ethical limits of confidentiality in the therapeutic relationship” (1995) 17 General Hospital Psychiatry 80 at 81.
II The hereditary nature of genes and an infringement on privacy

The hereditary nature of genes and its ability to reveal information about the relatives of a person is significant. Unlike most other personal information, genetic information is passed down through generations and may relay information about a person’s relatives. For example, the presence of a genetic disease in a person is indicative of the likely carrier status of his parents and, potentially, other blood relatives as well.

In Iceland, the hereditary nature of genetic information was grounds for the Supreme Court to rule that a person had an interest to privacy that the Icelandic Health Sector Database infringed on. In Gudmundsdóttir v. Iceland, the Supreme Court of Iceland concluded that even though the deceased’s daughter did not have a right as a relative to request that information of the deceased be withheld from the Health Sector Database, she did have a separate interest to privacy under the Constitution.\(^{73}\) The Court held that Article 71 of the Icelandic Constitution that guarantees the protection of privacy applies to the information recorded in medical records.\(^{74}\) It was held that the information entered into medical records —and consequently, the database— is highly detailed and that data relating to the hereditary characteristics of the deceased might also apply to the daughter.\(^{75}\) This infringement of privacy was reinforced by the fact that provisions for the encryption and transfer of data were indefinite and inadequate to protect the privacy interests of people.\(^{76}\) Thus, the Supreme Court ruled in favour of the deceased’s daughter on the basis of her constitutional right to privacy and the hereditary nature of certain aspects of her father’s medical information that relates to her.

Unlike the Icelandic Constitution, the New Zealand Bill of Rights Act 1990 does not provide for an express right to privacy. However, this does not mean that New Zealand will not recognize the familial nature of genes and a family member’s privacy interests.\(^{77}\) As discussed in more detail in Chapter Three, the experience of Iceland highlights the special consideration that needs to be given to genetic information and how the extensive storage and use of health information in biobanking affects how individuals might feel about privacy.


\(^{74}\) Constitution of the Republic of Iceland 1944 (Iceland), art. 71.

\(^{75}\) Gudmundsdottir, R. vs. The State of Iceland (2003), at 1.

\(^{76}\) Gudmundsdottir, R. vs. The State of Iceland (2003), at 9.

\(^{77}\) In fact, as is discussed in Chapter Four, the particular characteristics of genes to Māori people —that it, amongst other things, represents the spiritual and physical heritage of a person— is likely to be something that is prioritized and recognized in any policy making relating to genetic material.
III The Health Information Privacy Code of New Zealand

The Health Information Privacy (Temporary) Code was issued in 1993 as a temporary code to coincide with reforms in the health sector at the time. Only a temporary measure, the code was eventually superseded by the Health Information Privacy Code 1994 (HIPC) which addressed many of the issues and uncertainties that arose during the time of the temporary code. The HIPC lays out health sector-specific information privacy principles that apply to health information relating to all identifiable individuals. The Code applies to all agencies that provide personal or public health or disability services in New Zealand and, in some instances, information held off-shore by a New Zealand agency.

The HIPC is a regulation under the Privacy Act 1993 and is administered by the Privacy Commissioner. The Privacy Commissioner has a significant role in protecting the personal information privacy of New Zealanders and has responsibilities such as promoting an understanding of information privacy principles; monitoring the use of unique identifiers; examining new legislation for its possible impact on individual privacy; and inquiring into any matter where it appears that individual privacy may be affected.

In addition to the HIPC, the Ministry of Health released Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes (the Guidelines) in 2007. The purpose of the Guidelines is to guide Health and Disability Ethics Committees when they consider applications for research concerning the use of human tissue for future unspecified research. Finally, other enactments that may play a role in health information privacy include the Health Act 1956, the Human Tissue Act 2008 and the Health and Disability Commissioner Act 1994 that established the Code of Health and Disability Services Consumers’ Rights in 1996. Together, these various Acts and guidelines guide

80 Health Information Privacy Code 1994, Commentary at 11.
81 Privacy Act 1993, s 13(1)(a).
82 Ibid, s 13(1)(c).
83 Ibid, s 13(1)(f) and (o).
84 Ibid, s 13(1)(m).
researchers in protecting patient and participant interests in the use, storage and processing of human tissue and other health information.

A (Informational) Privacy in Biobanking
The advent of biobanking has created a need to re-evaluate current norms in biomedical research. Certain features of biobanks distinguish them from more traditional biomedical research and thus pose new challenges to established norms and values. For the purposes of this thesis, “biobank information” may be defined as the ongoing environmental, clinical and biographical data about an individual acquired in the course of biobanking, including information generated from research on genetic samples, but excluding the raw genetic sample.85

The process of recruiting, acquiring, processing and storing genetic information of participants all raise issues of privacy, although in very different ways. Of the various definitions of privacy available,86 Allen’s categorical breakdown of the different forms of privacy best describes the privacy concerns that typically arise in a biobank:87

1. Informational privacy concerns about access to personal information;
2. Physical privacy concerns about access to persons and personal spaces;
3. Decisional privacy concerns about governmental and other third-party interference with personal choices; and
4. Proprietary privacy concerns about the appropriation and ownership of interests in human personality.

The recruitment of participants and an individual’s decision to accept or decline an invitation to participate may be an interest in decisional privacy and a freedom from unwanted interference in one’s personal choice. When an individual has chosen to participate, there are physical privacy interests that arise during the acquisition of genetic material.88 Following the acquisition of biobank information, the processing and storage of this information raise concerns about informational privacy and the ability to prevent

85 The inclusion of genetic samples into the definition of “personal information” is a fairly new development and one embraced by New South Wales privacy legislation. In New Zealand, the Law Commission has recommended against a similar inclusion. See: Law Commission Review of the Privacy Act 1993: review of the law of privacy, stage 4 (NZLC R123, 2011) at [3.32]–[3.39].
88 These interests are discussed in more detail in Chapter Three.
unwanted access by third parties. Finally, the distribution of biobank information may raise proprietary privacy concerns when commercial value is obtained from research carried out on biobank information.

In biobanking, extensive volumes of genetic data annotated with varying amounts of medical, lifestyle and personal information is crucial to a biobank’s value to population research. A database with broad phenotypic data and extensive genotypes significantly expands the scope of uses of the biobank, making genome wide association studies across whole population groups possible on any trait or condition for which data were collected and gives researchers the ability to find risk factors that put certain groups of people at risk of disease.

However, the manipulation of biobank information creates substantial informational privacy challenges. Biobank research, characterized by rapid scanning of markers and information across large cohort sizes, is typically “group-level” and thus poses a very small threat to a person’s body and mind. However, the breadth and depth of information sought from participants raise fears of unauthorized disclosure that can infringe a person’s right to privacy. Furthermore, biobank research poses the additional potential harm resulting from a breach of confidentiality that may be difficult to anticipate if it stems from a novel insight into the association between genes and health data that is produced by the research itself. The pursuit of a greater understanding of our genes has created a conscious awareness in people of the rapidly diminishing gap between what scientists are capable of discovering and what was once a very vast “unknown” in our genetic makeup.

Without wide population uptake, the value of a biobank is reduced. This is because a broad sampling of participants across the population is required to ensure a cohort that is representative of the general population. Having more volunteers from certain groups in a population and less from others may create skewed research. In the long-term, this sample bias may be translated into uneven research across population groups resulting in greater population inequality. Thus, unless the different privacy concerns that may arise

90 Lars Øystein Ursin “Biobank research and the right to privacy” (2008) 29 Theoretical Medicine and Bioethics 267 at 268.
are identified and addressed early, there is a risk of losing the opportunity to demonstrate an awareness of the interests at stake and developing and maintaining trust amongst the public for medical research. Without the goodwill of participants who entrust personal information with biobanks, these research platforms are worthless.

The versatility of biobanking creates a vast number of scenarios in which an individual’s privacy interests may be at stake. However, this chapter is restricted to the application of the HIPC and its information privacy principles to BiobankNZ. For this reason, only informational privacy concerns is discussed. However, it is important to note that all aspects of privacy to different extents become an issue in biobanking although they are beyond the scope of this thesis.

Finally, it is worth noting the current scandal unfolding regarding the Accident Compensation Corporation (ACC) and its accidental disclosure of private health information. Described as “one of the worst privacy breaches in New Zealand history”, it was reported that a file containing the personal details of more than 9000 claimants, including 137 cases dealing with injuries resulting from sexual assault or sexual abuse was emailed to an unauthorized recipient in 2011.\(^{92}\) Unfortunately, this incident is not isolated,\(^{93}\) and has led to the Office of the Privacy Commissioner and the ACC Board jointly commissioning an inquiry into the privacy breach.\(^{94}\) The full ramifications of this breach remain unknown, although fears have already been raised amongst many over data remaining confidential in this “technological age” where “things get out too easily”.\(^{95}\)

The privacy breach committed by ACC is likely to affect how much people trust an agency with confidential personal information. Additionally, it is likely to be an obstacle BiobankNZ must overcome to regain public trust and garner participation. However, this is outside the scope of this thesis and the focus remains on the ability of the HIPC and its principles to protect the privacy interests of biobank participants.

\(^{92}\) “ACC boss says privacy breach a genuine mistake” *TVNZ ONE News* (Online ed, 13 March 2012).
\(^{93}\) Kirsty Johnson “ACC tries to plug another breach” *Stuff* news (Online ed, 25 March 2012); “ACC’s new privacy breach: 100 clients” details emailed” *The New Zealand Herald* (Online ed, 17 May 2012).
\(^{94}\) Audrey Young “Inquiry into ACC privacy breach” *The New Zealand Herald* (Online ed, 23 March 2012).
\(^{95}\) Amelia Romanos “ACC breach horrifies abuse victims” *The New Zealand Herald* (Online ed, 13 March 2012).
**B The Law Commission’s review of the Privacy Act 1993**

In August 2011, the Law Commission released its review of the Privacy Act 1993, as part of a wider project reviewing the law of privacy in New Zealand. Since then, the New Zealand Government has announced its decision to repeal and re-enact the Privacy Act 1993. The report of the Law Commission assessed the value and application of the Act’s principles and also addressed questions such as whether the Privacy Commissioner needs more powers; whether the complaints process could be streamlined; whether agencies which lose people’s information should have to tell them; and what obligations should be on agencies which send personal information overseas. As the parent Act of the HIPC, any amendments to the principles in the Privacy Act ultimately affect the HIPC and how it applies to the privacy of health information.

In its report, the Law Commission noted that the law governing health information and privacy mainly comprises the Privacy Act 1993, the HIPC and the Health Act 1956, “with a number of other provisions scattered across a number of statutes”. It is recommended that this “not very coherent” framework of laws needs separate review due to the sensitivity, complexity and importance of healthcare. The report stressed the need to review how health information as a whole is handled and recommended considering enacting separate legislation governing health information.

The recommendations of the Law Commission’s report have a small impact on health information in general, and an even smaller impact on health information in biobanking. However, of the three recommendations, one recommendation does have an impact on the use and disclosure of health information in biobanking. This recommendation is discussed in detail in the discussion of Rule 11.

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96 For more information, see: “Review of Privacy” Law Commission <www.lawcom.govt.nz>.
97 The Beehive “Government to overhaul Privacy Act” (press release, 27 March 2012).
98 Law Commission, above n 85, at iv.
99 Ibid, at [19.6].
100 Ibid, at [12.85].
101 Ibid, at [12.87].
102 Ibid, at [12.87]–[12.88].
104 See Rule 11: Limits on disclosure of health information on page 50.

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C  Do BiobankNZ data qualify under the HIPC?

The HIPC and its information privacy rules apply generally to “health information” of “identifiable individuals” that is held by public or private sector “agencies”. The extent to which the HIPC protects biobank information depends on several things, including:

(i) whether biobank information can be considered “health information”;
(ii) whether BiobankNZ is an “agency” as defined by the code; and
(iii) whether biobank information is “identifiable” or is considered “anonymous or aggregated statistical information”.

1 “Health information”

Clause 4(1) of the HIPC defines “health information” as:

(a) information about the health of that individual, including his or her medical history; or
(b) information about any disabilities that individual has, or has had; or
(c) information about any health services or disability services that are being provided, or have been provided, to that individual; or
(d) information provided by that individual in connection with the donation, by that individual, of any body part or any bodily substance of that individual or derived from the testing or examination of any body part, or any bodily substance of that individual; or
(e) information about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.

Participation in BiobankNZ requires the donation of human tissue and the collection of personal and health information. The information collected from each participant at recruitment and at later stages thus qualifies as “health information” under paragraph (d) since it is collected and stored in association with the donation of DNA. In addition, any subsequent research findings that can be related to a particular individual are also considered “health information” since it is “derived from the testing...[of] any bodily substance”.

105 Health Information Privacy Code 1994 [HIPC], cl 4.
106 Ibid.
107 Ibid, cl 4(1).
2 “Agency”

The HIPC only applies to specific agencies defined in the Code. These include health and disability service providers;\(^{109}\) bodies that are part of the training, registration and discipline of health professionals;\(^{110}\) insurance agencies, claims managers and employers\(^{111}\) accredited under the Accident Compensation Act 2011;\(^{112}\) and other bodies that do not fall within the previous classes.\(^{113}\) The HIPC applies to information held in the public or private sector, including information subsequently transferred and held outside New Zealand.\(^ {114}\)

As a repository that provides a service to researchers by collecting, processing and storing the health information of volunteer participants, BiobankNZ can be described to “provide services in respect of health information”\(^ {115}\) and is therefore an agency under the Code. In addition, the Privacy Commissioner may also add BiobankNZ to the list of specified health agencies in Schedule 1 pursuant to paragraph (p).

3 “Identifiable individuals”

The HIPC applies only to specific aspects or classes of “personal information”\(^ {116}\) or “information about an identifiable information”\(^ {117}\) and “does not apply to anonymous or aggregated statistical information where individuals cannot be identified”.\(^ {118}\)

At first glance, “identifiable” and “anonymous” might appear distinct enough to make application of the Code fairly straightforward. However, this is not the case, especially in biobanking.

While identifiability—the ability to associate data with a specific individual—may be broadly accepted as important in biobanking and long-term research, the consistency seems to end here. A review of the literature reveals a plethora of terms to describe different types of privacy protections and recommendations that use very different

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\(^{109}\) Ibid, cl 4 (2)(a)–(c).
\(^{110}\) Ibid, cl 4 (2)(d)–(g).
\(^{111}\) Ibid, cl 4 (2)(i)–(j).
\(^{112}\) Previously known (until 1 August 2011) as the Injury Prevention, Rehabilitation and Compensation Act 2001.
\(^{113}\) HIPC, cl 4 (2)(p)–(k).
\(^{114}\) Ibid, Commentary at 11.
\(^{115}\) Ibid, cl 4 (2)(k).
\(^{116}\) Section 2 of the Privacy Act 1993 defines “personal information” as “information about an identifiable individual”.
\(^{117}\) HIPC, cl 4(1).
\(^{118}\) Ibid, at Introduction.
terminologies. As will be explained, this complicates things and poses the question: whose standard of “identifiable” and “anonymous” ought to be adopted in the application of the HIPC?

(a) Re-identifiability in biobanking

A feature of biobanking is the availability of a large amount of data, collected over the course of participants’ lifetimes, which permits researchers to conduct longitudinal studies of large groups. To accomplish this, a biobank needs to have an effective means of re-identifying and linking individual samples to its associated data so that information can be updated throughout the individual’s lifetime.

Linking refers to having a tie between a sample and its associated data. Linking is desirable as an isolated sample has very limited research use. However, this is tempered by the need to safeguard participant confidentiality, which is often achieved through the use of coding. Coding has become a well-known and increasingly sophisticated mechanism involving combinations of encryption, bar codes, simple, double or triple codes. Coding creates a restricted link between a sample and its identifying information and permits, under limited circumstances, re-identification of samples. The ability to re-identify a participant depends on the complexity of the coding and keyholder access.

Having a link between samples and associated data has many benefits: information can be updated as a participant progresses or modified to improve accuracy; a participant can withdraw participation from future studies at any time and a biobank can locate and destroy its samples and data; participants can be re-contacted with clinically significant findings; and data can have a measure of standardization. It is generally accepted that complete anonymization of samples limits research potential and is less than ideal in protecting participant interests. For these reasons, it is favourable for biobank information to be processed and stored in a way that permits re-identification, where necessary, while still maintaining high levels of participant privacy.

121 Stefan Eriksson and Gert Helgesson “Potential harms, anonymization and the right to withdraw consent to biobank research” (2005) 13 European Journal of Human Genetics 1071 at 1071.
Often, identifiers are unnecessary for a specific research project and anonymization may take place. Anonymization is the act of rendering samples and data unidentifiable by irreversibly stripping identifiers from samples. Anonymized samples are often mistaken as “anonymous” information from which it is distinct because anonymous data is data that was absent of any identifiers from the point of collection. As discussed later, researchers working with anonymized data that is not considered “identifiable” need to meet fewer legal and ethical obligations.

Thus, there are benefits of maintaining a database of linked information that permits re-identification where necessary. Where identifiers are no longer necessary, anonymization is also a common method to permanently de-identify information. However, the reality is more complicated. Different international bodies and countries have all created separate privacy mechanisms resulting in standards of identifiability anywhere on a continuum from overtly identifiable, to potentially identifiable by deduction, to totally unidentifiable. With international organizations and countries sounding a “cacophony of terms”, whose definition of “non-identifiable” or “anonymous” should New Zealand adopt?

(b) International recommendations and biobanking terminology

One of the most common complaints by many in the field of biobanking is the lack of consistent terminology and standard between biobanks. A significant area of discrepancy is in sample coding and anonymization. There is tension between the desirability of information identifiability to facilitate long-term research and interest in protecting participant privacy and confidentiality. This tension is exacerbated by, first, a lack of guidance on the desirability of identifiability by international guidelines; and second, how best to achieve the standard of desirability.

123 Ibid.
124 This is discussed in more detail on page 30.
126 Bartha Maria Knoppers, above n 122, at 925.
127 Effy Vayena, Agomoni Ganguli-Mitra and Nikola Biller-Andorno, above n 120, at 28.
It is generally accepted that the most effective way of respecting participants and families and protecting privacy is by ensuring that the donor is not identifiable. A review of the various recommendations by different bodies highlighted the importance of protection but also addressed particular aspects of sample anonymity:

- data “should not normally be linked to an identifiable person”
- but “can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law”
- where data de-identification is not possible, an “alias or code” to protect patient identity is preferable over readily identifiable data
- participants should be informed of the degree of data identifiability and of the security mechanisms in place to ensure confidentiality

While “anonymous” may simply be understood as something “of unknown authorship or origin”, “anonymity” can also be represented in degrees. The World Health Organization has described “absolute anonymity” as being where “no means are available to link data to an identifiable individual” and “proportional or reasonable anonymity” as being where “no reasonable means of identification of specific individuals is available”. However, the WHO guidelines fail to provide a standard for “reasonable” and how far removed data must be from its identifying information before the threshold can be met for “no reasonable means of identification”.

Despite the different organizations weighing in on the issue of participant privacy, scholars have highlighted the lack of precise information on the desirable degree of identifiability and how to achieve it. Specifically, what is the best form of coding that balances both the interests of participants and researchers?

128 Ibid.
130 International Declaration on Human Genetic Data, art 14(c).
131 Ibid, art 14(d).
132 WMA Declaration on Ethical Considerations regarding Health Databases (adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002) at [17].
136 Effy Vayena, Agomoni Ganguli-Mitra and Nikola Biller-Andorno, above n 120, at 28
What has resulted is confusing terminology caused by numerous interpretations based on published recommendations. As pointed out by Knoppers and Saginur, terms like “identifiable”, “linked anonymized”, “reversibly de-identified”, “proportional anonymity” and “unidentifiable for research purposes” have all been used to describe coded samples. Terms used to describe anonymized data include “absolute anonymity”, “non-identifiable”, “irretrievably unlinked”, “irreversibly de-identified” and “permanent anonymization”.¹³⁷

The HIPC excludes health information that is “anonymous” or where “individuals cannot be identified”, but whose standard of “anonymous” and un-identifiability should be adopted?

(c) “Identifiable” and “anonymous” in the HIPC

Judging by the current state of confusion around sample and data identifiability in biobanking, it is important to consider the best interpretation of “identifiable” and “anonymous” as this then determines the scope of the HIPC on health information retained by BiobankNZ.

Lawmakers in New Zealand appear equally uncertain about the distinction (or lack thereof) between anonymous and anonymized information. Commentary in the HIPC states that s 22H of the Health Act 1956 permits the “disclosure of ‘anonymized’ health information that does not permit the identification of the person to whom it relates”. However, the actual heading of s 22H refers to “anonymous health information”—that is, health information that does not enable the identification of the individual to whom the information relates.¹³⁸

On the other hand, an authority on the subject has pointed out that the purposive approach to interpretation by the Ombudsmen, the Privacy Commissioner, and the Courts is correct.¹³⁹ “Information about an identifiable individual” includes “identification on the basis of a link identifying the individual, whether that link is by the recipient’s knowledge from other sources, or by other means, such as context, identification numbers, and the like”.¹⁴⁰ The Ministry of Health takes this approach in the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (the Guidelines) in which “un-

¹³⁷ Bartha Maria Knoppers, above n 122, at 926.
¹³⁸ Health Act 1956, s 22H
¹³⁹ Paul Roth Privacy Law and Practice (looseleaf ed, LexisNexis) at [PVA2.12].
¹⁴⁰ Ibid.
identified/de-linked tissue” is defined as tissue where “the identity and personal information of an individual who has donated human tissue is no longer identifiable or linked to that individual’s tissue sample”.

If one adopted the definition in the HIPC and the Health Act, anonymized health information is treated as “anonymous” health information and therefore excluded under the HIPC. The less severe, “non-identifiable” health information would then refer to coded information which still retains identifiers that are restricted to a small number of people. This approach immediately exempts BiobankNZ information from current privacy legislation as both anonymized and coded information would be excluded from the Rules of the HIPC as “anonymous” and “non-identifiable” information.

On the other hand, if the latter definition is adopted, information that is “no longer identifiable or linked” to a sample would refer to samples that have been anonymized. This narrower interpretation is consistent with distinguishing it from anonymous information that never contained any identifiers and makes the HIPC relevant to an establishment like BiobankNZ. Taking the purposive approach extends the reach of the HIPC to include coded information that may not be identifiable to most people but which still retains a link to its identifiers.

**D Is the HIPC appropriate?**

From Part B above, if the narrow approach is taken, health information (with the exception of anonymized non-identifiable data) stored in BiobankNZ can be considered “identifiable” information and thus protected by the Rules of the Code. Bearing in mind that the Code came into force in 1994, prior to the emergence of large-scale biobanking, this section aims to test the applicability and appropriateness of the privacy rules in protecting health information stored in a biobank.

**1 Rule 1: Purpose of collection of health information**

Rule 1 requires information that is collected to be “for a lawful purpose connected with a function or activity of the health agency” that is also “necessary for that purpose”. As explained in the commentary, a “lawful purpose” does not require explicit legal authority

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142 Bartha Maria Knoppers, above n 122, at 925.
143 HIPC, Rule 1.
for a collection to take place.\textsuperscript{144} In the case of BiobankNZ, the lawful establishment of the agency to collect and retain health information in association with bodily samples, for the purposes of contributing to a national repository for research, is likely to be considered a lawful purpose. With regard to whether a collection is “necessary for that purpose”,\textsuperscript{145} the Human Rights Review Tribunal previously held the view that only a “reasonable” standard of necessity needs to be met.\textsuperscript{146}

In biobanking, while BiobankNZ is likely to be subject to close monitoring to ensure compliance with an established ethical framework,\textsuperscript{147} there is no “research protocol” — unlike in traditional health research— until an independent researcher applies to the biobank for data. BiobankNZ can only show that in anticipation of a broad range of research focuses, it is likely to collect more, rather than less, information from participants and that this is necessary to facilitate future research. This distinction highlights fundamental differences between traditional protocol-driven research and BiobankNZ: first, BiobankNZ collects a lot more health information; and second; the collection process is subject to a different standard of ethical approval.

Thus, even though BiobankNZ collection purposes are likely to be lawful under Rule 1, it is important that there are checks in place to ensure that the scope of information collected and stored does not extend beyond what is “reasonably necessary” for the purposes of biobank research.

2 \textit{Rule 2: Source of health information}

Rule 2(1) states that a health agency must collect health information directly from an individual concerned. Where this is not possible, the Code offers a range of circumstances where an agency may be exempted from the general rule.

In biobanking, the depth and breadth of health information sought from each participant makes it desirable that health information is acquired directly from the individual volunteering for participation in the biobank. However, in some instances of biobanking,

\textsuperscript{144} Ibid, Commentary at 13.
\textsuperscript{145} Ibid, Rule 1(b).
\textsuperscript{146} The “necessity” test in this case applied to Principle 1 of the Information Privacy Principles (on which the Health Information Privacy Principles are based on). \textit{Lehmann v Canwest Radioworks Limited} (Decision No 35/06, HRRT 8/04, 21 September 2006) at [50].
\textsuperscript{147} This is the case for the UK Biobank that is subject to the oversight of an independent Ethics and Governance Council which ensure the biobank”s strict adherence to the UK Biobank Ethics and Governance Framework. See generally: UK Biobank “Ethics” <www.ukbiobank.ac.uk/ethics>. 
collecting health information directly from an individual is not possible. This may be when the genetic history of a participant is being assembled and participants have to reveal health information concerning related family members, and when results from research on specific samples are fed back to the biobank to enrich the database.

First, as part of the process of assembling a comprehensive background on each participant, BiobankNZ will need to collect information on a participant’s family medical history. This would be in non-compliance with the general rule as it involves collecting specific health information about members of a participant’s family, some of who may not agree to such disclosure. However, collecting health information about a participant’s relatives is important to achieving one of the goals of biobanking—that is, to establish associations between lifestyle, genetics and disease. By enforcing the rule that health information can only be collected directly from the source, it encumbers the collection of anonymous data.

Second, a key function of a biobank is to provide data to facilitate research. This means that, ideally, one of its key features will be the steady (and regulated) use of biobank information and the routine return of any findings from research on biobank information back into the database. This strengthens the biobank’s research potential because it allows prospective researchers to build on the work of previous researchers.

However, the communication of results of biobank research to participants remains a divided issue. While some research outcomes have been successfully identified and replicated with significant clinical implications for patients, similar studies have been

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148 I note that the data is likely to be collected without any identifiers and therefore be anonymous information.

149 Disclosure of results is outside the scope of this thesis although it is touched upon briefly on page 42. For a recent discussion on this issue, see also: Susan E. Wallace and Alistair Kent “Population biobanks and returning individual results: mission impossible or new directions?” (2011) 130 Human Genetics 393; and Ellen Wright Clayton and Amy L. McGuire “The legal risks of returning results of genomics research” (2012) 14(4) Genet Med 473.

150 For example, genetic associations have been identified in Type 1 diabetes, breast cancer and Crohns disease. See respectively: John A Todd and others “Robust associations of four new chromosome regions from genome-wide analyses of type 1 diabetes” (2007) 39 Nature Genetics 857; Simon N Stacey and others “Common variants on chromosomes 2q35 and 16q12 confer susceptibility to estrogen receptor-positive breast cancer” (2007) 39 Nature Genetics 865; and John D Rioux and others “Genome-wide association study identifies new susceptibility loci for Crohn disease and implicates authophagy in disease pathogenesis” (2007) 39 Nature Genetics 596.
“strikingly inconsistent”. Furthermore, the results of such research are often aggregate (as opposed to individual), remain unvalidated in a clinical setting and as such rarely have clinically significant implications for individuals. Thus, based on the current limitations of biobank research, the return of research results to individuals happens only in exceptional circumstances. Such circumstances are rare and may include occasions where there is “information revealing a condition likely to be life-threatening…Or [one that is] grave [and] that can be avoided or ameliorated”.

An implication of this general non-disclosure is that study outcomes are collected from researchers and fed directly into the biobank, bypassing study subjects altogether. For clarity’s sake, findings from research on biobank data can be regarded as “health research information”—that is, information relating to a specific individual’s health that is discovered in the course of research.

In the HIPC, an agency is exempted from the general rule (that requires a health agency to collect health information directly from an individual concerned) where reasonable grounds for non-compliance exist. Where this occurs, the onus is on the health agency to justify its actions. In the case of a BiobankNZ, several exceptions are useful:

(2) It is not necessary for a health agency to comply with subrule (1) if the agency believes, on reasonable grounds, that —

(a) the individual concerned authorizes collection of the information from someone else having been made aware of the matters set out in Rule 3(1); or

(d) compliance is not reasonably practicable in the circumstances of the particular case;

(e) the collection is for the purpose of assembling a family or genetic history of an individual and is collected directly from that individual; or

(g) the information —

(i) will not be used in a form in which the individual concerned is identified; or

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153 Privacy Act 1993, s 87
154 HIPC, Rule 2.
(ii) will be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or
(iii) will be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned; or

... 

(i) the collection is in accordance with an authority granted under section 54 of the Act.

In collecting the health information of a participant’s family members, BiobankNZ is likely to be exempted from the general rule under Rule 2(2)(e) that permits the collection of health information not directly from the source if it is for the purpose of assembling a family or genetic history and the information is collected directly from the individual. BiobankNZ can justify relying on this exception on the basis that assembling a family or genetic history is necessary for the purposes of gathering a comprehensive medical history for the purposes of research.

Preventing the disclosure of individual research findings to participants, but collecting them as health research information from researchers to add to the biobank database, can be seen as a significant restriction on a participant’s right to access his health information. However, for the reasons mentioned above, it is necessary to facilitate efficient biobank practices and disclosure seldom has practical implications for research subjects because of the group-level of the research typically carried out. To be exempt from the general rule on these bases, BiobankNZ must fall into the exceptions under Rule 2(2), of which several might apply.

(a) Individual authorization

The first exception lies in sub-paragraph (a) which permits non-compliance where the individual concerned authorizes collection of the information and has been made aware of Rule 3(1) which states that: \(^{156}\)

…the health agency must take such steps as are, in the circumstances, reasonable to ensure that the individual concerned … is aware of —
(a) the fact that the information is being collected; and
(b) the purpose for which the information is being collected; and

\(^{155}\) This is related to Rule 6 and is discussed in greater detail later on page 41.
\(^{156}\) HIPC, Rule 3(1).
(c) the intended recipients of the information; and
(d) the name and address of —
   (i)  the health agency that is collecting the information; and
   (ii) the agency that will hold the information; and
(e) whether or not the supply of information is voluntary or mandatory and if
    mandatory, the particular law under which it is required; and
(f) the consequences (if any) for that individual if all or any part of the requested
    information is not provided; and
(g) the rights of access to, and correction of, health information provided by Rules 6
    and 7.

Thus, before authorization may be sought from the individual to collect health research
information directly from researchers, the individual must be made aware of a number of
points. Most notably, BiobankNZ must ensure that individuals are aware that information
collected is intended for use by future researchers and that the cycle will repeat as health
information compounds over time. Furthermore, the collection of health research
information from researchers will be mandatory under a standard supply agreement that
all researchers will have to agree to prior to receiving any BiobankNZ data. Finally, as
will be discussed later, the participant will have limited rights of access to, and correction
of, health information provided by Rules 6 and 7.

(b) Compliance not reasonably practicable

The second exception is in sub-paragraph (d) of Rule 2 that states that non-compliance is
permitted where it is not reasonably practicable in the circumstances of the particular case
to collect information directly from the individual concerned. This exception is less
burdensome than Rule 2(2)(a) as BiobankNZ does not need to obtain authorization and
only needs to prove that it is not reasonably practicable to collect information directly
from each participant following the conclusion of each study. This can be demonstrated
by the fact that, in addition to the reasons mentioned above, because BiobankNZ exists as
a medium (or facilitator) between researchers and the actual participants, researchers are
unlikely to ever have contact with individual participants and therefore cannot be
reasonably expected to provide individual results. In addition, the sheer volume of
information transfer envisaged between BiobankNZ and researchers makes individual
notification largely impractical. However, this exception that permits non-compliance “in
the circumstances of the particular case”157 may prove onerous if BiobankNZ needs to
justify its actions for every individual participant in each study.

157 Ibid, Rule 2(2)(d), emphasis added.
(c) The “general research exception”

The third exception is in sub-paragraph (g) and can be described as the “general research exception”. The general research exception states that compliance is not necessary when: 158

(g) the information —
   (i) will not be used in a form in which the individual concerned is identified; or
   (ii) will be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or
   (iii) will be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned…

Thus, as long as BiobankNZ can show that health information will not be “used in a form in which the individual concerned is identified”, 159 the exception applies. This is consistent with the general aim of biobanking to provide coded or anonymized data to researchers. Provided the key to the code remains undisclosed to researchers, health information will be used in a form that cannot be associated with an individual. However, if providing identified data to researchers is necessary to facilitate the purposes of a study, BiobankNZ may disclose the identifiable information if the study has been approved by an ethics committee, if required, and so long as the results of the study are not “published in a form that could reasonably be expected to identify the individual concerned”, 160 or if the information will be “used for statistical purposes” and in a published format that will not “reasonably be expected to identify the individual concerned”. 161

(d) Special authorization by the Privacy Commissioner

The final exception to the general rule that may apply to BiobankNZ is if “the collection is in accordance with an authority granted under section 54 of the Act”. 162 Section 54 of the Act states, inter alia, that the Privacy Commissioner may authorize a collection that would otherwise be in breach of a rule if the Commissioner is “satisfied that, in the

158 Ibid, Rule 2(g).
159 Ibid, Rule 2(2)(g)(i).
special circumstances of the case ... [the] disclosure outweighs, to a substantial degree, any interference with the privacy of the individual that could result from that collection”.\textsuperscript{163} Thus, Rule 2(2)(i) grants the Commissioner discretion to create a special exception to the rule. However, the onus is on BiobankNZ to prove that collecting health research information from individuals concerned outweighs, “to a substantial degree”,\textsuperscript{164} any interference with the privacy of those individuals. While there are valid participant interests in demanding that health information is gathered directly from the participants, significant impracticalities do exist that balance such interests. Thus, satisfying this standard may not be too onerous as the significant impracticalities in obtaining health research information directly from individuals and the methods that will be employed to protect information from being identified are likely to mitigate any “interference with the privacy of the individual that could result from that collection”.\textsuperscript{165}

Thus, because biobanking is designed as a platform for research to which new research findings are continually added, it is impracticable —perhaps, even impossible— for BiobankNZ to comply with Rule 2(1). However, as set out above, several exceptions are available into which BiobankNZ fits —some comfortably and some slightly less so. Bearing in mind that biobanking is a relatively new concept, the Commissioner might grant a special exception to the general rule under Rule 2(2)(i) so as to more adequately recognise the features of BiobankNZ while still providing a standard of privacy for participants.

3 Rule 3: Collection of health information from an individual

Rule 3 requires that individuals be informed of a number of aspects surrounding the collection of their health information. The purpose of Rule 3 is to ensure full disclosure by the health agency to the individual as to the implications of a collection.

Thus, in compliance with Rule 3, volunteers to BiobankNZ must be informed, prior to the collection of health information, of a number of things. They are: the fact that information is being collected;\textsuperscript{166} that information is collected for the purposes of future unspecified health research\textsuperscript{167} and that intended recipients are researchers who have

\textsuperscript{163} Privacy Act 1993, s 54(1)(b).
\textsuperscript{164} Ibid, s54(1)(a).
\textsuperscript{165} Ibid.
\textsuperscript{166} HIPC, Rule 3(1)(a).
\textsuperscript{167} Ibid, Rule 3(1)(b).
obtained ethics approval;\textsuperscript{168} information about BiobankNZ as the agency for collection and storage;\textsuperscript{169} that the disclosure of health information is voluntary;\textsuperscript{170} that there are no consequences for the individual of non-disclosure;\textsuperscript{171} and their (restricted) rights of access to, and correction of, health information as provided by Rules 6 and 7.\textsuperscript{172}

As noted in the commentary, while meeting the requirements of Rule 3 is similar to what might be expected in the process of obtaining informed consent under the Code, they are two separate obligations and attaining compliance under one does not mean compliance under the other has been similarly attained.\textsuperscript{173} The right to be fully informed is discussed in more detail in Part IV of this chapter and in Chapter Three.

4 Rule 4: Manner of collection of health information

Rule 4 governs the manner in which health information may be collected from an individual or from a third party.\textsuperscript{174} Rule 4 forbids the unlawful collection of information and also when, “in the circumstances of the case”,\textsuperscript{175} collection might be considered unfair\textsuperscript{176} or intrusive “to an unreasonable extent upon the personal affairs of the individual concerned”.\textsuperscript{177}

BiobankNZ must ensure that in its collection of information it does not act outside its lawful scope and is in compliance with other relevant laws, such as the Code of Rights and the Mental Health (Compulsory Assessment and Treatment) Act.\textsuperscript{178} In addition, BiobankNZ must ensure that volunteers are not being unfairly treated and that necessary precautions are taken to ensure that participants do not feel like their personal affairs have been unreasonably intruded upon.

\textsuperscript{168} Ibid, Rule 3(1)(c).
\textsuperscript{169} Ibid, Rule 3(1)(d).
\textsuperscript{170} Ibid, Rule 3(1)(e).
\textsuperscript{171} Ibid, Rule 3(1)(f).
\textsuperscript{172} Ibid, Rule 3(1)(g). See also discussion of Rule 6 (page 41) and 7 (page 45).
\textsuperscript{173} Ibid, Commentary at 23.
\textsuperscript{174} Where this is permitted under an exception in Rule 2(2).
\textsuperscript{175} HIPC, Rule 4(b).
\textsuperscript{176} Ibid, Rule 4(b)(i).
\textsuperscript{177} Ibid, Rule 4(b)(ii).
\textsuperscript{178} The Code of Health and Disability Services Consumers’ Rights 1996 and Mental Health (Compulsory Assessment and Treatment) Act 1992.
In general, provided BiobankNZ acts in a transparent and honest manner and with consideration for the participant, it is unlikely to be in breach of Rule 4.

5 Rule 5: Storage and security of health information

Rule 5 requires every agency in possession of health information to protect the information “as it is reasonable in the circumstances to take”\(^\text{179}\) against loss;\(^\text{180}\) unauthorized access, use, modification, or disclosure;\(^\text{181}\) or other misuse.\(^\text{182}\) In addition, where it is necessary to pass on information to a third party, “everything reasonably within the power of the health agency” must be done to prevent unauthorized use or disclosure.\(^\text{183}\) Finally, disposal of documents containing health information must be done in a way that preserves the privacy of the individual.\(^\text{184}\)

Rule 5 highlights aspects of information security and “should not be regarded as a complete or definitive treatment” since information security is a “continually evolving subject”.\(^\text{185}\) However, the commentary elaborates on specific areas of information security such as physical, operational and technical security; security of transmission; disposal or destruction or transfer of health information; the importance of security plans and privacy breach disclosure policies.\(^\text{186}\)

Secure storage and security of health information is pivotal in biobanking. Without guarantee of maximum protection, the confidence in biobanks to keep information secure from unwanted access reduces and the risk of a breach of privacy is increased. While the deliberation of information security is outside the scope of this thesis, it is suffice to say that privacy of participant data is paramount and something that requires careful consideration to ensure it is sufficiently robust against unwanted access.

\(^{179}\) HIPC, Rule 5(1)(a).
\(^{180}\) Ibid, Rule 5(1)(a)(i).
\(^{181}\) Ibid, Rule 5(1)(a)(ii).
\(^{182}\) Ibid, Rule 5(1)(a)(iii).
\(^{183}\) Ibid, Rule 5(1)(b).
\(^{184}\) Ibid, Rule 5(1)(c).
\(^{185}\) Ibid, Commentary at 30.
\(^{186}\) Ibid, Commentary at 30–37.
6 Rule 6: Access to personal health information

Rule 6 states that where a health agency holds information in such a way that it can “readily be retrieved”, the individual concerned is entitled to obtain confirmation of whether or not the agency holds such information, and to have access to the information.\textsuperscript{187} “Readily” retrievable information refers to information that can be retrieved “without undue difficulty”\textsuperscript{188} and only under limited circumstances can access be refused. These limited circumstances are stated in Part 4 of the Privacy Act.\textsuperscript{189}

In BiobankNZ, it is envisaged that information will undergo at least double coding to ensure data security. Double coding requires assigning codes to participants and their samples with the code linking the number to identifying information accessible only to a small number of people.\textsuperscript{190} There is presently no guidance on whether the decryption process required in order to access specific records in a biobank makes information not “readily” retrievable. In \textit{Mitchell v Police Commissioner},\textsuperscript{191} the Tribunal found that even though the information in question could not be found at all relevant times, the fact that they were eventually found and presented at a later date, as well as the fact that the defendant had failed to pursue obvious lines of inquiry and failed to make a reasonable search, meant that they were not justified in refusing access to the information.\textsuperscript{192} “Readily retrievable” is “a question of objective fact”.\textsuperscript{193} It is likely that even though BiobankNZ information will require decryption in order to access information on specific persons, the fact that any reasonable attempt by a person with keyholder access is likely to produce decrypted information means that information will likely be considered “readily retrievable”. Thus BiobankNZ is unlikely to be able to justify a refusal for request under s 29(2)(a).\textsuperscript{194}

Information stored by biobanks includes the physical sample and any associated data relating to the sample. The associated data includes a comprehensive background that is collected from participants at recruitment, and more contentiously, any new information from future studies carried out on biobank information. The return of research findings to

\textsuperscript{187} Ibid, Rule 6(1).
\textsuperscript{188} Paul Roth, above n 139, at [PVA6.9(h)].
\textsuperscript{189} Privacy Act 1993, ss 27–29.
\textsuperscript{190} Helen Swede, Carol L. Stone, Alyssa R. Norwood “National population-based biobanks for genetic research” (2007) 9 Genetics in Medicine 141 at 146.
\textsuperscript{191} \textit{Mitchell v Police Commissioner} [1995] NZAR 274; (1995) 1 HRNZ 403
\textsuperscript{192} \textit{Mitchell v Police Commissioner} [1995] NZAR 274 at 279.
\textsuperscript{193} Ibid, at 278.
\textsuperscript{194} Privacy Act 1993.
be consolidated into the database strengthens the research potential of BiobankNZ. However, the benefits of returning research findings to individual participants are less clear.

(a) The return of individual results in biobanking

The general return of research results to individual participants in biobanking is contentious. As explained earlier, research results are often experimental, part of aggregated results and not validated in a clinical setting. There is a growing body of literature debating the nature of biobank research and the policy and clinical implications of disclosure. One argument against disclosure is that the return of research findings has the potential to create upset and confusion disproportionate to any benefit that a participant might derive from reporting results. For example, most direct-to-consumer personal genome tests currently have limited analytic and clinical validity and even less specific clinical utility. What more the preliminary research findings on samples in a biobank? There is concern that incomplete understanding of the limited predictive value of such information may lead to a “cascade effect” of avoidable anxiety, upset and confusion.

On the other hand, survey data of public opinion show that people want access to their results. It has been argued that respect for participants underlies the responsibility to return research results and this respect requires researchers to meet most, if not all, requests for results. However, the true meaning of studies indicating that participants prefer the return of results has been questioned. Ultimately though, Meyer argues that such empirical data can still play a role in informing the protocol of researchers who want

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195 See the discussion of Rule 2: Source of health information on page 33.
199 David I Shalowitz and Franklin G. Miller, ibid.
200 Ibid, at 740.
and are able to return results.\textsuperscript{202} Furthermore, it is suggested that: “Subjects have interests in receiving a much wider range of results than is often acknowledged, and most of the psychosocial risks they are said to face from disclosure remain speculative.”\textsuperscript{203}

A thorough discussion on the return of individual results is beyond the scope of this thesis. However, it is worthy to note that there are immense ethical and legal implications that arise when researchers make disclosure of results normal practice.\textsuperscript{204} These issues need to be carefully teased out and addressed to ensure that the role of the clinician and researcher is not conflated and that any future policies fully consider the potential outcomes of disclosure.

Thus, as it presently stands, health research information should not be accessible to individuals unless absolutely clinically relevant\textsuperscript{205} or, perhaps, where it is possible to “prevent or lessen serious threat” to public safety or an individual’s health.\textsuperscript{206} However, ideally, basic health information should remain accessible to individuals to permit updates so that the database remains relevant and participants contactable.

Part 4 of the Act lays out the circumstances in which access to information may be refused such as: where disclosure of information prejudices the security, defence or international relations of New Zealand and a number of other states;\textsuperscript{207} where it is necessary to protect trade secrets;\textsuperscript{208} and in other very limited circumstances to which biobanking does not apply.\textsuperscript{209} Unfortunately, the interests of BiobankNZ in preventing


\textsuperscript{203} Ibid.

\textsuperscript{204} It is cautioned that disclosing research results as standard personal practice might result in it becoming standard of care, based on it being a growing norm, without consideration for the process of disclosure and its wider implications. See: Ellen Wright Clayton and Amy L. McGuire, above n 201.

\textsuperscript{205} The discovery of clinically relevant findings is rare in population research. See generally: Bartha Maria Knoppers and others “The emergence of an ethical duty to disclose genetic research results: international perspectives” (2006) 14 European Journal of Human Genetics 1170.

\textsuperscript{206} This is discussed in more detail in the discussion of Rule 11: Limits on disclosure of health information on page 50.

\textsuperscript{207} Privacy Act 1993, s 27.

\textsuperscript{208} Ibid, s 28.

\textsuperscript{209} Ibid, s 29.
access to health research information do not fall under any other exceptions.\textsuperscript{210} Thus, for BiobankNZ to reject requests for access to health information for other reasons would be a breach of the HIPC.

The commentary for the Code describes situations where requests for access to personal information during medical research might be made.\textsuperscript{211} The commentary indicates that where future requests might prejudice the validity of a research design, participants must be informed of the fact at the time of consent. However, this does not then permit access to be forbidden to participants. Instead, where a participant insists on access to information and the information is readily retrievable, the request must be dealt with in accordance with the Privacy Act and the participant may be treated as a study withdrawal. However, in the case of BiobankNZ, equating BiobankNZ to a medical research study and withdrawing participants every time a participant gains access to information jeopardizes the credibility of the biobank amongst researchers and compromises the long-term potential of the biobank.

Thus, two problems arise in this respect. First, unless BiobankNZ can argue the remote possibility that coded health information is not “readily” retrievable,\textsuperscript{212} it appears that requests for information access cannot be rejected. Second, the HIPC’s lack of distinction of “health information” means that basic health information cannot be addressed separately from research health information. This lack of distinction creates an “all or nothing” situation where if access to information is permitted, a participant has access to both basic health information and research health information. This broad-brush approach potentially creates a situation where BiobankNZ either permits access to all health information or BiobankNZ cannot easily maintain up-to-date basic health information on its participants.

Thus, unless these issues are remedied by an amendment to the Code or to the Act, the capacity of participants to obtain access to either all or none of their health information is a risk to the biobank and will undermine its ability to facilitate and promote research.

\textsuperscript{210} Another class of exemptions that exist that do not apply to biobanking is under section 55 of the Privacy Act 1993 where certain personal information is excluded from access requests.

\textsuperscript{211} HIPC, commentary at 47.

\textsuperscript{212} Ibid, Rule 6(1).
Rule 7: Correction of health information

As discussed above, the lack of distinction between basic health information and health research information in the code is a significant issue that is not easily resolved. Health research information in this context is information “derived from the testing or examination of any…bodily substance of that individual”\(^{213}\) and therefore considered “health information” under the code.

Rule 7 states that an individual is entitled to request correction to his health information.\(^{214}\) In the event this correction is refused, the individual may request — and the agency must do all that is reasonably possible to oblige this request — \(^{215}\) to attach to the health information “a statement of the correction sought but not made”.\(^{216}\)

If an individual gains access to his health information under Rule 6, he may make a request to BiobankNZ to correct certain information. This is helpful in maintaining the database with updated information although it might prove to be an issue if an individual requests to correct research health information on the misbelief\(^{217}\) that the information is misrepresentative of his current status. When this occurs, BiobankNZ is permitted to decline the request on the grounds that health research information is experimental and not directly indicative of a person’s health like basic health information is.\(^{218}\) Furthermore, the entitlement to correct one’s health information is based on attempts to reduce the possibility of receiving treatment on the basis of inaccurate information.\(^{219}\) Because BiobankNZ functions as a repository for future research and performs no clinical function, there is no risk of treatment based on inaccurate information.

It is pertinent to note that the right to seek correction is not dependent on an individual having been granted access.\(^{220}\) Thus, even if an individual has been refused access to his information, he may still request correction of information that he is aware of. BiobankNZ encourages participants to proactively update the database where basic health

\(^{213}\) Ibid, Clause 4(1)(d).
\(^{214}\) Ibid, Rule 7(1)(a).
\(^{215}\) Ibid, Rule 7(3).
\(^{216}\) Ibid, Rule 7(1)(b).
\(^{217}\) I say misbelief because an informed person would understand that research health information is the result of experimental findings and has not been corroborated in a clinical setting yet.
\(^{218}\) HIPC, Rule 7(3).
\(^{219}\) Ibid, Commentary at 48.
\(^{220}\) Ibid, Commentary at 49.
information has changed. Thus, the entitlement to seek correction—as well as the discretion to refuse the request—is consistent with the aims of BiobankNZ.

8 Rule 8: Accuracy etc. of health information to be checked before use
Rule 8 requires agencies to check the accuracy of health information prior to its use. The agency must have “regard to the purpose for which the information is proposed to be used” and that the information is “accurate, up to date, complete, relevant and not misleading.”

This Rule primarily exists to ensure that decisions made in health care and those relating to health care-related entitlements are based on accurate information. For the purposes of research where information is aggregated, and especially where “the checking process would unnecessarily intrude on the individual’s privacy”, fewer checks are necessary.

At risk of sounding less concerned towards the accuracy of information, BiobankNZ must be cautious of the extent to which participants are re-contacted and whether re-contact on the basis of checking information accuracy justifies this intrusion of participant privacy. Regular re-contact for the purposes of checking accuracy might exhaust the goodwill of participants and create participant fatigue.

9 Rule 9: Retention of health information
Rule 9 states that a health agency must not hold information longer than what is necessary for the purposes for which the information may lawfully be used. As noted in the commentary, agencies may retain information for purposes beyond what it was originally collected for, provided there remains a lawful purpose for doing so.

In the case of biobanking, the intention is to retain health information indefinitely for the purposes of future research. As mentioned in the commentary with regard to health research, where researchers wish to keep identifying information or identified specimens longer than what is required of the original project, it is expected that agreement will be

221 Ibid, Rule 8(1).
222 Ibid, Commentary at 51.
223 Ibid, Commentary at 51.
224 Ibid, Rule 9(1).
225 “Lawful” in the context of the code is mentioned earlier under the discussion of Rule 1 on page 32.
226 HIPC, Commentary at 53.
sought from an ethics committee.\textsuperscript{227} Similarly, it is anticipated that BiobankNZ will be accountable to an ethics committee to ensure that the interests of participants remain protected.

\textit{10 Rule 10: Limits on use of health information}

Rule 10 places restrictions on the use of health information — generally speaking, health information should not be used for purposes other than those for which it was originally collected. In biobanking, concern regarding “use” of health information primarily involves the disclosure of health information to authorized researchers for use in population research.

The unforeseen nature of future research and the aim of biobanking to facilitate research in multiple disciplines mean that it is hard to provide participants with anything but a general indication of the use of their health information at the time of collection. Besides informing them of the general purpose of BiobankNZ — that is, to facilitate research into links between lifestyle, health and disease — it is undesirable to elaborate more in the event an unanticipated purpose arises that is outside the scope of the original stated purpose.

At the same time, it is in the interests of participants to have the use of their health information restricted. BiobankNZ and researchers should not use the broad purposes of BiobankNZ to justify \textit{any} type of research that might disrespect participants and even violate privacy.

(a) Objectionable research

The intentionally indeterminate nature of biobank research and the fact that participants may not necessarily be re-contacted for consent\textsuperscript{228} to the use of their data creates situations in which research carried out might be objectionable to a participant. People may object to research with particular aims. Examples include studies aimed at developing diagnostic or prognostic tests for conditions that are untreatable; research with potentially stigmatizing outcomes; or research solely for commercial benefit.\textsuperscript{229}

\textsuperscript{227} Ibid, Commentary at 54.
\textsuperscript{228} The issue of consent in biobank research is discussed in the next chapter.
\textsuperscript{229} W. Lipworth, R. Ankeny and I. Kerridge “Consent in crisis: the need to reconceptualize consent to tissue banking research” (2006) 36 Internal Medicine Journal 124 at 125.
In New Zealand, a team of researchers analyzing the monoamine oxidase gene as a genetic marker for alcohol and tobacco response traits caused great upset when they claimed that Māori research participants demonstrated a gene which caused significantly higher levels of the monoamine enzyme—an enzyme that had earlier been linked to addiction, aggression and risk-taking. The research was criticised as appalling and later dismissed as “irresponsible” and unsupported. However, this was not before furious reaction from Māori leaders and global publicity over the link between the gene and a predisposition to violence and criminality. The effect of the “warrior” gene controversy had very negative effects for the Māori community. Furthermore, samples for the research derived from the reanalysis of stored tissue samples, something that would most certainly have damaged the trust of Māori towards researchers obtaining and storing tissue samples. The “warrior” gene controversy was stigmatizing towards Māori and emphasized the importance of respect for the values and interests of the community in research and the need to protect the community from harm.

This example of objectionable research highlights the need to earn and retain the trust of research participants through responsible and accountable research. Being mindful of the effects of research and its potential to cause harm for certain groups in a community is crucial in ensuring that a biobank and its research adds value to a society and remains a trusted establishment.

230 D Hall and others. “Tracking the evolutionary history of the warrior gene across the south pacific: implications for genetic epidemiology of behavioural disorders.” (Poster presentation at 11th International Congress of Human Genetics, Brisbane, Australia, August 2006).
231 For a review of the research on Monoamine Oxidase A and its link to vulnerability to alcohol, opiate or cocaine addiction, see: Mary Kreek, David Nielsen and K. Steven LaForge “Genes Associated with Addiction” (2004) 5 NeuroMolecular Medicine 85 at 90.
232 Jon Stokes “Māori “warrior gene” claims appalling, says geneticist” The New Zealand Herald (online ed, 10 August 2006).
234 See for example: “Violence is blamed on “warrior gene” in the Maoris” The Telegraph (online ed, 10 August 2006); and “Once were warriors: gene linked to Māori violence” The Sydney Morning Herald (online ed, 9 August 2006).
(b) Rule 10 does not provide a sufficient safeguard against potentially controversial research

Rule 10 provides several exceptions to the rule limiting the use of health information. Examples of some exceptions relevant to BiobankNZ include: where an individual has authorized its use;\textsuperscript{236} where the purpose for which the information is used is “directly related to the purpose” in connection with which the information was obtained;\textsuperscript{237} and where the information is used in a form in which makes it hard to identify the individual.\textsuperscript{238} Commentary to Rule 11 describes “directly related” purposes as those that could “reasonably be assumed to be within the expectations of the person from whom the information was collected”\textsuperscript{239}

If BiobankNZ provides participants with a relatively broad purpose for the collection of health information, any future research relating to the purpose is likely to fall within the either the ambit of Rule 10 or one of its exceptions. This may be favourable for researchers who then do not need to seek re-consent for the use of health information for a related purpose, but is not in the interests of participants. Rule 10 sets a very low bar for seeking authorization for new research —provided BiobankNZ can prove that research carried out is within the scope of its purpose, there is no requirement to seek new authorization.

In addition, the nature of large scale studies and its general use of unidentifiable data means that any type of large scale study is likely to fall into one of the general research exceptions under Rule 10(1)(e). Thus, there is no limitation on the use of health information as long as it can be proven that the information is used in a form where the individual is not identified;\textsuperscript{240} where the information is used for statistical purposes and is published in a form where an individual cannot “reasonably be expected to be identified”;\textsuperscript{241} or where the information is used for research purposes, ethics approval has been obtained where necessary, and an individual is unlikely to be reasonably identified in the study publication.\textsuperscript{242}

\textsuperscript{236} HIPC, Rule 10(1)(a).
\textsuperscript{237} Ibid, Rule 10(1)(b).
\textsuperscript{238} Ibid, Rule 10(1)(e).
\textsuperscript{239} Ibid, Commentary at 63.
\textsuperscript{240} Ibid, Rule 10(e)(i).
\textsuperscript{241} Ibid, Rule 10(e)(ii).
\textsuperscript{242} Ibid, Rule 10(f)(iii).
As such, the limits imposed by Rule 10 are insufficient to guard against controversial or objectionable use. The ability of BiobankNZ to justify any use of health information, especially under the general research exception, makes it too easy to engage in research that may be acceptable under the Code but is not in a participant’s interests.

In order to place checks on the power of BiobankNZ to permit research into areas not reasonably anticipated during the original collection of health information, more stringent requirements must be put in place to protect the privacy interests of participants. This may need to come in the form of independent regulation to ensure that the interests of participants remain paramount in research. However, this must also be balanced with the nature of the research—that it is group-level and thus less intrusive and “risky”—and the desire not to fatigue participants with vexatious re-contact.

11 Rule 11: Limits on disclosure of health information

Rule 11 places limits on the disclosure of health information concerning an individual (living or deceased) to third parties. Generally speaking, disclosure should only be to the individual concerned or to an individual’s representatives where the individual is deceased or unable to exercise his rights under the Rules. This rule is closely related to Rule 10 as disclosure of health information to third party researchers is a primary use of health information stored by BiobankNZ. Rule 11 describes a number of circumstances when disclosure may be allowed, with the final decision on whether to disclose or not left to the agency.

(a) Generally permissible disclosure

In the case of BiobankNZ, certain situations may be relevant:

(1) A health agency that holds health information must not disclose the information unless the agency believes, on reasonable grounds, that —
   (a) …
   (b) the disclosure is authorised by—
       (i) the individual concerned; or
       (ii) …

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244 Ibid, Commentary at 61.
245 Ibid, Rule 11.
(c) the disclosure of the information is one of the purposes in connection with which the information was obtained.

…

Rule 11(1)(b)(i) permits disclosure to a third party if the individual concerned authorizes it. Authorizati

…

Rule 11(1)(b)(i) permits disclosure to a third party if the individual concerned authorizes it. Authorization “implies a general understanding of what is being agreed to by the individual concerned”, is “stronger than that of consent”, and “denotes a positive and conscious act by the individual”. Thus, in order to obtain authorization, BiobankNZ must provide sufficient information and ensure that the individual concerned understands and positively indicates agreement to what is being asked of him. This is similar — albeit slightly less stringent — to the standard of informed consent required under the Code of Rights.

Where disclosure is “one of the purposes in connection with which the information was obtained”, authorization from the individual concerned or his representative is not required. It was anticipated that this might arise where information is required for further treatment of an individual, for administrative purposes or monitoring an individual during care and treatment. This scenario is less relevant in biobanking as the process of seeking consent (and the necessary standard of authorization) for use will necessarily cover disclosure of information to others.

(b) Some exceptions to the general rule of non-disclosure

Rule 11(2) permits non-compliance with subrule (1)(b) if the health agency believes “on reasonable grounds” that it is neither “desirable” nor “practicable” to obtain authorization from the individual concerned. In biobanking, some of these exceptions apply, such as when:

(c) the information —

(i) is to be used in a form in which the individual concerned is not identified; or

246 Ibid.
247 Ibid, Commentary at 62.
248 Paul Roth, above n 139, at [PVA6.5(e)].
249 Ibid.
250 The requirements of informed consent in New Zealand is discussed in Chapter Three on page 71.
251 HIPC, Rule 11(1)(c).
252 HIPC, Commentary at 62.
253 HIPC, Rule 11(2).
(ii) is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(iii) is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(d) the disclosure of the information is necessary to prevent or lessen a serious and imminent threat to —

   (i) public health or public safety; or

   (ii) the life or health of an individual concerned or another individual; or

   …

(i) non-compliance is necessary —

   (i) to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution, and punishment of offences; or

   (ii) for the conduct of proceedings before any court or tribunal (being proceedings that have been commenced or are reasonably in contemplation); or

   …

(k) the disclosure of the information is in accordance with an authority granted under section 54 of the Act.

First, in the event that authorization obtained by BiobankNZ from participants is considered insufficient, BiobankNZ can still disclose health information under Rule 11(2)(c) provided it can prove that it is either “not desirable” or “not practicable” to obtain authorization from the individual concerned. As mentioned above, this general research exception permits disclosure where certain conditions are met — most of which can be met easily by study designs envisaged by BiobankNZ. In this instance, it can be argued that the large number of individuals from whom authorization will need to be sought for participation in individual studies makes it impracticable and an exception under Rule 11(2)(c) is justified.

Second, subrule 2(i) permits non-compliance where either necessary to avoid prejudice to the maintenance of the law or for the conduct or any court or tribunal proceedings.

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254 HIPC, Rule 2(2)(i)(i).
Similarly, subrule 2(k) permits disclosure where it is in accordance with s 54 of the Privacy Act. Section 54 states, inter alia, that the Commissioner may authorize disclosure if, “under the special circumstances of the case”, the Commissioner is satisfied that there is “public interest in the collection” or that disclosure “outweighs, to a substantial degree, any interference with the privacy of the individual that could result” from the disclosure.\textsuperscript{256} The Commissioner may also authorize disclosure where it “involves a clear benefit to the individual concerned that outweighs any interference with the privacy of the individual”.\textsuperscript{257} However, this discretion under s 54(1) is not unfettered — where an individual has “refused to authorize…disclosure”, s 54(3) states that the Commissioner “shall not grant an authority under subsection (1)”.\textsuperscript{258}

Third, subrule 2(d) permits an exception to disclose health information if it is necessary to “prevent or lessen a serious and imminent threat to”\textsuperscript{259} either public health or public safety; or to the life or health of the individual concerned or another individual.\textsuperscript{260} In a recent report, the Law Commission recommended that the word “imminent” in the threshold be deleted from the exceptions.\textsuperscript{261} The Law Commission felt that the current threshold is inappropriate as sometimes a threat will be serious but may not eventuate for some time.\textsuperscript{262} This recommendation is reflected in the Privacy (Information Sharing) Amendment Bill that was introduced to Parliament on 16 August 2011.\textsuperscript{263} It is likely that a similar change will be made to the HIPC if this Bill passes; this means that provided no other obligations of confidentiality apply, BiobankNZ will be able to disclose information about a participant’s genetic condition if it believes, on reasonable grounds, that it is a serious threat to the health of relatives and disclosure is necessary to prevent or lessen the threat, even if the condition may not manifest for many years.

A major concern with these subrules is that the scope of permissible disclosure to third parties is fairly wide. For example, subrule 2(i) permits disclosure under certain circumstances in the law. In an extreme, but not implausible scenario, BiobankNZ could

\textsuperscript{256} Privacy Act 1993, s 54(1)(a).
\textsuperscript{257} Ibid, s 54(1)(b).
\textsuperscript{258} Ibid, s 54(3).
\textsuperscript{259} HIPC, Rule 11(2)(d).
\textsuperscript{260} This exception also exists in Rule 10(1)(d) which governs the limits on use of health information.
\textsuperscript{261} Law Commission, above n 85, at chapter 3, R30. This recommendation applies to the exception in both Rules 10 and 11.
\textsuperscript{262} Ibid, at [3.119].
\textsuperscript{263} Privacy Commissioner Proposed Amendment No. 7 to the Health Information Privacy Code 1994 Information Paper (February 2012) at 2.
permissibly disclose incriminating health information, against the interests of a participant, in “the prevention, detection, investigation, prosecution and punishment of offences”.264

The effect of Rule 11 on limiting disclosure is very weak and leaves BiobankNZ with wide (and potentially wider in the future) discretion to decide whether or not to disclose the information. Under Rule 11(2), BiobankNZ need only show that seeking authorization is “not desirable or not practicable”265 before disclosure is permitted with participants having no right to veto. The commentary notes though that the decision is also subject to any relevant ethical and professional obligations that might impose stricter limits as well as any duties of confidentiality.266

While Rule 11 might place limits on the disclosure of information, I conclude that the HIPC does not sufficiently protect the interests of BiobankNZ participants against unwanted disclosure. Without any currently established ethical and professional obligations on biobanks in New Zealand, the discretion to disclose without the authorization of participants is wide for BiobankNZ with little reassurance for participants.

12 Rule 12: Unique identifiers
Rule 12 prohibits health agencies from assigning a unique identifier to an individual unless it is necessary to enable the health agency to carry out any one or more of its functions efficiently.267 A “unique identifier” is defined as an identifier that is assigned to an individual for the purposes of the operations of an agency and that uniquely identifies that individual in relation to that agency.268 A health agency must clearly establish the identity of individuals before assigning a unique identifier.269 In addition, only agencies expressly authorized in statute or regulation or those listed in Schedule 2 of the HIPC may assign the same National Health Index number (NHI) to an individual.270

264 HIPC, Rule 11(2)(i)(i). In H v G (High Court, Auckland M 1868/98, 14 May 1999, Salmon J) the Court made an order that a Guthrie Card (newborn blood spot card) be released in order to carry out DNA testing to ascertain paternity. This was later accepted as admissible evidence in H v G (1999) 18 FRNZ 572.
265 HIPC
266 Ibid, Commentary at 61.
267 Ibid, Rule 12(1).
268 Privacy Act 1993, s 2.
269 HIPC, Rule 12(5).
270 Ibid, Rule 12(3).
Assigning unique health identifiers is a necessary process of de-identifying information in BiobankNZ and allowing the agency to perform its functions. Two unique identifiers — the unique health identifier and a “research identifier” — are created to keep identifying information separate from research information with the key that links both codes restricted to a small number of people. This helps to uphold participant privacy by preventing researchers from associating health information to specific individuals.

Figure 1. An example of how BiobankNZ might use coding to protect participant privacy.

The NHI is a unique combination of letters and numbers that is used to identify individuals when they use health and disability services in New Zealand. An NHI only contains the name and address, date of birth, sex and ethnicity of a person and does not contain any clinical information. The purpose of the NHI is to identify individuals and ensure that patients are matched accurately to their health records to prevent confusion in clinical care and treatment. Where a person has a significant medical condition, it is stored in another system, the Medical Warnings System (MWS). A “flag” is then attached to an individual’s NHI where necessary to ensure that health providers take MWS information into account during treatment.

In biobanking, it is extremely useful to be able to link samples with updated health information. This strengthens the resource by allowing researchers to identify particular diseases that develop in participants and make comparisons against genetics and other exposures to identify causes of disease. Biobank data that is not updated is limited in its research use as it does not allow researchers to study long-term outcomes. However, re-

272 Ibid.
273 Ibid.
contacting participants and relying on participants to proactively inform a biobank of significant life events is not an effective means of doing so. The hassle of re-contact might create a bias in the participant group, automatically excluding people who prefer avoiding the hassle of re-contact.

The UK Biobank updates its information by linking its database with other national registries. Current and future registries linked to the UK Biobank include those on death, cancer, hospital admissions, primary care records and other records. By linking databases, the UK Biobank is able to automatically update their comprehensive records of participants and maximize the scope and accuracy of research on participants.

There are currently no provisions permitting BiobankNZ—or another similar establishment—to attach an individual’s NHI to his records within the BiobankNZ. This would be very helpful in keeping personal and health information updated. In addition, it also avoids the dilemma of keeping basic health information accessible but not research health information because participant contact information can be kept up to date through the NHI database. However, to link NHI numbers with BiobankNZ's database without express authority by statute or regulation is unlawful and a breach of the HIPC. Finally, New Zealand’s lack of a centralized database for health information means that even if an NHI may be linked to BiobankNZ's database, there is still a significant way to go before any biobank in New Zealand can enjoy extent of linkage enjoyed by UK Biobank.

E  Is the HIPC sufficient to protect a participant’s privacy interests?

An assessment of the HIPC against the backdrop of biobanking has revealed a number of significant shortcomings in the Code’s ability to protect the interests of biobank participants. Some troubling issues include the lack of distinction between basic and research health information, the current limits on the use of health information, the discretion of BiobankNZ to disclose information to third parties, and the restriction on the use of unique identifiers.

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274 HIPC, Rule 12(3)(a).
275 Despite no centralized database like in other countries, New Zealand does have several national health and disability collections that are operated by the Ministry of Health. These collections have the potential of being linked BiobankNZ to strengthen its resource.
First, the lack of distinction between basic health information and research health information means that both types of information can be accessed under the entitlement of individuals to access their personal health information.\textsuperscript{276} On the one hand, it is preferable for biobank participants to have access to their basic health information so that participant information can be kept up to date. On the other hand, research health information and incidental findings should rarely be revealed to participants as incomplete understanding of the predictive value of such information can lead to unnecessary anxiety, upset and confusion.\textsuperscript{277} The lack of distinction creates a clumsy “all or nothing” approach that fails to meet the need of BiobankNZ to maintain an up-to-date database that facilitates long term research.

Second, the current limits on the use of health information do not sufficiently protect biobank information from unwanted use. Under Rule 10, BiobankNZ only needs to prove that research is within the scope of its purpose for research to proceed without new authorization. In the likely scenario that new studies fall under the general research exception, new research will not even require participant authorization before commencing. This very low standard set by Rule 10 is troubling for biobank participants who have little guarantee in the restrictions on biobank data use set out in the law.

Third, the limits placed on BiobankNZ on the disclosure of health information is weak and leaves wide discretion for BiobankNZ to disclose information to third parties. The lack of common law duties of confidentiality or any current professional or ethical obligations for an establishment like BiobankNZ means that the HIPC will be a principal source of privacy protection for participants. However, the restrictions on disclosure are weak and without other frameworks to augment this rule, there is little reassurance for biobank participants against unwanted and unauthorized disclosure.

Finally, the use of unique identifiers is crucial to the work of BiobankNZ and upholding participant privacy. In addition, the restriction on BiobankNZ from linking its database with the NHI database is a disadvantage as the database can help keep the BiobankNZ database updated with current personal and basic health information.

\textsuperscript{276} HIPC, Rule 6
\textsuperscript{277} This is sometimes referred to as the “Cascade Effect” where a chain of events is initiated by an unnecessary test, an unexpected results or anxiety that may cause avoidable adverse effects. See: Richard A. Deyo, above n 197.
In conclusion, the HIPC is likely to be able to apply to health information stored and used by BiobankNZ. However, the slight misfit of the Code against the unique traits of BiobankNZ is evident and is not ideal. However, the scope of protections of the HIPC can also be strengthened by other Rules and guidelines such as The Code of Health and Disability Services Consumers’ Rights and The Guidelines on the Use of Human Tissue for Future Unspecified Research.

IV The Code of Health and Disability Services Consumers’ Rights

The Code of Health and Disability Services Consumers’ Rights (“Code of Rights”) is a regulation under the Health and Disability Commissioner Act 1994. It came into force on 1 July 1996 and was established to “promote and protect the rights of health consumers and disability services consumers, and, to that end, facilitate the fair, simple, speedy and efficient resolution of complainers relating to infringement of those rights”.278 The very extensive breadth of the Code of Rights places obligations on any person or organization providing any form of health care service to the public and holds the provider to a high standard of accountability. Unlike the HIPC that centers on an individual’s authorization, the Code of Rights is based upon the right of health care consumers to make informed choices.

With regard to privacy, right 1(2) states that: “Every consumer has the right to have his or her privacy respected.”279 It is, however, a very limited role as “privacy”, for the purposes of the Code of Rights, “means all matters of privacy in respect of the consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates”.280 This means that privacy matters that are dealt with by the Privacy Commissioner are excluded from the Code of Rights. In other words, the right to privacy in the Code of Rights is a right to personal physical privacy and not a right to personal informational privacy (the focus of the discussion).

V The Use of Human Tissue for Future Unspecified Research Purposes (“Guidelines”)

278 Health and Disability Commissioner Act 1994, s 6.
279 The Code of Health and Disability Services Consumers’ Rights [Code of Rights].
280 Ibid, cl 4.
The Guidelines were published by the Ministry of Health in 2007, following public consultation on an earlier discussion document. The Guidelines permit researchers to obtain consent to use human tissue for future unspecified research subject to participants being provided with specific information and sufficient options before gaining their consent. The Guidelines sit beneath the Operational Standard for Ethics Committees and guide Health and Disability Ethics Committees in their consideration of applications for research concerning the use of human tissue for future unspecified research.

This discussion is limited to Part 2 of the Guidelines that outlines the information that must be provided to participants before seeking consent for future unspecified use of human tissue. Unlike the HIPC that deals primarily with matters of informational privacy, the Guidelines address issues surrounding sample privacy. However, the Guidelines remain relevant because the standards imposed by the Guidelines complement the HIPC and arguably demand a higher standard of consideration for participants.

This discussion intentionally excludes issues surrounding consent as this is discussed in Chapter Three.

A Part Two: Information to be provided

The Guidelines provide a non-exhaustive list of information that must be provided to participants prior to seeking consent for use of the human tissue. While it is uncertain which ethics committee BiobankNZ will be accountable to, it is assumed that BiobankNZ, at the very minimum, will be required to comply with the Guidelines since the biobank collects, stores and processes human tissue for future unspecified research purposes.

In this discussion, the term “donors”, as used in the Guidelines, applies equally to biobank participants. The requirements in regard to information that must be provided may be condensed into twelve main points:

First, researchers must give an indication of the type and nature of research to be carried out and its implications for the donor. In addition, where possible, researchers must

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282 Ibid, at 3.
283 Ibid, at [5].
also explain to the potential donor why he is being sought and specifically what tissue is being sought.\textsuperscript{284}

As a resource to enable population health research, BiobankNZ's intention will be to recruit as many participants as possible. As explained earlier, it is neither feasible nor practical to provide a detailed breakdown of the research that will be carried out. However, it is possible for BiobankNZ to provide a list of various anticipated research areas (for example, research in diabetes, heart disease, mental disease) and provide participants with the option to exclude certain types of research. This satisfies the criteria and also allows participants to retain some control over the kinds of research that may be carried out on their samples by permitting participants to opt out of certain types of research.

Second, the Guidelines state that researchers are required to inform participants of the possible researchers or institutions that might use the samples,\textsuperscript{285} and whether a sample is likely to be sent overseas.\textsuperscript{286} In addition, participants must be informed of whether their samples can be accessed by commercial biomedical companies or used in commercial research collaborations, if known.\textsuperscript{287}

As a tool for health research, it is likely that BiobankNZ data will be made available to all bona fide researchers, regardless of affiliation or location. This maximizes the research potential of biobank information and will expand the scope of research carried out on diseases prevalent in the New Zealand population. However, the nature of biobanking means that participants are unlikely to be given more than a broad and vague indication of where their samples might be sent. Thus, in the interests of guarding against data misuse, BiobankNZ can adopt a stringent application process to ensure that potential researchers are screened and that protocols meet set criteria before biobank information is released.

Third, researchers are required to acknowledge that all future unspecified research in New Zealand is subject to ethical review.\textsuperscript{288} The Guidelines highlight the possibility that unless data sent overseas is sent in conjunction with a New Zealand research project,

\textsuperscript{284} Ibid.
\textsuperscript{285} Ibid, at [6] and [16].
\textsuperscript{286} Ibid, at [7].
\textsuperscript{287} Ibid, at [17].
\textsuperscript{288} Ibid, at [8].
future research is unlikely to be considered by an overseas committee with New Zealand representation.\textsuperscript{289}

In the case of BiobankNZ, this expectation can be met and exceeded by requiring all potential biobank research to undergo the same process of ethics approval, regardless of the location of research, as part of the application process. However, BiobankNZ’s ability to screen protocols is limited to the application process and ongoing inspections on actual research conditions are unlikely and not practical.

Fourth, researchers are required to inform participants of whether their identity and details will remain linked with their samples or whether the sample will be de-linked \textit{at the time of research}.\textsuperscript{290} This has significant implications for privacy as linked samples remain identifiable and thus researchers must comply with the HIPC. On the other hand, de-linked information is anonymized information and not subject to the same Rules. In addition, participants must also be informed of the fact that they relinquish their right to withdraw from studies once information has been anonymized.\textsuperscript{291}

The Guidelines only require researchers to inform participants of sample identifiability at the time of research. However, it is silent on whether participants must be informed of sample identifiability at the point of storage and processing but prior to research. Under the Guidelines, researchers are thus not obliged to inform participants of the identifiability of their samples while stored in the biobank.

Fifth, participants must be informed of whether they may be contacted in the future regarding their tissue sample.\textsuperscript{292} This re-contact is likely to be one concerning consent for future research and is discussed later.\textsuperscript{293} In addition, participants must be informed of whether or not, and under what circumstances, information about future research will be made available to the donor.\textsuperscript{294}

The Guidelines do not state whether information that must be made available to the donor relates to details of future research study designs or actual information on the outcomes

\textsuperscript{289} Ibid.
\textsuperscript{290} Ibid, at [9].
\textsuperscript{291} Ibid, at [10].
\textsuperscript{292} Ibid, at [11].
\textsuperscript{293} See page 79.
of future research. However, due to the large scale of population studies and the volume of research anticipated, it is unlikely that individuals will be informed every time their data is used for approved research and even more unlikely that individuals will be contacted with the study outcomes. As a result, it has become increasingly acceptable for biobanks to periodically publish biobank updates on current research as well as any aggregated results from completed studies. This allows biobank participants to remain updated on research news without creating a disproportionate burden on the biobank to inform participants every time a study commences and ends.

Six, researchers must acknowledge to participants that they will not own any intellectual property that may arise from any future research.295 This is a contentious aspect of proprietary privacy that is not within the scope of this thesis.296

Seven, researchers are required to inform participants of the limits of withdrawing biobank consent.297 In the case of BiobankNZ, the nature of biobanking and mechanisms to protect privacy severely restricts the ability of a participant to withdraw entirely from participation. If there is a provision to withdraw consent, BiobankNZ must inform participants that only samples and information held by the biobank can be destroyed.298 Samples or information used in research before the request to withdraw are unlikely to be able to be traced and returned or destroyed.299 This imposes an obligation on BiobankNZ to be very precise of the full extent of the limitations of potential withdrawal and its implications on participant privacy.

Eight, researchers are required to acknowledge to participants that their decision regarding consent for use of their tissue sample for future unspecified research will not prejudice the quality of their current or future clinical care.300 This is reaffirmed in the structure of a typical biobank and its independence from any clinical facility or health service provider.

Nine, participants must be informed of the conditions surrounding the storage of their tissue samples, how samples will be disposed of and whether there is a cultural protocol

295 Ibid, at [12].
296 For more information on property rights and benefit-sharing for DNA donors, see for example: Gary E. Marchant “Property Rights and Benefit-Sharing for DNA Donors?” (2004–2005) 45 Jurimetrics 153.
298 Ibid.
299 Ibid.
300 Ibid, at [14].
for its disposal.\textsuperscript{301} The integrity of biobank samples and information is an important part of respecting individual privacy as well as group privacy. This clause requires BiobankNZ to put careful thought into its research aims, governance and any protocols with respect to participant information in order to minimise any potential harm to individuals or groups of people.

Ten, researchers are required to describe to participants the provisions for ensuring participant confidentiality.\textsuperscript{302} This clause specifically requires BiobankNZ to disclose any privacy risks in participating and explain the steps that will be taken to protect participant confidentiality. In doing so, participants are likely to get a better understanding of the risks involved with biobanking and any steps taken by BiobankNZ to minimise potential harm.

Eleven, researchers are required to acknowledge the different cultural views that may inform participant choices.\textsuperscript{303} In addition, researchers must inform participants that cultural concerns may arise when tissues are sent overseas as the processes used for monitoring and tracking what happens to tissue samples may not be acceptable to certain participants.\textsuperscript{304} New Zealand’s unique population and obligations under the Treaty of Waitangi mean that consideration must be given towards any cultural views and concerns that might inform the decision making of potential participants. Establishing culturally appropriate guidelines and protocol for biobank information handling will ensure that the interests of participants are protected and recruitment bias is minimized. Chapter Four focuses specifically on Māori views on the collection of human tissue and concerns towards genetic research.

Finally, researchers are required to inform participants that they may want to discuss the issue of donation with those close to them. This is consistent with the interests of participants in some cultures who place emphasis on collective decision-making. In some cultures, an individual’s value of personal autonomy can take lesser place to a recognized importance of whanau decision-making, especially concerning matters of the human body. Respect for cultural differences and the importance of collective decision-making to certain groups is recognized in other legislation such as the Human Tissue Act 2008 that imposes a duty on the decision-maker to take into account an immediate family’s

\textsuperscript{301} Ibid, at [15].
\textsuperscript{302} Ibid, at [18].
\textsuperscript{303} Ibid, at [19].
\textsuperscript{304} Ibid, at [20].
cultural and spiritual needs, values and beliefs when giving informed consent or objection to organ donation.\(^{305}\)

In summary, the Guidelines require researchers seeking consent for future unspecified use of human tissue to ensure that donors are given as much information as possible regarding the use of their tissue. This promotes personal autonomy by allowing potential donors to make an informed decision based on the information available to them.

**B The Guidelines in comparison with the HIPC**

The HIPC and the Guidelines create a broader framework for privacy protection in biobanking. However, while the HIPC and Guidelines may apply to similar situations, there are significant differences between the two documents. While these differences can be attributed to the different contexts in which they were created, they bring into question the overall efficacy of the framework in promoting participant autonomy and protecting privacy in biobanking.

First, the Guidelines and the HIPC apply to different aspects of biobanking. The HIPC applies only to information provided in connection with a biobank donation\(^{306}\) in contrast to the Guidelines that apply to information that BiobankNZ must provide to participants before seeking consent for donation of tissue.\(^{307}\) This focus on different aspects of biobanking means that there is currently no single comprehensive standard of privacy protection for both samples and health information.

Second, the Guidelines demand very precise disclosure on certain aspects of tissue use. This is compared to the slight “misfit” of the HIPC Rules to biobanking and the resultant ability of BiobankNZ to slip through some Rules unregulated as a result of the exceptions to some Rules. On the other hand, the Guidelines specify a number of aspects of future research —such as potential uses, security, ethics and cultural concerns— that researchers must disclose to participants with little exception. This requirement of thorough disclosure promotes greater participant awareness and comprehension and arguably affords better respect for participant autonomy, and thus privacy, as compared to the HIPC.

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\(^{305}\) Human Tissue Act 2008, s 42.

\(^{306}\) HIPC, Commentary at 9.

Third, the HIPC lays out rules for the ongoing collection, storage and use of health information. This means that as long as a health agency retains health information of a participant, it is subject to those rules. On the other hand, despite the arguably better “fit” of the Guidelines to biobanking, the Guidelines are not an ongoing standard. The Guidelines require researchers to carefully contemplate a number of aspects of sample privacy prior to seeking consent. However, these guidelines merely exist as a threshold for ethics approval by Health and Disability Ethics Committees. Beyond the ethics committees, there exist no mechanisms to ensure that researchers fulfill the standards set out.

Finally, on a note related to the above point, the HIPC and the Guidelines are very different instruments in law. The HIPC has the effect of law on all health agencies\(^{308}\) unlike the Guidelines that merely serve as a guide for ethics committees. The Guidelines have no force in law and the worst outcome for failure to meet and follow the Guidelines is the inability to obtain ethics approval or withdrawal of approval, respectively, from Health and Disability Ethics Committees. On the other hand, failure to abide by the rules of the HIPC can invoke the involvement of the Privacy Commissioner’s Office and have other legal repercussions.\(^{309}\)

Thus, both the Guidelines and the HIPC relate to the privacy interests of biobank participants. However, they apply to different aspects of biobank privacy and their statuses in the law are significantly different.

**VI Where to from here?**

Biobanking is a significant long-term investment for any country that relies heavily on the trust of its citizens and their participation. While the standard of privacy protection promised by biobanks is important, the ability of the law to enforce this standard can be argued to play a bigger role in participant confidence. People will be reluctant to entrust hugely personal information to an agency if there is no confidence in the ability of the law to protect their privacy interests.

The HIPC, while admirably thorough in its health information privacy protection, is inadequate in protecting the interests of biobank participants. The unique features of biobanking require very precise standards of privacy in some areas while also requiring

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\(^{308}\) Privacy Act, s 53.

\(^{309}\) For a more detailed explanation of the complaints process, see: HIPC, Commentary at 75–77.
more flexibility in other areas. This ensures the ability to provide maximum possible privacy protections for participants while keeping the scope of use of data open for the future.

On the other hand, while the Guidelines may promote respect for participant autonomy by emphasizing maximum disclosure, the Guidelines have little force outside the role of ethics committees. The use of the Guidelines as a standard for obtaining ethics approval is insufficient to protect participant privacy in biobanking. There is currently no ability to ensure fulfillment of these Guidelines over the course of the “lives” of data in the biobank.

In conclusion, it is not impossible to view the HIPC and the Guidelines together as a more comprehensive framework for privacy in biobanking. However, it is hard not to view this combination as a bit of a “mish mash” of protections with significant loopholes in the framework that will need to be plugged by amendments to the law. Considering the large cost of biobanking—both in terms of financial resource and participant goodwill—it seems more prudent in the long run, at least in the case of New Zealand, to create a new instrument that provides comprehensive protection tailored to the nuances of biobanking. However, questions lie in whether creating a biobank-specific ethics framework that BiobankNZ must adhere to, or an entirely new piece of biobank-specific legislation, is the best way forward.

The next chapter will consider the consent issues that arise in biobanking and, in particular, the appropriateness of the Code of Health and Disability Services Consumers’ Rights in obtaining the necessary consent for biobanking.
CHAPTER THREE: CONSENT IN BIOBANKING

The advent of biobanking has challenged the immutable role of informed consent in biomedical research. The massive scale of biobanks and their role as a resource for future research makes obtaining meaningful informed consent from participants tricky. Some argue that maintaining traditional consent norms may harm the social utility and scientific value of a biobank and have called for a re-look at informed consent.\(^{310}\) This chapter considers the role of informed consent in New Zealand and the wisdom in modifying traditional consent norms for the sake of biobanking.

In this chapter, I discuss the introduction of the Code of Health and Disability Services Consumers’ Rights in New Zealand and informed consent under this Code. I discuss the Operational Standard under which the majority of ethics committees in New Zealand operate and its status in the law. This chapter applies the law of informed consent in New Zealand to BiobankNZ and discusses the capacity of the current law to balance the interests of health research while protecting the interests of biobank participants. In my study of the law, I also discuss the different biobank experiences of the United Kingdom and Iceland.

I conclude that New Zealand’s combination of law, codes and other regulations does show flexibility towards modifying informed consent to accommodate the unique character of biobanks. However, with modification of the traditional norm comes a need to ensure that the interests of research subjects are protected. I argue that more needs to be done in New Zealand to cement the standard in order to ensure that the interests of human subjects remain upheld in this changing environment.

I Informed consent in New Zealand

The legal obligation of informed consent arose from the horrors of medical experimentation during World War II. The Nuremberg Code was established in 1948 as a result of criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Amongst the charges were medical experiments on concentration camp prisoners without their consent that led to the permanent crippling and deaths of many. The Nuremberg Code declared

that “the voluntary consent of the human subject is absolutely essential” and was the first international document to advocate voluntary participation and informed consent.\(^{311}\)

The Declaration of Helsinki by the World Medical Association followed shortly after in 1964. The Declaration established recommendations for medical doctors in biomedical research involving human subjects and reiterated the importance of informed consent and ethical research on human subjects. Today, this document serves as a guiding statement in human research ethics that has influenced biomedical research policy around the world.

Informed consent is justified primarily on the basis of respect for autonomy and is an obligation on researchers who seek to include humans in research. At its minimum, it requires researchers to provide information about the research protocol, including all potential risks to participants, regardless of how remote they may be.\(^{312}\) Around the world, events such as the Alder Hey scandal\(^{313}\) and the Tuskegee Syphilis Experiment\(^{314}\) mar the history of medical research and serve as a reminder of the importance of informed consent and the dangers of researchers that overlook this standard. New Zealand does not lie exempt.

The principle of informed consent features prominently in The Code of Health and Disability Services Consumers’ Rights (the Code). The Code became law on 1 July 1996 and is legislation passed under the auspices of the Health and Disability Commissioner Act 1994 (the Act). The Code guarantees the rights of all health and disability consumers with respect to services provided by health care and disability services providers in New Zealand.

Under s 20(1)(a) of the Act, the Code is specifically required to contain provisions relating to the principle that “except where any enactment or provision of the Code otherwise provides, no health care procedure shall be carried out without informed consent.”

\(^{311}\) Nuremberg Code (1947) at [1].

\(^{312}\) Timothy Caulfield, Ross EG Upshur and Abdallah Daar “DNA databanks and consent: A suggested policy option involving an authorization model” (2003) 4 BMC Medical Ethics 1 at 2.


This is fulfilled in Rights 5, 6 and 7 of the Code that form the elements of informed consent required under the Act. However, before informed consent under the Code is discussed, it is important to understand the context and historical climate in which the Code came about and why informed consent sits so firmly entrenched in New Zealand health care today.


The Code was created following a commission of inquiry by Justice Silvia Cartwright on the “Unfortunate Experiment” and allegations of other unauthorized studies carried out at the National Women’s Hospital in the sixties. Revelation of unauthorized experiments by Doctor Herbert Green of the natural history of carcinoma in situ led to national outcry and “a revolution in doctor-patient relations in New Zealand”.

In 1966, a study of the natural history of carcinoma in situ was conducted at the National Women’s Hospital in Auckland. Despite world medical opinion that intraepithelial lesions were precursors of cervical cancer, Green was unconvinced and thus designed a trial with his female patients that involved deliberately not treating those with abnormal cervical smears. Not only did Green fail to obtain the consent of the women for the procedure, the Cartwright Report also found that the majority of his patients were unaware of their participation in the trial. This deliberate departure from standard treatment for cervical carcinoma in situ led to tragic consequences for some patients.

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315 Health and Disability Commissioner Act 1994, s 20(1)(a) [HDC Act].
316 The actions of Dr Green and his associates were first made public in an article in Metro Magazine. See: Sandra Coney and Phillida Bunkle “An Unfortunate Experiment at National Women’s” Metro (New Zealand, June 1987) 46.
317 The findings of the Cartwright Report not just exposed the extent of unauthorized actions committed by doctors on patients, it also revealed a much wider dysfunction in the attitudes of doctors to science and accountability. For a more comprehensive account, see: Charlotte Paul “The New Zealand Cervical Cancer Study: Could it happen again?” (1988) 297 Brit Med J 533.
321 The Inquiry found that only one of the 81 women interviewed during the investigation was fully aware of the fact that she was part of a research trial. See: SR Cartwright, above n 319, at 68.
322 Since then, proof has emerged that the risk of cancer for those in the core group was ten times higher than those treated with curative intent. Eight women from the core group eventually died of cancer. See:
and raised many issues about the conduct of the persons and bodies (from university authorities, hospital management to the practicing professionals) involved. The “grave omissions” of Green and other professionals responsible for overseeing the research were widely condemned.323

Prior to the Code, the principal safeguard for the patient was the integrity and good faith of the doctor.324 The inquiry highlighted the failure of the medical profession to effectively confront and resolve troubling issues that arose from the incidents and this led Cartwright J to a call for a shift from doctor to the patient.325 A key recommendation of the Cartwright Report was for a patients’ rights legislation “to codify principles and be a rule against which ethical and medical standards can be measured”.326

B The Code of Health and Disability Services Consumers’ Rights (the Code)

The effect of Green’s actions and the subsequent Cartwright Report led to “unparalleled changes in New Zealand’s medical law and ethics”.327 In an effort to rectify the mistakes made and to safeguard the interests of future patients, the law shifted in emphasis to the rights of the patient and recourse where a breach occurs. In October 1994, the Health and Disability Commissioner (HDC) Act was enacted. It created the Office of the Commissioner and also implemented the recommendations of Cartwright J in her 1988 Cervical Cancer Inquiry Report. On 1 July 1996, the Code of Health and Disability Services Consumers’ Rights was made by regulations328 and applies to all health and disability providers in New Zealand. The Code sets out ten rights of all health and disability consumers under the Code and affirms the duties of providers in delivering services.329


323 SR Cartwright, above n 319, at 83.
324 Charlotte Paul, above n 317, at 538.
325 SR Cartwright, above n 319, at 176.
326 Ibid, at 172.
328 HDC Act, s 74.
For the past decade and a half, all health and disability consumers in New Zealand have enjoyed a “highly progressive” health care and medico-legal system in which a set of guaranteed rights as consumers and a statutory complaints process exists. These ten rights are:

1. Right to be treated with Respect
2. Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation
3. Right to Dignity and Independence
4. Right to Services of an Appropriate Standard
5. Right to Effective Communication
6. Right to be Fully Informed
7. Right to Make an Informed Choice and Give Informed Consent
8. Right to Support
9. Rights in Respect of Teaching or Research
10. Right to Complain

The principle of informed consent is guaranteed under s 20(a) of the HDC Act that states that:

“Except where any enactment or any provision of the Code otherwise provides, no health care procedure shall be carried out without informed consent.”

Despite specific reference to only health care procedures, the Health Commissioner exercised its authority under s 20(2)(a) and extended the right to informed choice and informed consent under the Code to disability services consumers as well. No disability service can be provided without the informed consent of the consumer.

According to the Act, “informed consent” is defined as consent that is “freely given” and “obtained in accordance with such requirements as are prescribed by the Code”. Within the Code, Rights 5, 6 and 7 embody the elements of informed consent under the Code. The right to effective communication between parties, the provision of all necessary information to the consumer and the consumer’s right to freely give competent consent all contribute to a process that involves a minimum level of competence, disclosure,

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331 Code of Rights, cl 2.
332 Health and Disability Commissioner Act 1994, s 20(a) (emphasis added).
334 HDC Act, s 2.
understanding, voluntariness and consent. Provided an agency falls within the broad definition of “provider”, there is an obligation to uphold the rights of its “consumers” including ensuring that informed consent has been obtained before a service is provided.

The application of the Code to biobanking depends on whether BiobankNZ is considered a “provider” under the Code and whether participants are “consumers”. If so, the right to give informed consent generally applies with little exception.

II Does the Code apply to BiobankNZ?

There are two points at which the Code might apply to BiobankNZ: first, when a sample is first taken; and second, when research is carried out on health information. At the point of sample collection, it is anticipated that a suitably qualified person will make the collection and thus be considered a health provider and subject to the Code. Thus, the discussion of informed consent in this chapter is restricted to the period post-collection and prior to storage and future use of health information.

After sample collection, consent is needed for the indefinite storage of health information and for future unspecified research. For the sake of simplicity, this analysis will restrict itself to whether BiobankNZ comes within the ambit of health provider under the Code and therefore whether the Rights of the Code apply to participants of BiobankNZ. In this chapter, “health consumer” and biobank “participant” are used.

Section 3 of the Act provides a number of definitions of “health care provider” and includes “any other person who provides, or holds himself or herself or itself out as providing, health services to the public or to any section of the public, whether or not any charge is made for those services”.

335 Katharine Greig, above n 333.
336 Clause 3 of the Code states limited circumstances under which a provider may be found not in breach of the Code. See discussion later on page 78.
337 HDC Act, s 3(h).
338 While it is also relevant whether researchers who obtain health information from BiobankNZ are subject to the Code of Rights, for now it is probably safe to say that this analysis applies equally to BiobankNZ and researchers alike.
Section 2 of the Act defines “health services”.\(^{339}\)

(a) means—

(i) services to promote health:

(ii) services to protect health:

(iii) services to prevent disease or ill health:

(iv) treatment services:

(v) …

BiobankNZ is likely to fall within the definition of “health care provider” because its aims and goals of genetic research to improve overall population health can be considered a service to “promote health”, \(^{340}\) “protect health”\(^ {341}\) as well as “prevent disease or ill health”\(^ {342}\) in the long term. Furthermore, Right 9 extends the Rights in the Code to “those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research”.\(^ {343}\) Thus, provided that a participant can be considered a “consumer” in terms of the Act, it is likely that the Code of Rights extend to BiobankNZ participants.

Section 2 of the Act defines a “health consumer” as “any person on or in respect of whom any health care procedure is carried out”.\(^ {344}\) A “health care procedure” is defined as “any health treatment, health examination, health teaching, or health research administered to or carried out on or in respect of any person by any health care provider; and includes any provision of health services to any person by any health care provider”.\(^ {345}\)

It is likely that the research carried out on BiobankNZ health information will be considered “health research … carried out on or in respect of any person by any health care provider”.\(^ {346}\) BiobankNZ falls within the definition of “health provider” as set in the Act and has duties to its participants under the Code.

\(^{339}\) HDC Act, s 2.
\(^{340}\) Ibid, s 2(a)(i).
\(^{341}\) Ibid, s 2(a)(ii).
\(^{342}\) Ibid, s 2(a)(iii).
\(^{343}\) Code of Rights, Right 9.
\(^{344}\) HDC Act, s 2.
\(^{345}\) Ibid, s 2.
\(^{346}\) Ibid, s 2.
III Informed consent under the Code

BiobankNZ is subject to all the duties under the Code. With regard to satisfying the threshold of informed consent, BiobankNZ must ensure that it complies with Rights 5, 6 and 7.

A Right 5: Right to Effective Communication

Right 5 states that a consumer has “the right to effective communication” in a way that enables him to understand the information provided.347 This includes being in an environment where open, honest and effective communication can happen.348 In order to satisfy this duty, BiobankNZ should conduct its initial assessments with participants in a setting where maximum information can be provided to the participant in a way in which it can be fully understood.

B Right 6: Right to be Fully Informed

Right 6 states that every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive.349 This includes an explanation of his condition;350 an explanation of the options available, including an assessment of the expected risks, side effects, benefits and costs of each option;351 advice of the estimated time within which the services will be provided;352 notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval;353 any other information required by legal, professional, ethical and other relevant standards;354 and the results of tests and procedures.356

The rights of a health consumer under Right 6 are arguably more relevant in a clinical setting than the sort of long-term research setting anticipated by BiobankNZ. Research on health information can happen many years after sample collection and may involve

347 Code of Rights, Right 5(1).
348 Ibid, Right 5(2).
349 Ibid, Right 6(1).
350 Ibid, Right 6(1)(a).
351 Ibid, Right 6(1)(b).
352 Ibid, Right 6(1)(c).
353 Ibid, Right 6(1)(d).
354 Ibid, Right 6(1)(e).
355 Ibid, Right 6(1)(f).
356 Ibid, Right 6(1)(g).
purpose and direction that were not contemplated at the recruitment. Thus, the future-driven aims of biobanking make it impossible for BiobankNZ to stipulate to participants exactly how their health information will be used in research and the persons who will have access to the resource. As a repository for future health research, BiobankNZ needs to be fairly open (within reason) to different kinds of research studies that might arise. As such, the level of information provision demanded by Right 6 is impossible and impractical for BiobankNZ to meet.

Biobanks generally require participants who are willing to donate health information without fully knowing, at the point of recruitment, the exact uses and risks related to his donation. In biobanking, a “reasonable consumer” would expect to be informed of the indefinite future of his health information—that the expected “life” of his health information and any future research plans remain to be determined. It will be made explicit to BiobankNZ participants that donation of health information is altruistic and for the purposes of longitudinal population research. In addition, the participant will be informed of how health information will be collected and stored and the informational risks associated with storing health information in a biobank. The sort of information with which BiobankNZ can provide participants is markedly different to what is conceived as being “fully informed” under Right 6. However, all BiobankNZ participants will be provided the same level of information and this standard of information provision could be considered what a “reasonable consumer, in that consumer’s circumstances, would expect to receive”. In this case, every reasonable consumer expects to receive limited information as determined by the nature of biobanking.

Right 6(2) states that before a decision may be made, “every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, needs to make an informed choice or give informed consent”. As mentioned above, while the information that BiobankNZ provides might not include information on certain matters (for example, a detailed explanation of the risks involved or the results of testing), it is standard information that will be provided to all participants at the time of recruitment and thus what a “reasonable consumer, in that consumer’s circumstances, would expect to receive”. However, what is unclear is whether the information that BiobankNZ will

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357 Ibid, Right 6(1).
358 Ibid, Right 6(1).
359 Ibid, Right 6(2).
360 Ibid, Right 6(1) and (2).
provide will be sufficient to be what a consumer “needs to make an informed choice or give informed consent”.\(^\text{361}\) I return to this issue after my discussion of Right 7.

\section*{C Right 7: Right to Make an Informed Choice and Give Informed Consent}

Right 7(1) states that services may only be provided where a consumer has made an informed choice and gives informed consent. Exemptions include where any enactment, or the common law, or any other provision of this Code provides otherwise.\(^\text{362}\) Right 7(2)–(4) relate to the competency of a consumer and Right 7(5) relate to advance directives in health care. These are less relevant to BiobankNZ because the biobank is likely to restrict participation to persons who are fully competent at the time of recruitment and advance directives relate to health care procedures that do not apply in biobanking.

Right 7(6) states that informed consent to a procedure (where this is required) must be in writing if the consumer is to participate in any research.\(^\text{363}\) This obligation is satisfied by having participants sign an acknowledgement of the information with which BiobankNZ has provided them and an agreement to participate in BiobankNZ.

Right 7(7) states a consumer has a right to refuse services and to withdraw consent to services. This means that a person may withdraw participation from BiobankNZ and may also have a right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.\(^\text{364}\) Accordingly, BiobankNZ must comply with any requests to withdraw participation and also return or dispose of any blood samples obtained from the participant, according to his wishes. However, no distinction is made between bodily substances and health information acquired at recruitment and during the course of research. Thus, BiobankNZ may still be able to use the health information of a participant who has withdrawn, provided all links between the health information and the identifiable person have been permanently destroyed.\(^\text{365}\)

\(^{361}\) Ibid, Right 6(2).

\(^{362}\) Ibid, Right 7(1).

\(^{363}\) Ibid, Right 7(6)(a).

\(^{364}\) Ibid, Right 7(10).

\(^{365}\) Some authors have argued that anonymization should not be an automatically permissible response to requests of withdrawal nor should requests for withdrawals necessarily stop research on identifiable samples. But in my opinion this conflicts with our idea of voluntary consent. See for example: Stefan
Right 7(8) relates to a consumer’s right to express preferences over service providers and have those preferences met where possible. This is unrelated to biobanking.

Right 7(9) states that a consumer has a right to make a decision about the return or disposal of any body part or bodily substance removed or obtained during a health care procedure.366 This right is particularly complicated in biobanking as the right to make a decision about the disposal of samples stored in BiobankNZ has implications for the long-term retention of samples in a biobank (and thus the long-term success of the biobank) and the complexities that arise with regard to participant withdrawal.367

Finally, Right 7(10) states that no body part or bodily substance removed in the course of a health care procedure may be stored, reserved or used otherwise. This rule may be disregarded under certain circumstances such as where informed consent from the consumer has been obtained368 or where an ethics committee has approved the research.369 This is consistent with the intention of BiobankNZ to permit research within the scope of participants’ consent and to release health information to researchers for ethically approved studies.

**D Will BiobankNZ fulfill the requirements of informed consent under the Code?**

The requirement of informed consent under the Code is very consumer rights-based. The Code requires health providers to consciously ensure that all three rights that embody informed consent are satisfied before a health provider is deemed to have satisfied the threshold and fulfilled its duties to consumers. At issue here is whether a biobank participant is considered “fully informed”, as per Right 6, to fulfill the requirements of informed consent. Specifically, if BiobankNZ discloses what is considered to be information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, but still fails to satisfy the other limbs that contribute to a “fully informed” consumer, is BiobankNZ deemed to have provided insufficient information for the consumer to give informed consent?370

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366 Code of Rights, Right 7(9).
367 The complexities associated with participant withdrawal are discussed at various points in this thesis.
368 Ibid, Right 7(10)(a).
369 Ibid, Right 7(10)(b).
370 Ibid, Right 6(2).
On a strict interpretation, it is unlikely that BiobankNZ will ever be able to obtain informed consent from participants at recruitment. This is because BiobankNZ cannot foresee and preempt the kind of research and the actual investigators that will carry out research on participants’ health information. On the other hand, it can be argued that a broad interpretation can also be taken and that participants are “fully” informed when they have been given maximum information to the extent that is possible and accepted in the biobanking industry and exercise full autonomy when making their choice to participate.\(^\text{371}\) If the information provided is information “that a reasonable consumer, in that consumer’s circumstances, would expect to receive”, then perhaps as long as a participant is aware of the limitations of information provision and is able to comprehend the risks involved, it is fair to say that he has exercised his free right to choose and his choice is acceptable. However, this argument is illusory and ignores the fact that “the details that are a customary component of the traditional consent process cannot be disclosed”.\(^\text{372}\) Being fully informed includes the expectation that a person has to hear full details of a study or a procedure for without having heard it, the person cannot be said to fully understand what is involved.\(^\text{373}\)

The information that a biobank can provide to a participant at recruitment lacks because nothing definitive relating to specific research can be given to participants. It has been argued that even if the risks associated in biobanking may be less than in a traditional experimental study, “the more general the consent is, the less informed it becomes. It is misleading to use the notion of informed consent for participation in research that is unforeseen and has not been specified in a research protocol”.\(^\text{374}\) Thus the notion that biobank participants can give informed consent should be rejected and a modified process should be considered.

\(\textbf{E \ Exception to the rule: Provider compliance}\)

Clause 3 of the Code is the provider compliance provision and the “escape clause” of the Code. The provider compliance provision states a provider is not in breach of the Code

\(^{371}\) See for example: Mark Sheehan “Can Broad Consent be Informed Consent” (2011) 4(3) Public Health Ethics 226.

\(^{372}\) Timothy Caulfield, above n 310, at 213.

\(^{373}\) In Director of Proceedings v Harman, the Health Practitioners Disciplinary Tribunal held that the even though the patient did not want to hear “the gory details” of the procedures, Dr Harman should have pressed on the issue as the patient could not otherwise fully understand what was involved and given her informed consent. 107/Med06/37D, 31 May 2007 at [136].

provided that the provider took all “reasonable actions in the circumstances to give effect to the rights, and comply with the duties”. The onus is on the provider to prove that it took reasonable actions and “the circumstances” include the consumer’s clinical circumstances and the provider’s resource constraints.

Under this provision, BiobankNZ can seek an exception on the grounds that it is near impossible to obtain informed consent without large expense and jeopardizing the social utility and scientific value of the biobank. The way BiobankNZ is designed and its purpose makes it impossible for the biobank to give details on future research that may be carried out on a participant’s health information. However, in briefing each participant, BiobankNZ would have explained this impossibility but also explained potential uses and potential harms and risks that may arise. However, such information would necessarily be very broad in scope and not precise enough to fulfill the criteria of informed consent in the Code.

As a significantly large and national initiative that will require the participation of many, it is arguably unwise for BiobankNZ to permanently rely on the provider compliance of the Code to obtain an exception to such a “central tenet of biomedical research”. Informed consent is a widely accepted standard for any form of research involving human participants, and considering the historical context in which the Code of Rights was created, any moves away from the accepted standard of the Code should be carefully considered.

F What if BiobankNZ sought informed consent before every study?

In order to satisfy its obligations under the Code, BiobankNZ could obtain informed consent from each participant before health information is used in research. By that stage, there will be enough information about the research planned to be able to fully inform potential research participants and obtain their informed consent. However, one quickly realizes that doing so defeats the purpose of BiobankNZ as a platform for an indefinite number of future research projects.

375 Code of Rights, cl 3(1).
376 Code of Rights, cl 3(2).
377 Code of Rights, cl 3(3).
378 Timothy Caulfield, above n 310, at 210.
A significant problem is the issue of re-contacting participants to obtain informed consent before every study. Biobanks are large scale and longitudinal in nature and thus contain the health information of a huge number of participants that may range from recent to decades old. A large amount of financial and human resource needs to be committed to tracing and re-contacting participants before each study and some participants may have since relocated or died making the task even more difficult. For the living, an indefinite number of repeated contact for the purposes of obtaining informed consent may create consent fatigue amongst participants. Participant attrition becomes a risk when participants feel inconvenienced by persistent re-contact.

Additionally, a biobank exists as a research repository for use by other researchers. As a ready resource for researchers, it is anticipated that a large volume of research will be carried out on BiobankNZ health information. Every time a new study is proposed, which party should be seeking the informed consent? BiobankNZ, who represent the participants, or individual researchers who conduct the research but may not have the resources to make contact with each person? This adds a layer of complication as BiobankNZ functions as the contact point between researchers and participants and the health information released to researchers may not contain identifiers.

Thus, imposing the criteria of informed consent in biobanking is problematic. The Human Genetics Commission’s report concluded similarly, stating that “the difficulties involved in tracing and securing re-consent for different forms of medical research may make obtaining fresh consent impractical and would seriously limit the usefulness of large scale population databases”. The cumbersome expectations of informed consent defeat the purpose of having a ready resource that cuts current costs for researchers and promotes increased research.

**IV Guidelines for Use of Human Tissue for Future Unspecified Research Purposes**

380 In the Registry of the Canadian Stroke Network, researchers reported facing numerous obstacles obtaining informed consent and also estimated spending approximately $500,000 (Canadian dollars) on consent-related issues during the first two years. See: Jack V. Tu and others “ImpRACTICABILITY OF INFORMED CONSENT IN THE REGISTRY OF THE CANADIAN STROKE NETWORK” (2004) 350 N Engl J Med 1414.

The Guidelines for Use of Human Tissue for Future Unspecified Research Purposes is intended as guidance for ethics committees when considering applications for future unspecified human tissue research. They were discussed in the earlier chapter for their application to biobank donor privacy and will now be discussed for their application to consent in biobank.

The Guidelines were published to make clear that New Zealand researchers are permitted to obtain consent to use human tissue for future unspecified purposes subject to donors being provided with specific information and sufficient options before gaining consent. Guideline 1 states that “consent may be given for the use of tissue in future unspecified research. The requirements for informed consent are set out in the Operational Standard for Ethics Committees and within these guidelines”.

A Operational Standard for Ethics Committees

The Guidelines sit subordinate to the Operational Standard for Ethics Committees (the Operational Standard) and serve as a guide for Health and Disability Ethics Committees when they consider applications for research. The Operational Standard derives its public authority from the terms of reference of ethics committees established by the Minister of Health under s 11 of the New Zealand Public Health and Disability Act 2000 that states:

11 Ministerial committees
(1) The Minister may by written notice—
   (a) establish any committee that the Minister considers necessary or desirable for any purpose relating to this Act or its administration or to any services; and
   (b) appoint any person to be a member or chairperson of the committee; and
   (c) terminate the committee or the appointment of a member or chairperson of the committee.
(2) Every committee established under this section (other than the committees referred to in sections 13 to 16) has the functions that the Minister determines by written notice to the committee.
(3) Every committee established under this section—
   (a) consists of such members as the Minister determines; and
   (b) may, subject to any written directions that the Minister gives to

the committee, regulate its procedure in any manner that the committee thinks fit.

(4) Each member of a committee established under this section is appointed on any terms and conditions (including terms and conditions as to remuneration and travelling allowances and expenses) that the Minister determines by written notice to the member.

(5) Nothing in this section or in sections 13 to 16 limits any powers that the Minister has under any other enactment or rules of law.

However, the Operational Standard’s precise legal status remains ambiguous and it has no generally binding force outside the health sector.383

A number of arrangements and contracts between different agencies that have a role in health research ensure that a high standard of compliance with ethical standards and accountability exists. The key players in this interconnected relationship are the National Advisory Committee on Health and Disability Support Services Ethics (NEAC), the Health Research Council Ethics Committee (HRCEC) and the Health and Disability Ethics Committees (HDEC). An elaborate relationship exists overall between the determiner of the national ethics standard (the NEAC), the ethics committee of the principal national health research funding agency (the HRCEC), and regional health and disability ethics committees (HDEC) to ensure that the terms of the Operational Standard are complied with before government funding for research is granted. While not all ethics committees are required to comply with the Operational Standard,384 it is a good idea as it has a “legitimating” function—the Operational Standard is based on widely accepted ethical principles, research approved by ethics committees that endorse the Operational Standard are more likely to be eligible for funding and there is the potential that a court might adopt the standard of the Operational Standard as what constitutes “reasonable” conduct on the part of a researcher or ethics committee in legal proceedings.385 Thus, all three bodies play a number of roles (some overlapping) to ensure that proposed research meets a minimum ethical standard before it can take place.

384 There is no law requiring that all ethics committees adhere to the Operational Standard and some institutional research ethics committees that are not seeking accreditation from the HRCEC may choose to adhere to another ethical standard such as the Helsinki Declaration.
385 John Dawson, Mary Foley and Nicola Peart, above n 383, at 54.
Under the Operational Standard, informed consent requires three components:\textsuperscript{386}

i. that adequate information is provided to enable an informed judgement to be made

ii. that information provided is in a form and manner that will enable it to be understood by each individual

iii. that the consent is voluntary in nature (participation free from manipulation, coercion, inducement or any other undue influence).

With respect to the information that should be provided, it must include:\textsuperscript{387}

i. the purpose, intended outcomes or benefits (to the individual and/or the community) of the treatment or research

ii. an explanation of the procedures to be followed, including the identification of those procedures that are experimental

iii. what will be required of the consumer or participant (where relevant), the total time span of the research or treatment, the nature and extent of the participant’s involvement, and the number, type and volume of specimens sought

iv. all foreseeable risks, side-effects or potential harm that are material to the research participant, and how significant risks will be monitored and managed

v. arrangements relating to compensation for personal injury

vi. a statement to the effect that potential participants who decline to participate will nonetheless be given the best standard treatment

vii. the right to withdraw from the research or innovative practice at any time, and to withdraw data from any participation until a specified time, without affecting treatment or future health care

viii. (where relevant) advice that a new procedure or drug may not be available to the participant on cessation of the study

ix. an individual’s rights as set out under the Code of Health and Disability Services Consumers Rights 1996, and the availability of consumer advocates and of relevant complaint procedures from sources independent of the researcher

x. the right of access to health information about that individual as set out in the Health Information Privacy Code 1994

xi. that any queries or concerns regarding an individual’s rights as a research participant may be raised directly with a health and disability advocate or with the ethics committee that approved the proposal

\textsuperscript{386} Ministry of Health \textit{Operational Standard for Ethics Committees: Updated edition} (Wellington, 2006) at [29] [Operational Standard].

\textsuperscript{387} Ibid, at [30].
xii. how long the data and/or tissue will be kept, how the data and/or tissue will be stored, who will be responsible for the secure storage of the data and/or tissue, and how the data and/or tissue will be destroyed

xiii. the research participant’s access to research findings

xiv. the responsibilities of the researchers

xv. names and contact details of people leading the research and available to answer any questions, or to be notified should the participant wish to withdraw consent.

The requirements of informed consent under the Operational Standard is a lot more detailed and skewed towards research than it is under the Code, which takes a more broad-brush approach. Under the Operational Standard, a specific checklist of information must be provided before informed consent can be obtained. Thus, in this area, the Operational Standard functions in conjunction with the Code to provide specific guidance for informed consent in research. This is in line with Right 6(1)(e) which requires that information required by the relevant ethical standard also be observed.

The Operational Standard also states that in “uncommon” and “limited circumstances”, ethics committees may waive the need for informed consent “where it is not practicable to get consent, or where the ethics committee is satisfied that the potential public benefit in allowing the research to proceed outweighs the very strong need to protect an individual’s right to consent”. Obtaining consent for future unspecified research in biobanking falls within this limited circumstance and the Guidelines were created as a guide in this modified process of consent. Where a researcher is seeking approval for future unspecified research, both the Operational Standard and the Guidelines should be observed.

The consent obtained for future unspecified research is distinct from consent to collect the sample and consent to use the sample in specified research. The Guidelines only apply to the use of human tissue and any information that is derived from human tissue. It thus only applies to an aspect of “health information” as we understand it as it excludes any other personal, medical or lifestyle information obtained during an interview and in conjunction with a sample collection.

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388 Ibid, at [36].
389 Guidelines, above n 382, at [2].
B The Guidelines For the Use of Human Tissue for Future Unspecified Research Purposes

The Guidelines lay out specific information that must be included before consent may be sought.391

5. An indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought.

6. Known possible researchers or institutions that might use the tissue sample, if possible.

7. Whether the donor’s sample is going to be, or is likely to be sent overseas, where possible, to what country or countries.

8. Acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation.

9. Whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked.

10. A statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw in the future.

11. Whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician.

12. Acknowledgement that the donor will not own any intellectual property that may arise from any future research.

13. Whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any

information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or destroyed.

14. Acknowledgment that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care.

15. Where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance.

16. Whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries.

17. Whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known.

18. What provisions will be made to ensure patient confidentiality.

19. That different cultural views may inform choice about donation of tissue; for example, for some Māori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi.

20. That cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors.

21. That donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi.

Thus, the Guidelines require researchers to provide potential donors with a comprehensive list of possible end outcomes for samples and the implications these outcomes may have to a donor and other interested parties.
In drawing up the Guidelines, it was anticipated that a lot of “unknowns” would exist since the research is future-oriented and unspecified. Hence, with regard to the type and nature of research, who might have access to health information, and whether and where health information might be sent overseas, the Guidelines grant flexibility to researchers and acknowledge that information need only be provided where possible. However, this obligation on researchers to give potential donors an indication of the type and nature of research to be carried out, where possible, discourages totally unrestricted future research. While the Guidelines do not explicitly ban blanket consent that permits unrestricted research, it does nudge researchers to narrow the scope of consent and consider the type and nature of research for which they are seeking consent.

According to Guideline 8, researchers are required to acknowledge that all future unspecified research in New Zealand will be subject to ethical review. However, what is notable is that when a sample is sent overseas for research, unless it is carried out in conjunction with a New Zealand research project, an overseas committee without New Zealand representation may carry out the ethical review. This practice does not guarantee the standard held by the overseas ethics committee and —more pressingly— the standard held to protect the values surrounding human tissue storage and research valued by some groups in New Zealand. This is particularly relevant for research involving Māori participants who may have special cultural requirements for how their tissue samples are used.

The Guidelines do not impose a requirement on researchers to keep donors updated on the uses of their samples. Guideline 11 states that researchers need only inform the donor whether they may be contacted in the future regarding their sample and whether or not, and under what circumstances, information about the future unspecified research will be made available to donors and/or their clinicians. Thus, there is no obligation to maintain an ongoing relationship with donors and, provided there is ethical approval, any form of research may be conducted without the knowledge of the donor.

Guideline 12 requires that donors acknowledge no ownership over intellectual property that may arise from any research. The issue of property rights in human tissue is highly

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392 Ibid, at [5].
393 Ibid, at [6].
394 Ibid, at [7].
395 This issue and other Māori-related issues are discussed in Chapter 5.
contentious and is outside the scope of this thesis. However, Guideline 12 does ensure that potential donors are aware that they have no claim over intellectual property that may arise and reduces the likelihood of litigation that may otherwise arise.

Guideline 13 requires researchers to inform potential donors of any possibility of withdrawing consent in the future and the practicalities that may prevent complete withdrawal of samples that are distributed prior to a request. The different levels of withdrawal are closely linked to identifiability of samples because the ability of samples to be located and destroyed depends on whether they have been retained with identifiers. This is closely linked to Guideline 9 that requires researchers to explain whether samples will retain identifiability and, presumably, their implications for privacy.

Guideline 14 requires researchers to ensure that a donor’s decision to consent to use of his tissue sample will not affect the quality of a donor’s current or future clinical care. While this is less of an issue with BiobankNZ since it is likely to operate completely separate from clinical providers, it is prudent to ensure that potential donors do not feel coerced into participating in fear of compromising their future clinical care. In addition, this is a good avenue to ensure that potential biobank participants are fully aware of the limitations of biobank research and that direct clinical benefit is unlikely for biobank participants.

Guideline 17 requires researchers to disclose any plans or intentions to use samples to engage in any commercial research. Commercial research on human tissue samples may be unacceptable to some donors who disagree with people obtaining financial benefit from human tissue. Thus, any intentions to collaborate commercially with other parties should be disclosed to potential donors. This is especially important in BiobankNZ as it is likely that health information will be made available to all researchers with legitimate research aims in order to maximize research.

Finally, the Guidelines acknowledge diverse cultural norms and values towards human tissue collection, storage, research and disposal. Researchers are required to inform potential donors of where and how long tissue samples will be stored and whether there is a cultural protocol for its disposal. In addition, researchers need to acknowledge to potential donors the different cultural views that may inform choice about donation of


\[398\] Guidelines, above n 382, at [15].
that cultural concerns may arise when tissue samples are sent overseas and that processes for monitoring and tracking may not be acceptable to some donors;\textsuperscript{399} and that donors may want to discuss the potential donation with those close to them.\textsuperscript{400} This recognition of different values between cultures balances the importance of personal autonomy valued in Western societies with the acknowledgement that in some cultures, the collective views of interested parties play a significant role in decision-making.

\textbf{C The Guidelines: really just suggestions?}

The Guidelines take a very flexible approach towards future unspecified research. There is recognition of the difficulties of “unknowns” in future research and thus the Guidelines allow flexibility in terms of information that must be provided to potential donors. Compared to the Code and the Operational Standard, the Guidelines offer the most relevant and comprehensive standard applicable to biobanking. However, it does have a major shortfall: it has no “teeth” in law and is essentially a document of flexible suggestions.

The Guidelines create a standard that is very adaptable towards the unknowns of future research. Provided a researcher discloses what he does know to potential donors, it is not hard meet the standard of the Guidelines. However, complying with the Guidelines does not guarantee ethics approval and approval of the study still depends on a balance of the merits of the potential research with the potential risks to tissue donors. There are a number of aspects of the Guidelines that create too much flexibility to the disadvantage of participants.

First, as discussed above, Guideline 8 does not require New Zealand representation in ethics approval where samples are destined for overseas research. However, the structure of a biobank is such that all potential research applications, regardless of where they are received from, can undergo ethics approval with New Zealand representation before samples are released to researchers. In this way, all research can be assessed to ensure that not only is it ethically acceptable but that there are protocols in place that protect the interests of BiobankNZ participants. Second, the Guidelines do not require researchers to maintain contact with donors. The only requirement is that researchers are clear to potential donors whether there will be contact in the future regarding their sample and under what circumstances information regarding future research will be made.

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{399} Ibid, at [19].
  \item \textsuperscript{400} Ibid, at [20].
  \item \textsuperscript{401} Ibid, at [20].
\end{itemize}
\end{footnotesize}
available. The success of a biobank depends greatly on cooperation and support of the public. Thus, it is in the interests of both the biobank and participants for there to be open channels of communication in order for the biobank to remain updated on participant details and for participants to be informed on the pursuits of the biobank.

The standards of the Guidelines and the Operational Standard are not legally enforceable on BiobankNZ in the same way that the Code is. Compared to the Code, the Guidelines are informal and merely function as a non-binding guide for ethics committees when evaluating the ethics of proposed research. Failure to meet the standards set by the Guidelines or Operational Standard will result in failure to obtain ethics approval and potential funding. However, unless a failure has also caused a breach in the Code, there are no mechanisms in the law to enforce the standard.

Most outstanding is the fact that the Guidelines only apply to human tissue samples and any information that is derived from human tissue. This distinction creates a gap as personal, medical and lifestyle information that is collected and stored in conjunction with the human tissue remains unprotected under these Guidelines. While an ethics committee might require human tissue and other information collected and stored in association with a biobank’s activities to come under the same standard, this is left to the discretion of the committee and not a guaranteed standard.

The combination of the Code, the Operational Standard and the Guidelines provides a framework that is surprisingly forward looking and supports biobanking and the use of human tissue for future unspecified research. However, a closer look reveals a framework that may be more permissive than is ideal, lacks the legal robustness of legislation, and is not watertight. Currently, there are separate and somewhat inconsistent regimes that apply separately to human tissue and its associated information. This patchwork of law and guidelines gives a helpful indication of the modifications to informed consent that ethics committees are willing to accept for future unspecified research. However, with modifications should come greater safeguards for participants and this is something that still lacks in the current law.

V Broad consent and the UK Biobank

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403 Ibid, at 4.
The UK Biobank is the first known population-based DNA biobank to be successful from conception to full operation. It has ethics approval from the North West Multi-centre Research Ethics Committee (which oversees research in the United Kingdom) as well as the Community Health Index Advisory Group (which oversees research in Scotland). It is known widely for its bold move to broad consent—a move that continues to be debated and questioned today. This section examines the consent model adopted by the UK Biobank and its justifications for deviating from traditional consent norms.

The UK Biobank Ethics and Governance Framework (the Framework) sets the overall standard for the UK Biobank project with safeguards in place to ensure that health information is only used for scientifically and ethically approved research. The Ethics and Governance Council (the Council) is an independent committee established by the Medical Research Council and the Wellcome Trust to ensure the biobank’s adherence to the Framework. It currently comprises of 13 members from a range of disciplines including law, ethics, medicine and social science. The Council acts as an independent guardian of the Framework and its role is to advise, monitor and report publicly on the activities of the UK Biobank. As an oversight body to monitor the biobank’s compliance to the Framework, the Council’s main power of enforcement is in its ability to make public statements of concern about the project. However, neither the Framework nor the Council possesses any formal status in the law. As a result, the long-term efficacy of the Council as a solution to the legal and regulatory challenges arising from biobanking as well as its capacity to enforce guidelines remains a debated issue. In addition, the investment by the major funders of the UK Biobank in the Council has been seen to demonstrate the latitude that the absence of proper regulation affords to larger well-resourced players to set their own rules as well as to potentially shape future norms in the field more generally.

404 Other countries such as Estonia, Singapore and Iceland have, for a variety of reasons, halted plans to establish a biobank.
405 “Ethics” UK Biobank <www.ukbiobank.ac.uk>.
406 Ibid.
407 “Frequently asked questions” UK Biobank Ethics and Governance Council <egcukbiobank.org.uk>.
409 Jean V. McHale “Accountability, Governance and Biobanks: The Ethics and Governance Committee as Guardian or as Toothless Tiger?” (2011) 19 Health Care Anal 231.
410 Susan MC Gibbons and others, above n 408, at 173.
A Broad consent

According to the UK Biobank Ethics and Governance Framework (the Framework), consent is sought for research in general that is consistent with the biobank’s stated purpose “because it will be impossible to anticipate all future research uses”.\footnote{UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 5 [UK Biobank EGF].} The consent sought from UK Biobank participants is broad consent because although it lacks the specificity of informed consent, it is still limited to a fixed range of research options.\footnote{B Hofmann “Broadening consent—and diluting ethics?” (2009) 35 J Med Ethics 125 at 126.} This is distinct from “blanket consent” that is a one-time general consent for all forms of future medical research.\footnote{Timothy Caulfield, Russell Brown and Eric M. Meslin “Challenging a Well Established Consent Norm?: One Time Consent for Biobank Research” (2007) 4 JIBL 69 at 69.}

The Framework sets the standard for the UK Biobank project and is the result of a public consultation process and the input of experts in research ethics, philosophy, law, science and social science, and consumer representation.\footnote{“Ethics” UK Biobank <www.ukbiobank.ac.uk>.} Under the Framework, consent is based on “an explanation and understanding” of, amongst other things:\footnote{UK Biobank EGF, above n 411, at 5.}

- The purpose of UK Biobank, the fact that it is a long-term research resource, and any risks and benefits of taking part
- The kinds of information and samples that will be collected at enrolment, which may include data that some participants consider especially sensitive
- The fact that there will be a link to the full record of medical and other health-relevant information and the need for participants to allow such linkage for as long as possible to maximize the value of UK Biobank as a research resource
- The fact that UK Biobank will be the legal owner of the database and the sample collection, and that participants will have no property rights in the sample
- The kinds of safeguards that will be maintained to protect the security of data
- The assurance that only research uses that have been approved by both UK Biobank and a relevant ethics committee will be allowed, and that data and samples will be anonymized before being provided to researchers
- The expectation that commercial entities will apply to use UK Biobank
• The possibility of being re-contacted in future by UK Biobank and the purpose of such contacts
• The intention to continue to hold and allow research access to data and samples after participants lose mental capacity or die
• The right to withdraw at any time without having to give a reason and without penalty, and the meaning of different levels of withdrawal
• UK Biobank’s commitment to maintaining active engagement with participants and society in general.

Furthermore, it is intended that the consent obtained at recruitment will apply throughout the lifetime of UK Biobank unless the participant withdraws. Additional consent will also be sought where proposed research falls outside the scope of existing consent. However, seeing as “consent will be sought for research in general that is consistent with UK Biobank’s stated purpose” and that the UK Biobank’s very broad purpose is to “support a diverse range of research intended to improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society”, it is unlikely that any bona fide proposed health research will fall outside the scope of existing consent.

As expected, the information provided to participants lacks the specificity of informed consent. Apart from explaining the aim of the resource and its long-term aims in health research, the biobank does not give participants details of each study. However, where the UK Biobank lacks in specificity of information regarding studies, it arguably provides in transparency of biobank processes. When seeking consent for participation, the biobank provides a careful explanation of different aspects of the biobank relevant to data collection and storage, including: information that will be collected, security of information, ownership rights, limitations of withdrawal, governance of the biobank, and hurdles that research users must pass before they may obtain access to anonymized information.

B How the Framework and the Guidelines compare

Under the Framework, the UK Biobank offers the assurance that only research uses approved by both UK Biobank and a relevant ethics committee will be allowed and that only anonymized data and samples will be provided to researchers. The UK Biobank acts as a gatekeeper for researchers seeking access to the resource by ensuring that

416 Ibid, at 5.
417 Ibid, at 5.
418 Ibid, at 3.
419 Ibid, at 5.
researchers comply with the conditions of access and that the interests of participants are protected throughout research. Furthermore, guaranteeing that only anonymized health information will be provided to researchers safeguards participant privacy and minimizes the chances of unauthorized breaches of confidentiality. In contrast, the Guidelines offer little of such assurance. First, although Guideline 8 requires that researchers acknowledge to potential donors that although all future research is subject to ethical review, there is no guarantee of a gatekeeper role between the samples and international researchers. Guideline 8 states that unless samples are sent in conjunction with a New Zealand project, there is no guarantee of New Zealand representation during ethical review. This is significant because traditionally, Māori place value on the sanctity of human tissue and its close link to the rest of the tangible and intangible world. Unless it can be guaranteed that this sanctity will be appreciated and respected, donations are potentially unlikely to be forthcoming from a significant portion of New Zealand’s population. Additionally, the Guidelines do not require that samples be anonymized before being passed on to researchers. Guideline 9 only requires that researchers inform potential donors of whether their identity and details will remain linked with the sample or be de-linked. There are no other safeguards in place to ensure the confidentiality of donor information.

According to the Framework, participants have no property rights in the samples and the UK Biobank has ownership over the database and the sample collection. However, this assertion of ownership is less clear in law. As noted by McHale, there is no specific statutory regulation of the use of samples from live donors in the United Kingdom and the position of property rights in excised samples is equally uncertain in common law. This assertion of ownership by UK Biobank is likely with the intention of reducing any property rights claims over future intellectual property rights that may arise from research on UK Biobank samples. This is in similar vein with the Guidelines that require researchers to acknowledge that the donor will not own any intellectual property that may arise from any future research.

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420 This is discussed in more detail in Chapter Four.
421 However, it is also important to realize that contemporary Māori views towards human tissue may be more open to the use of human tissue and organs in biomedical research and healthcare. This aspect is explored in more detail in Chapter Four.
422 UK Biobank EGF, at 5.
424 Guidelines, above n 382, at [12].
The UK Biobank requires participants to be furnished with a fairly thorough account of what participation entails. This allows potential participants to gain a full understanding of the nature of biobanking, particularly why the UK Biobank is limited in its ability to be more specific about future research studies, safeguards that are in place to protect the security interests of participants, and that participants give up control over their tissue samples. The details provided to each participant relate to the governance of the UK Biobank; participants cannot make decisions on each study but can make a decision based on the principles of the UK Biobank and how the biobank may make decisions on future research. It can be said that the inability of the biobank to give specific details on future research projects has forced the biobank to be more thorough in other areas of the biobank to ensure as full an understanding of the undertaking as possible.

Property rights in tissue samples are closely linked with commercial research on human tissue. UK Biobank creates the expectation in participants that commercial entities will apply to use the biobank resource. Provided researchers comply with the approval criteria of the UK Biobank, the resource will be available to all bona fide health researchers without preferential or exclusive access for any person. Similarly, the Guidelines require researchers to disclose any intentions to provide collected samples to commercial biomedical companies or if there are plans for any commercial research collaborations.

The most significant difference between the Framework and the Guidelines is probably the focus in the Guidelines on the different cultural views and concerns that may inform choices on donation. As mentioned above, the Guidelines recognize the significant roles of culture and family values that play a part in decision-making and also how a potential donor’s cultural beliefs and values may influence his opinion of tissue collection, storage, use and disposal. In contrast, the Framework makes no mention of any interests outside that of the individual participant. Furthermore, while the UK Biobank indicates that it will respect an enrolled participant’s decision to modify consent in the event of mental incapacity or death, the Framework is silent on what should happen if the family of an individual object to an individual’s participation. It appears that the only time a family member may have an input is when the member is acting on behalf of an individual who has lost mental capacity or died. However, this role is limited to notifying the UK Biobank of a change and a request to action the previous request to modify consent to

425 UK Biobank EGF, at 5.
426 “Principles of Access” UK Biobank <www.ukbiobank.ac.uk>.
427 Guidelines, at [17].
participation.\textsuperscript{428} This limitation on withdrawal is significant and may well prove to work quite differently in practice. The UK Biobank’s relatively recent participant recruitment means that requests by family members to withdraw a deceased participant are unlikely to have occurred yet.

In \textit{Gudmundsdottir, R. vs. The State of Iceland}, a daughter successfully won a bid not to have her deceased father’s health information transferred to the Icelandic Health Sector Database. As mentioned in Chapter Two, the case was argued on the basis of family privacy and the inadequacy of provisions in the law to protect her right to privacy. In the UK, there is potential for a similar claim to be made based on a person’s right to privacy, the hereditary nature of certain aspects of medical information and its implications for relatives of a participant. The UK Biobank asserts that “participants will not be withdrawn if they lose mental capacity or die”; instead, the UK Biobank “will continue to safeguard the confidentiality and security of all participants’ data and samples as long as it holds them, including after a person’s mental incapacity or death”.\textsuperscript{429} However, this may prove different in practice and a potential request for withdrawal by the family of a deceased may not be met with a firm stance against it but rather a compromise on the different levels of withdrawals and perhaps an offer to render the data of a deceased completely and permanently unidentifiable.\textsuperscript{430}

From an overall perspective, besides the lack of focus outside the individual interests of a participant in the UK Biobank, the Guidelines and the Framework cover very similar areas of information provision. However, given that the Framework was specifically created for the purposes of the UK Biobank, there are aspects of the information provision that are more suited to the nature of biobanking and arguably protect the interests of participants better. In addition, the two documents also have different legal statuses in the law of their respective countries and thus carry different implications for non-complying parties.

Despite the initial success of the UK Biobank, many scholars and commentators disagree with the ability to obtain consent from participants in the absence of specific details of the

\textsuperscript{428} UK Biobank EGF, at 10.
\textsuperscript{429} Ibid, at 10.
\textsuperscript{430} The full legal and practical implications of UK Biobank policies are outside the scope of this thesis. For now, it is interesting to note that the withdrawal policy of deceased UK biobank participants may not be as straightforward as proposed and there is room for family members to challenge policy.
research project. Many feel that the justifications for this deviation are insufficient and do not respect the principle of personal autonomy.

C Justifications for modifying informed consent

The three main justifications used for modifying informed consent are: the inconvenience and prohibitive cost of re-contacting participants before each study; the potential health benefits for the public; and the “minimal” risk to each participant.

The need to make contact with each participant in order to obtain consent before a study is normal ethical practice. However, it becomes exceptionally tricky when each study involves hundreds to thousands of participants and the information of each participant is used many times over in different studies. A key reason for creating a biobank was to establish a central repository that consolidates the comprehensive health information of a large number of people in one facility. This strategy in genetic research was adopted to facilitate easy access to health information for a number of different types of research while simultaneously avoiding the huge costs typically incurred in a normal study. The requirement of re-contact for informed consent in biobanking is logistically and financially onerous and can quickly exhaust both the goodwill of participants and the limited funding of researchers.

Biobank research has the potential to benefit both national and international communities and it is argued that the strict application of consent rules hinders potentially socially beneficial research. Large-scale biobank research is still in its infancy and its full benefits are yet to be fully seen. However, smaller-scale cohort studies—which in some ways are the small-scale equivalent of population biobanks—have produced knowledge that has dramatically changed our understanding of some diseases. The benefits of biobank research have less of a direct effect on individual participants and are probably more beneficial to future generations. The UK Biobank highlights this fact to participants by stating that participating in the biobank is “improving the health of future generations”. As a fairly new addition to genetic research, the full benefits of establishing and operating a biobank have yet to be fully seen. However, it is likely that the groups that have contributed to a biobank will benefit more from it compared to a non-participant since knowledge generated from research stems from health, lifestyle and

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432 For example, see: “The Nurses’ Health Study Findings: Some Highlights” The Nurses’ Health Study <www.channing.harvard.edu>.
location factors unique to participants. The potential public good that may arise from biobank research is often used as a justification for modifying consent norms—which move is poorly regarded by many who argue that prioritizing science, even those pursued for the sake of “public good”, over the interests of research participants conflicts with a foundational pillar of research ethics. Scholars continue to remind others of the horrific experimental abuse that happened in history involving studies without proper consent, undertaken in the hope of generating scientific data to benefit the public good.

Minimal risk is a pivotal concept that determines eligibility for expedited review and the possibility of waiver or alteration of consent requirements. Research that is minimal risk is granted a degree of flexibility in its design and how and if consent is obtained. This flexibility is justified on the basis that a proposed study has few physical, psychological, or social risks for participants and thus a more relaxed approach to consent requirements can be taken. Above the minimal risk threshold, a study warrants greater provision for the protection of participants, including being subject to ethical review. Some have theorised that the risk to biobank research participants are minimal, and outweighed by the significant benefits.

Risks and benefits in biobanking are different to those in experimental studies. Essentially, the risks and benefits in biobanking are seen as further removed from a participant and thus not as directly impacting as one might experience in an experimental study. Experimental studies usually involve physical experimentation on a person and thus a direct threat to his physical integrity and wellbeing. Such physical invasion requires participants to be furnished with specific benefits and risks before a decision is made. On the other hand, informational risk is one of the biggest threats in biobanking and, besides the initial sample collection, there is little or no interference with one’s physical body. Furthermore, research is group-based and conducted on the consolidated and anonymized information of a group of people. This group nature of biobank research means that an individual is unlikely to be more affected than others although group-based harms cannot be ignored. An example of group-based harm is stigmatization or discrimination of an individual, in relation to health information, that is affixed to an

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434 Timothy Caulfield, above n 310, at 216.
435 Ibid, at 216.
identifiable sub-population in society to which that individual is part of.\textsuperscript{438} Thus, however lacking as a direct physical threat, the risks in biobanking do exist and cannot be considered “minimal risk” enough to fall into a general exception of informed consent (like in epidemiological studies).

Similarly, the potential benefits that may arise from biobank studies are more remote and have very little direct benefit to an individual. Biobank research is often the preliminary testing ground for new hypotheses and many further levels of research and replication must take place before initial discoveries may be translated into clinical significance. In addition, because research is carried out on anonymized samples on a group-level, any discovery that does take place is not easily relatable to a specific individual and is likely to have more benefit to a community on a whole.

In conclusion, several arguments have been raised regularly as reasons for modifying informed consent and permitting broad consent as an acceptable alternative. However, whether these arguments are sufficiently principled and reasoned to justify such a radical shift from the established norm of informed consent has been questioned.\textsuperscript{439} In the more extreme, the opt-out approach to consent was attempted by Iceland, but with little success.

\textit{VI The Icelandic Healthcare Database, its ‘opt-out’ system and why it never took off}

The establishment of the Icelandic Healthcare Database (IHD) was driven by deCODE Genetics, an American biomedical company operating in Iceland. The Health Sector Database Act granted a 12-year licence to deCODE Genetics to exclusively create, operate and profit from the genetic information of Icelanders.\textsuperscript{440} This was despite the company reporting in its registration under the United States Securities Act 1933 that it foresaw potential “ethical and privacy concerns [that] may limit our ability to develop…and may lead to litigation against us or the Icelandic government”.\textsuperscript{441} The IHD

\textsuperscript{438} The potential for Māori and other group harms is discussed in more detail in Chapter 5.
\textsuperscript{441} deCODE Genetics Form S-1 Registration Statement under the Securities Act of 1933 (Filed with the United States Securities and Exchange Commission on March 8 2000).
drew widespread controversy for many reasons including: the fact that a private company was operating and obtaining exclusive benefit from the health information of Icelanders, the traditional standard of informed consent was done away with for an opt-out system, and data relating to deceased family members were automatically included with no option for relatives to demand the opting-out clause for the deceased.

An initiative rife with controversy, plans for the IHD were strongly opposed by many including the World Medical Association that “reaffirmed its commitment to patient confidentiality, the principle of informed consent, and the freedom of scientific research”.

The final nail in the coffin was the Icelandic Supreme Court’s ruling in *Gudmundsdóttir v. Iceland* that declared the legislation unconstitutional and a breach of privacy.

One of the more controversial aspects of the HSD was the way in which legislation disregarded necessity for informed consent. Instead, the legislation automatically included everyone in the population and gave living Icelanders the opportunity to opt-out of the database within a statutorily-defined period. Individuals could sign a form opting out and preventing the database from adding any new information on the requester. However, a person’s opt-out status lapsed on death and the data of an objector was automatically included after his death. In addition, only living individuals could opt out; the HSD Act expressly provided for the medical data of deceased individuals to be transferred with no provision for opting out, irrespective of the wishes of surviving relatives. Finally, children and incompetent persons could not exercise their right to opt-out unless their parents or guardians objected on their behalf.

This presumed consent model on the basis of community consent is a significant departure from the internationally accepted standard requiring informed consent for

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443 This case is also discussed earlier on pages 19 and 95.
research involving human subjects. DeCODE Genetics asserted that community consent was obtained after vigorous community consultation and debate and that individual consent was represented in presumed consent that was justified on the basis that two polls conducted prior to the legislation passing sufficiently showed “consent of society to the use of health care information according to the norms of society”.  

The use of presumed consent generated a lot of opposition and discussion on the ethics of such a model with many of the opinion that presumed consent is too weak a form of consent and lacks respect for autonomy and privacy. However, this move was defended by management of deCODE Genetics on the grounds that “presumed consent is the standard used for research on health care data that is produced in the process of delivering medical services” and that the ability to opt out of the database served to “enhance the authenticity of the presumed consent”.  

In addition, it was argued that because data could be rendered non-identifiable by encryption, it made research more similar to epidemiological research.

This controversy was further fueled by accusations that the Biobanks Bill was sped through Parliament with little discussion and buoyed by skillful publicity by deCODE Genetics. Carefully slipped in at the “11th hour”, Paragraph 4, Article 7 of the Biobanks Act also permits researchers to retain DNA derived from samples even if consent is revoked. Economic and medical progress were promised to “a society which possessed neither a vocabulary nor tradition to discuss biotechnology, bioinformatics or the regulation of biomedical research, and certainly no international models with which to discuss novel genomic database issues”.

449 Ibid.
450 Ibid.
451 Skuli Sigurdsson “Yin-yang genetics, or the HSD deCODE controversy” (2001) 20 New Genet Soc 103 at 105.
453 Skuli Sigurdsson, above n 451, at 105.
454 David Winickoff, above n 452, at 1734. The Biobanks Act, No. 110/2000, is distinct from the Health Sector Database Act although it is part of several pieces of legislation intended to govern what was to be a centralized database.
455 Skuli Sigurdsson, above n 451, at 105.
Finally, the legislation that was accused of being “totalitarian” and in contravention of the norms of respect privacy and autonomy\(^\text{456}\) met its demise when the Supreme Court declared it unconstitutional and expressed doubt on the initiative ever taking off.\(^\text{457}\)

The experience of the Icelandic Health Sector Database highlights lessons regarding the familial nature of genetic information and its implications for informational privacy as well as the caution that must be exercised when departing from the traditional norm of informed consent. The concept of a large-scale database for genetic research is relatively new and must be processed and introduced with consideration for the benefits and risks associated with this particularly sensitive type of human research.

\textit{VII Conclusion}

The introduction of informed consent to New Zealand was not accidental. Informed consent and respect for patients came about as a result of tragedy experienced in the hands of researchers who failed to protect the interests of patients. Accepted as the norm for years, the validity and application of informed consent is now being challenged by the unique nature of biobanking. Informed consent, and the need for specificity, is impractical in biobanking where the aim is to collect as much health information as possible to facilitate a broad spectrum of unspecified health research. This shift has caused a divide amongst scholars who have on one extreme, tried to defend the immutable status of informed consent and, on the other extreme, tried to justify modifying informed consent to accommodate biobanking in light of its potential to propel health research.

The potential of biobanking to generate an increased amount of genomic research and improve our understanding of diseases has caused many countries to reject informed consent in favour of less onerous models. These less demanding models of consent permit the collection, storage and future unspecified use of health information while still providing a measure of protection for participant interests. These different models have had different levels of success and in some instances—as in the case of Iceland—has come at a cost.


In New Zealand, modified consent is not novel and ethics committees are permitted to approve research that involves future unspecified research. However, I argue that this is insufficient. Different regimes for various aspects of health information and research have created a piecemeal system that is inadequate as long-term protection for future biobank participants. What New Zealand presently has is a good indication of a potential future in biobanking. However, more must be done to carefully integrate the different guidelines and law to create a coordinated framework that simultaneously guards the interests of participants while permitting and promoting new directions in research.
CHAPTER FOUR: MĀORI INTERESTS

Contemporary New Zealand is a myriad of cultures comprising of European, Māori, Polynesian, Asian and other groups.\(^{458}\) This ethnic diversity is similarly reflected in the views and beliefs of people towards the human body and biomedical research. For some, research involving the use of human tissue is acceptable and nugatory, while for others, human tissue is sacred and the notion of tissue donation highly unacceptable.

This chapter explores the perspective of Māori towards human genetic research and how cultural imperatives might influence this. The traditional beliefs and values of Māori towards human genetic research are quite different to that of the Western world. There is a heavy emphasis on spirituality and the sanctity of an intact body; these values consequently impact on Māori participation in human tissue donation and research. As tangata whenua,\(^{459}\) the beliefs and values of the Māori are “a living aspect”\(^{460}\) of New Zealand culture and need to be carefully considered and incorporated into research practice. This chapter also discusses some issues related to Māori that may arise in biobanking. However, this presentation of issues is brief and intended only to highlight the complexities of cross-cultural tensions and the need for more research in this area.

It is acknowledged that Māori as a group are extremely diverse and that between individuals and groups there may be different levels of acceptance of traditional values. The discussion in this chapter is not intended to represent the “Māori” view on human genetic research. Rather, it is meant as a guide to assist the reader in understanding factors that may influence (to different degrees) Māori decision-making towards human genetic research.

I Why Māori?

The Māori are the tangata whenua or indigenous people of New Zealand and enjoy protection by the Government under the Treaty of Waitangi. Regarded as the founding document of New Zealand,\(^ {461}\) researchers must respect the principles of partnership and sharing implicit in the Treaty and, where applicable, incorporate Treaty principles into all

\(^{458}\) In New Zealand, Europeans (67.5%) and Māori (14.6%) make up the two largest ethnic groups. See: “2006 Census Data” (2006) Statistics New Zealand <www.stats.govt.nz>.

\(^{459}\) “people of the land”

\(^{460}\) Greg Lewis and Neil Pickering “Māori Spiritual Beliefs and Attitudes Towards Organ Donation” (2003) NZBJ 31 at 32.

\(^{461}\) “Treaty of Waitangi” The Governor-General of New Zealand <gg.govt.nz>.
health research proposals. The three key principles under the Treaty are: partnership, participation and protection.

There is an overarching principle in Article 2 of the Treaty that requires the Crown to actively protect Māori rangatiratanga over taonga, both material and cultural. In the area of health research, active partnership and the inclusion of Māori input at all levels of the sector are important to ensure that Māori culture, values and practices are safeguarded and that Māori benefit from research.

Māori representation and participation in BiobankNZ are important and crucial to the long-term health strategy of New Zealand. On average, Māori people have the poorest health status of any ethnic group and are a priority group for health intervention. Active Māori participation in BiobankNZ will ensure that diseases disproportionately experienced in the Māori population are represented in biobank research.

II Donating tissue for human genetic research

Human genetic research is of concern to Māori because it does not sit well with the traditional Māori world-view. When research is carried out outside the paradigms of the Māori world-view, there is risk of it becoming unacceptable in Māori custom. In addition, the potential for commerce, politics and religion to drive the direction of research is feared as their influences may create “culturally unsafe scientific intrusion” that further alienates Māori.

Traditionally, Māori people have had a very holistic view of health and wellness. There is an emphasis on spirituality and the metaphysical and in order to gain an understanding of

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468 Māori Research Guidelines, at 3.
Māori concerns towards human genetic research, it is first important to understand a few concepts that underpin these beliefs.

**A  Māori wellness and the whare tapu wha model**

A conference organized by the Health Research Council in 1995 recorded the support of Māori attendees for genetic research and application. However, such research had to enhance the quality of life for Māori, as defined by Māori, and had to occur in a culturally appropriate manner. In ideal research situations, the knowledge of science and technological advancements is blended with Māori customary knowledge, drawing the benefits of research while still observing and keeping a wider spiritual context.

A key contrast between European and Māori world-views is that the Māori place spiritual and communal matters ahead of individual and material needs. Traditionally, Māori people view health and wellness holistically and this is demonstrated in the whare tapu wha model used to describe Māori wellness: four inter-related sides of the house that need to be strong and equal to ensure strength and symmetry. The four sides are taha wairua (spiritual health), taha hinengaro (mental health), taha tinana (physical health) and taha whanau (family health). All four cornerstones work together to represent health and wellbeing and an imbalance caused by any absence or damage to one aspect can affect the overall wellbeing of a person or collective.

The spiritual component (taha wairua) is recognized as an essential requirement for health. Although unseen and unheard, it includes the mauri (spiritual life force) of a person. Traditional Māori analyses of physical manifestations of illness focus on this aspect to determine whether damage here could be a contributing factor.

**B  Key concepts that may influence Māori perspective on genetic research**

To understand how cultural imperatives affect Māori perspectives on human tissue donation and research, it is necessary to understand a few key concepts, values and

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470 Ibid, at 3.
471 Ibid, at 3.
474 Whare = house; tapu = sacred; wha = four; this is one of many different models that illustrate this relationship. See: M.H. Durie “A Māori Perspective of Health” (1985) 20(5) Soc Sci Med 483 at 483.
practices.\textsuperscript{477} Of particular significance are the concepts of tapu, mauri and whakapapa that together represent an aspect of Māori life, identity and “rightness”.

1 Tapu

Tapu is a word used to describe ritual prohibitions and restrictions intended to protect individuals and the community of the danger of certain practices that may leave a person ritually unclean and vulnerable to serious illness, misfortune or death.\textsuperscript{478} The concept of tapu forms the basis of law and order and safe and unsafe practice amongst Māori. It refers to a way of observing and carrying out things and is a notion that goes to the heart of Māori religious thought.\textsuperscript{479} Tapu is “intrinsic spiritual integrity”\textsuperscript{480} that relates to the state of being set apart.\textsuperscript{481} Some parts of the body, blood and death are considered tapu and special practices are observed to accommodate this.\textsuperscript{482}

Cadaveric organ donations have been described as a process that “tears at the fabric of tapu”.\textsuperscript{483} Organ removal creates “interplay between the living and the dead that may upset the spiritual order” or whakapapa.\textsuperscript{484} In this manner, tapu is broken through the will of man; right standing is affected and the implications in the physical and spiritual are unknown. Spiritual retribution as a result may manifest in the physical or spiritual and affect the persons involved and their whanau.\textsuperscript{485}

2 Mauri

Mauri refers to the notion of a “unique living force”\textsuperscript{486} — a life force that permeates people and elements of the environment. It is a special power that makes it possible for everything to move and live in accordance with the conditions and limits of its

\textsuperscript{477} My short discussion of these Māori concepts is confined to how they relate to the human body and Māori identity. This discussion is also limited heavily by the fact that English translations of these concepts are often approximations at best.

\textsuperscript{478} James Irwin \textit{An introduction to Māori religion: its character before European contact and its survival in contemporary Māori and New Zealand culture} (Australian Association for the Study of Religions, Bedford Park, S. Australia, 1984) at 28.

\textsuperscript{479} Hirini Moko Mead \textit{Tikanga Māori: Living by Māori Values} (Huia, Wellington, 2003) at 30.

\textsuperscript{480} Mere Roberts and others “Whakapapa as a Māori Mental Construct: Some Implications for the Debate over Genetic Modification of Organisms” (2004) 16(1) Contemporary Pacific 1 at 2.

\textsuperscript{481} Hirini Moko Mead, above n 479, at 13.

\textsuperscript{482} Ibid, at 49.

\textsuperscript{483} Ibid, at 49.

\textsuperscript{484} Greg Lewis and Neil Pickering, above n 460, at 34.

\textsuperscript{485} Ibid.

\textsuperscript{486} Mason Durie, above n 472, at x.
existence.487 The Māori believe that everything in the natural world contain mauri including people, trees, plants, rivers, rocks and genetic material. In people, mauri is the “spark of life” or “life principle” that indicates that a person is alive488 and is the only thing that can bind the two parts of body and spirit of a person at birth.489 The mauri of a person is seen as an attribute of oneself and where there is unrest or disturbance to a person (for example, through illness or shocking news), the mauri is affected and no longer in a state of balance.490 At death, the mauri of a person is extinguished and the physical and spiritual parts of a person separate.491

3 Whakapapa

Whakapapa is most commonly understood in reference to the heritage, lineage or genealogy of a person that is gifted from his or her parents and their ancestors at birth. It is the very “foundation and acceptance as a Māori”492 and the link between generations of the past, present and future.493 Whakapapa is the “social component [of]…the genes” that defines one’s place in the kinship system—the whanau (family), hapu (sub-tribe) and iwi (tribe)—494 and is the legitimizing identity of a person upon which much of his or her rights, obligations and entitlements as a Māori rest on. Whakapapa defines and determines the role and membership of each individual within a group and is core to one’s belonging and identity as Māori.

C Donating tissue for human research

To Māori, the human gene may be described in two ways: ira tangata and whakapapa.495 Ira tangata refers to the “life principle”496 of mortals while whakapapa refers to genealogy. As Mead noted, the removal and storage of human tissue sits uncomfortably with Māori belief because:497

\[^{487}\	ext{Cleve Barlow Tikanga Whakaaro: Key Concepts in Māori Culture (Oxford, Victoria, 2004) at 83.}\]
\[^{488}\	ext{Hirini Moko Mead, above n 479, at 53.}\]
\[^{489}\	ext{Cleve Barlow, above n 487, at 83.}\]
\[^{490}\	ext{Hirini Moko Mead, above n 479, at 53.}\]
\[^{491}\	ext{Cleve Barlow, above n 487, at 83.}\]
\[^{492}\	ext{Aroha Te Pareake Mead “Human Genetic Research and Whakapapa” in Pania Te Whāiti, Mārie McCarthy and Arohia Durie (eds) Mai I Rangiwhaia: Māori Wellbeing and Development (Auckland University Press, Auckland, 1997) 126 at 128.}\]
\[^{493}\	ext{Robert Webb and Rhonda Shaw “Whanau, Whakapapa and Identity in Experiences of Organ Donation and Transplantation” (2011) 8(1) SITES 40 at 44.}\]
\[^{494}\	ext{Ibid, at 44.}\]
\[^{495}\	ext{Aroha Te Pareake Mead, above n 492, at 128.}\]
\[^{496}\	ext{Ibid, at 44.}\]
\[^{497}\	ext{Ibid, at 128.}\]
In stark contrast to the Western concept of isolating a human gene from any broader identity, for Māori, the physical human gene is inextricably linked to the metaphysical whakapapa, that is, the direct heritage from ancestors which must be transmitted to descendants. The general perception would be of considering human genes as collective cultural property and not the property of an individual. Western science, however would tend to argue quite the opposite and stress the uniqueness and very individuality of human genes.

The Western reductionist view of human genes sits completely opposite to how Māori view genes. While Western belief is that genetic material can be isolated from humans with little effect on normal human function and wholeness, the Māori see human genes as intrinsically linked and impossible to separate or isolate as an entity devoid of life.498 “Isolation, reproduction or manipulation of the physical gene would not alter the perception of Māori of the whakapapa and mauri inherent and inextricable from the gene.”499 The Māori believe that the human gene is taonga (treasure) that contains mauri and the removal of genetic material has ramifications for the ancestral line500 and cuts to the core of beliefs on identity and humanity. Altering genetic material disturbs mauri and is considered to be an unacceptable interference of the natural evolutionary link between generations.501

In addition, there is discomfort towards the idea of indefinite storage of genetic material. Māori feel strongly about the appropriateness of particular sites and objects for particular purposes.502 In the case of genetic research, the storage of genetic material in a facility runs counter to the cultural imperative that human remains belong either in the living body or returned to its place of origin in the earth.503 This becomes even more discomforting when genetic material is transported to another country where researchers may have an unacceptable level of understanding towards Māori cultural protocol.

498 Ibid, at 129.
499 Ibid, at 129.
500 Greg Lewis and Neil Pickering, above n 460, at 34.
501 Aroha Te Pareake Mead, above n 492, at 130.
502 Ibid, at 130.
503 Ibid, at 131.
III Tikanga Māori

While the concept of donating tissue for genetic research may rub against Māori values and belief, it is not entirely antithetical. Contemporary Māori views of genetic research stem from the desire to improve overall health and outcomes of Māori and participation in research is one aspect. Many Māori participate in health research that involves the donation of blood, urine and other bodily fluids despite traditional views towards it. Provided there is satisfactory Māori representation in ethics approval and there are appropriate and acceptable Māori protocols (tikanga Māori) for storage, use and disposal, the harms of such research can be minimized.

Tikanga refers to a “set of beliefs associated with practices and procedures to be followed in conducting the affairs of a group or individual”.\(^{504}\) It is a set of social practices that are ritually correct and designed to steer one in the direction of the “right and proper way” to conduct activities that have an impact on Māori.

For many years, Māori have advocated the inclusion of tikanga Māori as part of the formal process of ethical decision-making.\(^{505}\) The principles of partnership, participation and protection implicit within the Treaty of Waitangi create a framework on which to identify ethical issues such as: the different roles and responsibilities of researchers and the Māori community and how both parties may collaborate; the contribution that research will make towards useful and relevant outcomes; and how research addresses inequalities.\(^{506}\) Research that observes tikanga Māori honours the Māori as indigenous people and signatories of the Treaty and prioritises their interests over other personal or commercial interests.

The Guidelines for Researchers on Health Research Involving Māori (the Guidelines for Māori Research) were produced to assist researchers who intend to undertake biomedical, public health or clinical research involving Māori participants or research on issues relevant to Māori health.\(^{507}\) It is intended to assist researchers on developing culturally appropriate research projects that is responsive to Māori and was written specifically for applicants seeking funding from the Health Research Council (HRC).\(^{508}\) Only applicants

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\(^{504}\) Hirini Moko Mead, above n 479, at 53.
\(^{505}\) Māori Research Guidelines, above n 462, at 25.
\(^{506}\) Ibid, at 25.
\(^{507}\) Māori Research Guidelines, above n 462, at 1.
\(^{508}\) Ibid, at 2.
to the HRC are required to read these Guidelines for Māori research before making a submission to an ethics committee. However, the National Application Form for Ethical Review of a Research Project—the form that all researchers are required to submit for ethical approval—requires applicants to similarly indicate whether they have read the Guidelines for Māori research.509

A Kaupapa Māori

The Guidelines for Māori Research describe the different approaches to Māori health research. They are: research involving Māori; Māori-centred research; and Kaupapa Māori research. The differences between these approaches are the level of Māori involvement in participation and on the research team as well as the methodology adopted in research. Kaupapa Māori research embodies what is the most “ideal” type of research and is described as “research by Māori, for Māori and with Māori”.510 It is a philosophical framework that “embraces traditional beliefs and ethics”511 and is one way of research that emerged “at least partly in response to the largely negative impact of conventional Western research on Māori”.512

The “ideal” approach to research involving Māori, Kaupapa Māori, is, however, unsuitable in biobanking. This is because biobanking aims at research on whole populations—Māori people comprising one of many groups. Furthermore, Māori are unlikely to be singled out for research based on their ethnicity and so there may be less disempowerment and alienation to fear. Thus, even though Kaupapa Māori methodology is regarded as one of the best ways to conduct Māori research, the unique traits of biobanking and its broad focus on whole populations mean that such an approach as a whole is not suitable. However, researchers and BiobankNZ planners should still be encouraged to apply strategy drawn from aspects of Kaupapa Māori to their research involving Māori.

The Guidelines for Māori Research describe the process of considering Māori in research. It begins at the initial phases of planning and devising the research proposal, defining


how it impacts on Māori and benefits them and how they can be included in the research on the different levels (as researchers, advisors or participants). The purpose of the Guidelines is to assist researchers in considering prospective research from a Māori perspective and the different aspects that arise in the process of preparing and carrying out community consultations. Through careful planning and analysis, research that might be tapu—and therefore restricted—could proceed with less restriction provided that thorough discussion and careful boundaries are set up and there is mutual understanding.

**IV Biobanking and Māori**

The establishment of a population-based biobank will primarily be for the purposes of research on a population level. This means that recruitment will be targeted at the general population as opposed to single groups as in community-based research. However, the participation of Māori is crucial and their interests and considerations therefore very important.

**A What do Māori really think about biobanking?**

The concepts discussed above provide some insight into how traditional Māori values may impact on one’s perspective of biobanking. However, as with any group, these views are not indicative of the full spectrum of beliefs and values and it would be inaccurate and inappropriate to allow this to override individual beliefs and choice.

Based on traditional values and beliefs, it would be easy to assume that Māori will reject the notion biobanking. However, in reality, many feel just as great a desire to reduce the burden of disease in the population and improve overall health and wellbeing. There is recognition that technology can work towards achieving these end goals although such technology must also have consideration for what is important to Māori.

The Rakaipaaka Health and Ancestry Study (RHAS) is an ongoing multi-disciplinary genetic research project with the people of Nuhaka in the Hawke’s Bay. The RHAS has developed groundbreaking ethical procedures specific to Māori community-based

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513 Māori Research Guidelines, above n 462, at 6.
514 Ibid, at 29.
genetic research and the positive outcomes of the study have potential for application globally for the protection of indigenous groups.

Researchers of the RHAS obtained the support and consent of the local iwi community (Ngāti Rakaipaaka) before commencing. This community-driven project has not only provided researchers with detailed information of consenting Māori participants, it has also been a tool for empowering the community. The study has provided immediate and long-term benefits to participants and the wider community and injected confidence and awareness into a community that faces inequitable access to healthcare and experiences a disproportionate disease burden.

Through the course of the study, researchers learned the importance of maintaining iwi control over the research process and design and investing time into learning local dynamics, research priorities and key issues before research decisions were made. While sticking closely to a research timeframe might be important, researchers found that it was just as important that “research moves at the pace that the iwi are comfortable with, not driven solely by external deadlines”.

It is likely that most Māori would distinguish the use of gene therapy to help save the life of a critical patient from other forms of gene therapy, such as germ line gene therapy, and genetic screening. The RHAS has shown that when iwi are given sufficient control and influence over genetic research involving their members, and when the focus is on broad community health and wellbeing and social needs, it is possible to engage the support of iwi groups willing to work through the ethical and cultural challenges raised by genetic research.

517 Ibid.
518 tribal
520 Ibid, at 205.
521 Ibid, at 205.
522 Aroha Te Pareake Mead, above n 492, at 130.
523 Bevan Tipene-Matua and the Rakaipaaka Health and Ancestry Study Management Team, above n 519, at 211.
The establishment of a biobank requires massive investment financially and politically. Without the buy-in of a population willing to participate, a biobank is doomed to costly failure. While it may appear that the notion of biobanking and what it entails cuts against the grain of traditional Māori culture, the experience of the RHAS has shown this to be a premature assumption. More importantly, the experience of the RHAS has reaffirmed that the Māori people want what most want—to be educated, empowered and given the opportunity to improve their current circumstances. Participation in biobank research and obtaining insight into diseases disproportionately suffered by Māori people can contribute to these aims. However, how Māori people are approached for participation in BiobankNZ requires special consideration and their views must be consulted and not assumed.

B Protecting against group harms

There is a very cautious attitude towards genetic research on indigenous peoples. Intrusion on indigenous communities for the sake of research carries with it risks of stereotyping, discrimination, weakening group identity and undermining group claims and goals. Indigenous groups are often believed to be more genetically homogenous compared to other populations thus making genetic research on such groups preferable. However, such groups often lack strong advocacy to defend their interests and have, as a result, been subjects of unethical research and careless dissemination of results that have created discrimination and stigma towards a particular identifiable group.

In New Zealand, the “warrior gene” controversy reinforced negative stereotypes of Māori people by incorrectly singling them out as being genetically different from non-Māori. This “ascriptive harm” was a result of research that lacked scientific rigour and taken out of context by researchers, media and the wider public. While the controversy was

524 The Human Genome Diversity Project (HGDP) which aimed to collect tissue samples from 500–700 target indigenous groups was met with fierce opposition from indigenous groups. In New Zealand, the Mataatua Declaration (June 1993) called for an immediate halt to the HGDP “until its moral, ethical, socio-economic, physical and political implications have been thoroughly discussed, understood and approved by indigenous peoples.’ The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples June 1993 at [3-5].

525 Daniel M. Hausman “Group Risks, Risks to Groups, and Group Engagement in Genetics Research” (2007) 17(4) KIEJ 351 at 351.


528 Ibid, at 14.
fuelled by media hype, at its most basic level, it was also a failure on researchers to produce “socially robust” knowledge.\textsuperscript{529} Such knowledge requires consideration for the wider implications and impacts of research work and the obligation to present research findings in a socially responsible manner.\textsuperscript{530}

The assignment and assessment of high criminality of Māori on a unique gene by European researchers\textsuperscript{531} reinforced, amongst other things, distrust and fear towards Europeans and genetic research.\textsuperscript{532} Researchers have an obligation to ensure that research is not only carried out carefully and truthfully but that it is also disseminated in a socially responsible way. Researchers need to ensure that assessments carried out do not single out a sub-population group within society that then becomes negatively affected by the outcomes of such research.\textsuperscript{533}

\textbf{C Ownership and rights in human tissue samples}

The issue of property rights and ownership over stored tissue samples from living and cadaveric donors as well as material derived from research on tissue samples raise a number of issues, some related and some distinct. The ownership and property rights over excised tissue samples remain an unresolved issue.\textsuperscript{534} With respect to isolated and purified genetic material, intellectual property laws may apply and patents granted over such genetic material provided certain conditions are met. When a patent is granted, the applicant is granted up to 20 years of exclusive use.\textsuperscript{535} Intellectual property laws incentivize research and the commercial monopoly granted over successful patents helps to drive the cycle of research and commerce.

Unfortunately, neither the ownership of a sample nor property rights in something that was derived from a tissue sample is straightforward. The award of patent rights over isolated genetic material is a highly contentious issue and an evolving law in New

\begin{footnotesize}
\textsuperscript{530} Ibid, at 508.
\textsuperscript{531} G. Raumati Hook “Warrior Genes” and the disease of being Māori” (2009) 2 Mai Review 1 at 1.
\textsuperscript{532} Pauline Harris “Responsible research and the media trap” (2009) 2 Mai Review 1 at 2.
\textsuperscript{533} D Wensley and M King, above n 529, at 508.
\textsuperscript{535} Patents Act 1953, s 30(3).
\end{footnotesize}
There are many arguments against gene patents including the argument that it is immoral, that patents in fact inhibit research and act against the best interests of society and that patents over genetic material are so borderline that the validity of some are questionable.

Participants of the UK Biobank are informed at the time of consent that the UK Biobank will be the legal owner of the database and the sample collection, and that participants will have no property rights in the sample. Furthermore, access to data and/or samples is licensed to researchers under strict terms and conditions according to access agreements. The fees charged for a licence depends on whether any financial benefit will be derived from use of the resource. It appears from the terms of the UK Biobank Ethics and Governance Framework that property rights of participants over donated genetic material is indisputable. Any ownership rights that a person might have over his tissue sample is volunteered to the biobank upon participation; any benefits derived from research becomes a matter resolved by the terms of the access agreement signed between the biobank and researchers.

However, the actual application of the UK Biobank’s policy remains to be tested. Being a relatively new initiative, there have not been any intellectual property rights applications over material derived from UK Biobank samples. As noted by Cleary, while the United Kingdom Intellectual Property Office still grants patents over isolated DNA, the most recent judgment of the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd (Kirin-Amgen)* raises questions over the validity of some of these patents. In *Kirin-Amgen*, it was reaffirmed that isolated and purified genes is a discovery and not a

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536 At present, the Intellectual Property Office of New Zealand (IPONZ) examines patent applications on grounds of patentable subject matter and novelty, but do not examine for inventive step. In doing so, the IPONZ has unwittingly granted patents over isolated and purified genetic material that has become commonplace enough to be considered non-obvious and lacking in inventive step in other jurisdictions. In New Zealand, reform of the Patents Act 1953 is on the horizon and this will affect how patent applications are examined. For a very thorough examination of gene patenting in New Zealand, see: Thomas Cleary “Gene Patents: Should New Zealand Let the Gene Genie Out of the Patent Bottle?” (LLB(Hons) Dissertation, University of Otago, 2011).

537 Thomas Cleary, ibid, at 7.

538 The UK Biobank Ethics and Governance Framework Version 3.0 at 5.


540 The United Kingdom Intellectual Property Office presently examines patent applications on the basis of the Biotechnology Directive that states that an isolated gene ‘may’ constitute a patentable invention. For a discussion of this, see: Thomas Cleary, above n 536, at 17.

541 Thomas Cleary, ibid, at 17.
“practical product or process” that is patentable. Thus the policy of the UK Biobank regarding property rights in samples, data and their derivatives is not absolute and remains to be tested in the courts.

In New Zealand, patenting and commercializing material derived from the genetic material of a person for the exclusive benefit of a single person or entity sits contra to the traditional Māori worldview that genetic material is collective cultural property. The Western ethical framework that has shaped our legal rules on property and privacy sometimes fails to fully recognize cultural or spiritual harm based on alleged misuse of samples or knowledge gained from genetic research. As taonga (treasure) that represents the “metaphysical whakapapa” of many generations, failing to recognize the collective cultural property of a person’s genes would be extremely negative, and excluding Māori from the benefits derived from research on their genes graceless. The Western system of intellectual property laws that grant exclusory right over a patented gene is incongruous with the Māori conception of genes, genetic material and its value as collective cultural property.

In the Rakaipaaka Health and Ancestry Study (RHAS), the Ngāti Rakaipaaka iwi (tribe) has negotiated control over any intellectual property benefits that might derive from research on their community. Retaining control of rights over samples is possible because the RHAS focused on a single community group whose interests were represented in negotiations. Such negotiations may prove more complicated where research is carried out on a population level and the genetic material or health information of a single group is not specifically used.

Another solution to the problem of who benefits from research on groups may be found in the story of PXE International, a research advocacy foundation that initiates, funds and conducts research on pseudoxanthoma elasticum (PXE). In the case of PXE International, a team of parents harnessed intellectual property laws for benefit sharing and to drive research into a specific disease (PXE). They accomplished this by creating a hybrid model drawn from different aspects of academic models, commercial enterprises

542 Kirin-Amgen Inc v Hoeschst Marion Roussel Ltd [2004] UKHL 26 at [76] and [77].
544 Aroha Te Pareake Mead, above n 492, at 129.
and advocacy organizations. This hybrid model has created a voice and generated research momentum for a minority group of PXE sufferers whose disease might have otherwise been overlooked. PXE International established a blood and tissue bank and then engaged the expertise of researchers who worked to identify the gene responsible for the disease. Patent rights over the PXE genes were negotiated and assigned to both the founders of PXE International and researchers who discovered the gene. The work of PXE International continues to advance understanding of the disease and accelerate translational therapies for treatments of defects that are seen in PXE. PXE International is a story of how a minority group of sufferers was undeterred by the challenging nature of the intellectual property rights system and instead used it to their advantage by partnering with researchers and negotiating terms so as to obtain tangible benefits for sufferers of PXE.

The different experiences of RHAS and PXE International have demonstrated that it is possible to work within an established framework (in this case, what might appear to be a rigid intellectual property rights system) to negotiate benefit for different stakeholders. What could potentially have become negative experiences were instead used as opportunities to harness different expertise, increase advocacy and draw benefits from commerce to derive benefit for groups involved. Similarly, careful negotiation between Māori, BiobankNZ and researchers can mean that the rights to intellectual property and other benefits of research that involve Māori is shared amongst stakeholders. However, as mentioned above, because biobank research is unlikely to target a specific group (e.g. Māori or Indian people in a population) it might be more feasible that benefit-sharing is be spread across participants and not just specific groups within participants.

This aspect of biobanking and Māori interests is complex. The commercialization of genetic material derived from indigenous people has left Māori feeling understandably fearful and uncomfortable with an intellectual property system that disregards their view of genetic information. However, the approaches of RHAS and PXE International may inspire similar models harness the current system — in spite of inherent differences — for the benefit of Māori and in turn encourage research on diseases suffered by Māori and other New Zealanders alike.

545 Sharon F. Terry and others “Advocacy groups as research organizations: the PXE International example” (2007) 8 Nat Rev Genet. 157 at 160.
D Personal autonomy and the tension with group interests

The collective interests of Māori when it comes to decisions relating to tissue donation are likely to be recognized in biobanking in New Zealand. This may come in the form of a guideline (as is currently the case) that recognizes that a potential donor may have the interests of others around him to consider before giving a donation. However, the collective interests of a group are unlikely to override the individual consent of a donor. At the time of consent, personal autonomy is exercised and it is the individual choice of a person that is noted and accepted regardless of conflicting group interests that may have been voiced in decision-making.

However, the balance between group and family interests and personal autonomy becomes less clear when a participant dies. As is the case of organ donation in New Zealand, the autonomous choice of a person to donate his organs posthumously may not always be respected. The law requires the wishes of a deceased’s immediate family to be taken into account prior to an organ harvest. While the informed consent of a deceased person cannot theoretically be overridden, the fact that a physician must take into account the “cultural and spiritual needs, values, and beliefs of the immediate family” and the reassurance that a “family’s wishes will always be respected and organs and tissues will not be retrieved if the family has any objection” highlights how blurred this distinction is. This difference between the law and actual practice often happens out of respect for a grieving family and the need to maintain public support for organ donation.

In biobanking, what if the immediate family of a deceased participant permits continued storage and use of biobank information at the objection of extended family? While the answer may seem apparent — clearly the wishes of immediate family have more weight since they are more immediately affected by the hereditary nature of genetic information — it might be less so upon closer inspection. The extended family of a deceased participant may object to continued storage and use of biobank information for many reasons and their grounds for objection can be based on the familial nature of genetic nature and how it also discloses information about them as extended family and the additional fact that genetic information is whakapapa. The continued storage and use and

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546 Human Tissue Act 2008, s 18.
547 For a discussion on this point, see: Joanne Lee “New Zealand’s Organ Transplant Laws: Any Hints for Improvement from Singapore’s?” (2011) 2(3) NZLSJ 557.
548 Human Tissue Act 2008, s 18.
549 “Talk to your family” Organ Donation New Zealand <www.donor.co.nz>.
even commercialization of genetic information is disruptive to the whakapapa of Māori and affects the whanau, iwi and hapu as much as it affects immediate family members.

This tension between the personal autonomy, the wishes of immediate family and the wishes of extended whanau has been seen in “body napping” cases in New Zealand.550 In these cases, immediate family and extended whanau conflicted in how or where a body should be laid to rest. In these cases, the courts put significant weight on the personal views of the individual prior to passing and made decisions based on what it thought the deceased would have wanted. However, in the case of genetic information in biobanking, the argument that whakapapa is disrupted and deserves special protection adds complication to the matter. Is there special obligation under the Treaty to give special protection to whakapapa? If so, should this obligation override the express consent given by a person (who is now deceased) and the support of his immediate family?

The distinction between individual autonomy and group interests is blurred when it involves matters relating to genetics and where implications extend beyond an individual. This issue is particularly amplified for Māori who place immense value on genes and its collective representation of whakapapa. No easy method exists to determine how much weight should be given to different members within a Māori family when it comes to decisions on genetic material and how it impacts whakapapa.

V Conclusion

This chapter was written to provide some insight on how Māori people might feel about genetic research in general and participation in an initiative like BiobankNZ. However, it is acknowledged that there is great diversity in opinion and experience and that no one view applies to all.

The experience of the RHAS has shown that Māori are not entirely adverse to genetic research. Rather, the study teaches the importance of deep and meaningful community engagement and the tools that engage the support of indigenous groups. Careful planning not only ensures that groups are protected from harm but that communities are empowered and benefit in the process.

However, a key distinction between an initiative like BiobankNZ and the RHAS is the community focus of the RHAS in contrast to the population-wide focus of BiobankNZ. While the experience and lessons of the RHAS are valuable, not all can be applied to BiobankNZ. The tools used by PXE International to engage researchers while retaining rights over tissue samples may also be helpful in BiobankNZ.

This chapter is limited to the presentation of some issues that relate to Māori that may arise in biobanking. These issues outlined are important and emphasise the need to develop robust policy to ensure that Māori people are protected from harm in genetic research. However, it is stressed that this discussion is limited to traditional Māori thought and more research is needed to determine the sociological extent to which traditional and contemporary Māori values diverge in this area. Unlike in the United Kingdom, New Zealand has very strong obligations to protect Māori interests. This means that all potential issues and how they impact Māori must be carefully explored and debated before the idea of biobanking in New Zealand can be introduced.
CONCLUSION

Biobanks are huge investments for any country and have no guarantee of success. However, they are increasingly being recognized as essential research tools in human disease research and are potentially in the future for New Zealand. The aim of this thesis was to evaluate the adequacy of New Zealand’s privacy and consent laws to protect the interests of future biobank participants. This thesis concludes that:

1. The current legal framework for privacy and consent in New Zealand is promising albeit still lacking in some areas. The legal dilemmas that other countries have faced have not escaped New Zealand and more is required to protect the interests of participants. Most strikingly, current protections in the law for potential biobank participants exist in a number of documents (such as the HIPC, the Code of Rights and the Guidelines for Use of Human Tissue for Future Unspecified Research Purposes), and all have different legal statuses. Understandably, there lacks a consistent framework to protect the interests of potential participants; eventually, it will need to be considered whether some form of legislative reform is needed to address this need or whether a new code or ethical guideline issued under current law will suffice.

2. The Crown has obligations under the Treaty of Waitangi to protect the interests of Māori in New Zealand. This means that any implications for Māori values must be carefully considered and accommodated before any new law is introduced. Traditionally, Māori place high value on human genetic material other personal information and the potential for biobank policy to deeply affect, and even harm, Māori is real. However, as noted earlier, the sociological extent to which traditional and contemporary Māori values diverge in this area is fairly unknown and more research is needed to fully establish this.

3. Genetic exceptionalism is unjustified and special genetics legislation is problematic. Any potential reform to meet the need of biobanking must consider this position and ensure that legal protection does not unfairly discriminate between genetic information and other types of health information and between sufferers of genetic and non-genetic diseases.

The ability for a biobank to improve overall population health is promising. However, the dilemmas that biobanking raise are complicated and not easily resolved. The potential for biobank failure and harm to participants demands very careful consideration of the issues
at hand and how they affect New Zealand. While very limited in scope, this thesis represents a starting point, and hopefully one that is thoughtful of what is a very complex area.
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