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Engaging Maori in Biobanking and Genetic Research: Legal, Ethical, and Policy Challenges

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Engaging Maori in Biobanking and Genetic Research: Legal, Ethical, and Policy Challenges

Abstract

Publically funded biobanking initiatives and genetic research should contribute towards reducing inequalities in health by reducing the prevalence and burden of disease. It is essential that Maori and other Indigenous populations share in health gains derived from these activities. The Health Research Council of New Zealand has funded a research project (2012-2015) to identify Maori perspectives on biobanking and genetic research, and to develop cultural guidelines for ethical biobanking and genetic research involving biospecimens. This review describes relevant values and ethics embedded in Maori indigenous knowledge, and how they may be applied to culturally safe interactions between biobanks, researchers, individual participants, and communities. Key issues of ownership, privacy, and consent are also considered within the legal and policy context that guides biobanking and genetic research practices within New Zealand. Areas of concern are highlighted and recommendations of international relevance are provided. To develop a productive environment for "next-generation" biobanking and genomic research,"“next-generation" regulatory solutions will be required.

Keywords

Indigenous, Maori, biobanking, genetics, ethics, policy, law

Engaging Māori in Biobanking and Genetic Research: Legal, Ethical, and Policy Challenges

Research involving human biospecimens and genetic data analysed in conjunction with personal or health information is becoming increasingly important for the understanding of complex diseases, and associated applications for their prevention, diagnosis, and treatment. There is consensus in the scientific community that further progress will depend on access to larger numbers of biospecimens. As a result, there have been moves in New Zealand and elsewhere towards harmonization of biobanks (Du Plessis, 2007; Maschke, 2005). Most commonly this involves the adoption of evidence-based standards for the collection, storage, and handling of biospecimens. However, the ability to establish and harmonise biobanks will depend in part on participants' willingness to contribute.

It is essential that Māori and other Indigenous populations share in health gains derived from biobanking and genetic research. This review describes relevant values and ethics embedded in Māori indigenous knowledge, and how they may be applied to culturally safe interactions between Māori communities, participants, biobanks, and researchers. Key issues of ownership, privacy, and consent are also considered within the legal and policy context that guides biobanking and genetic research practices within New Zealand.

There are a number of formal (and informal) biobanks currently operating in New Zealand[1] that provide researchers with necessary access to specimens for ethically approved research. These entities tend to have well-established governance procedures that serve to protect participants' interests, including the requirement that all proposed research seeking access to biospecimens and relevant data be reviewed by a human research ethics committee. Formal biobanks generally have clear and transparent processes for the access to and use of samples in their collections; however, there are also numerous collections of samples held by research groups who conduct studies that may obtain consent for the future use of the samples. These samples are available for future research and, while the samples can only be used for ethically approved studies, the processes for access to and use of the samples are often less clear.

Biobanks provide researchers with access to biospecimens usually directly linked to clinical and other personal information. This function immediately attracts questions of ownership of the biospecimens and derived data, consent of the donor, the extent to which the donor can share in the results, and privacy and ethics, particularly when the material is derived from vulnerable populations. The issues of appropriate governance and donor rights thus become vitally important. It is not clear that existing regulatory solutions will meet the governance challenges presented by "next-generation" biobanking and genetic research involving extensive networks of collaborating institutions and large international data sets (Fullerton, Anderson, Guzauskas, Freeman, & Fryer-Edwards, 2010).

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[1] Examples are Middlemore Tissue Bank (Auckland), Cancer Society Tissue Bank (Christchurch), New Zealand Rare Diseases Biobank (Dunedin), The New Zealand Neurological Foundation Human Brain Bank (Auckland), and Melanoma Tissue Bank (Dunedin).

Māori Perspectives

Tikanga Māori refers to culturally grounded processes and practices that draw on the values and ethics embedded in matauranga Māori (Indigenous knowledge). For Māori, the issues of ownership, privacy, and consent can be informed by tikanga Māori (Hudson, 2004a). Similarly, tikanga can also inform the research process by ensuring culturally safe interactions with participants and communities (Jones, Crengle, & McCreanor, 2006). From a traditional Māori perspective, the concepts that most closely relate to ownership are concerned with control over access and use of a resource. The resource, for instance tissue, is recognised as a taonga[2] protected by kaitiaki (guardians) who mediate the relationships between that resource and people. To maintain the mauri (life force) of that resource (Marsden, 2003), Māori developed customs to ensure that the resource would be available to the next generation (taonga tuku iho). The value of human tissue in a traditional context is reflected in the tikanga (correct practice) applied to activities involved with healing (Jones, 2000; Mark & Lyons, 2010) or death (Barlow, 1991; Nikora, Marsters, & Te Awekotuku, 2012), including pure/tohi (positive spiritual intervention), mākutu (negative spiritual intervention), tangi (funeral process), and hāhu (process of interring bones). Tikanga were developed to moderate the potential use and misuse of human tissue and limit the risks for people, their whānau, and their communities (Roberts, 2005). While the nature of potential uses and misuses has changed in contemporary times, the basic recognition of human tissue as a taonga, belonging to both the person and their communities, remains (Cram, Pihama, & Barbara, 2000). All are relevant to understanding why Māori prioritise a duty of kaitiakitanga or "obligated stewardship" (Ministry for the Environment, 2002).

For Māori, the notion of privacy is complicated by a value system that prioritises collective good over individual autonomy. Traditionally, most healing would be done in a community setting so that community members would be aware of the issue and contribute to its solution (Port, Arnold, Kerr, Glavish, & Winship, 2008). In this regard, the privacy of health information restricts the ability of the extended family and wider community to fulfil this function (Hudson, 2004b). Nevertheless, the concept of restricting access to sensitive, or potentially dangerous, knowledge was known to traditional communities. Tohunga (experts) were the stewards of information that was considered inherently special or personally sensitive, which they retained on behalf of the collective (Boulton, Hudson, Ahuriri-Driscoll, & Stewart, 2014).

Similarly, the interrelationship between individuals and family or kin groups also affects the manner in which consent is constructed. The importance of community support and engagement in construction of research has been argued for theoretical (e.g., Kaupapa Māori, community based participatory research) (Pihama, Cram, & Walker, 2002; Smith, 1998) and functional (integrated knowledge translation) (Canadian Institutes of Health Research [CIHR], 2012) reasons. This type of engagement addresses issues relating to the safety of the study for the community (Hudson, 2004b) and forms the cornerstone of establishing a "collective" consent for the project (Hudson, 2009; Hutchings, 2009). The concept of collective consent is complementary to an individual consent as it indicates community support for a study within which an individual can consent to participate (Hudson, 2004b). Similarly, collective decision-making, where significant others (family, authority figures) support an individual to make decisions about participation, also contributes to how Māori consent to genetic research (Hutchings, 2009; Tupara, 2012).

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[2] The term "tissue" generally applies to a group of cells that perform a specific function. For Māori, it is suggested that tissue, as a discreet component of the tinana (body), has always been a taonga (treasure).

Identifying a Māori view on biobanking and genetic research is challenging as there are a number of views and perspectives evident across this community (Cram et al., 2000; Te Momo, 2007). As with all new technologies, there is limited opportunity for Māori to critique or explore the risks and opportunities. However, when given the space to consider how their interests are related to specific contexts (Cram, Phillips, Tipene-Matua, Parsons, & Taupo, 2004; Hutchings & Reynolds, 2007), Māori have demonstrated the ability to identify and conceptualise Māori values (Tupara, 2012) and to adapt relevant tikanga to these new situations (Hudson, Roberts, Smith, Tiakiwai, & Hemi, 2012).

Genetic engineering and modification is inconsistent with tikanga Māori in that it seeks to change whakapapa (genealogy or the ways by which people come into relationship with the world, people, and life). This, in turn, will disturb the mauri and balance of the individual and the community (Cram et al., 2000). Nonetheless, in the health context (Roberts & Fairweather, 2004), some Māori do give support to the notion of genetic research (Hudson, Ahuriri-Driscoll, Lea, & Lea, 2007; Tawhara, 2005; Tipene-Matua, 2006), genomic research (Ahuriri-Driscoll et al., 2007), and biobanking (Tipene-Matua, 2006).

Tikanga has been adapted in a number of hospitals for dealing with tissue in clinical settings (Auckland District Health Board, 2003) and research laboratories (Cheung, Gibbons, Dragunow, & Faull, 2007; Hudson, Allan, Bedford, Buckleton, & Stuart, 2008). In these settings, the integration of tikanga Māori, such as the use of karakia (prayers), cleansing with wai (water), and the eating of kai (food), within standard processes provides a level of cultural safety for both the whanau (family) and the researcher/clinician (Cheung, 2011). Tikanga also provide guidance around appropriate restrictions of use, access for families, and methods of disposal (Auckland District Health Board, 2003). These applications provide a foundation for identifying issues of significance that are likely to have relevance for genetic research and biobanking.

Tikanga Māori is flexible (Hemara, 2006). If we consider that some Māori actively participate within the area of genetic research, this would lend support for the use of tikanga concepts (Mead, 2003). Taonga, kaitiaki, and rangatiratanga (the right to exercise authority, autonomy, self-determination, self-management, and ownership) are primary considerations when reflecting on the relationship between tikanga Māori, tissue, and using tikanga concepts, and implications for Māori of tissue use in the context of genetic research and biobanking (Cheung, 2011). The obligation of kaitiaki to ensure the viability of taonga (in this case, tissue) would suggest that a meaningful governance role is required within the employment of a biobank (Ministry of Health, 2014; Health (Cervical Screening (Kaitiaki)) Regulations, 1995). The concept of rangatiratanga would then support the rights of Māori to make decisions over their taonga and ensure that the mauri (essence, vitality) of the taonga remains strong (Tupara, 2012). If an approach that recognizes tikanga Māori is taken, then processes that set standards of behaviour such as governance, regulation, and ethics will need to be consistent with principles of taonga, kaitiaki, mauri, mana (control), and rangatiratanga.

The development of culturally grounded processes for biobanking and genomic research would have to consider how Māori principles and values are operationalised alongside existing principles, a process which is likely to highlight normative, epistemic, or preference differences (Hope, Molster, & O'Leary, 2009).

Biobanking and Genetic Research: Relevant New Zealand Legislation

In New Zealand, the Health Act (1956), Human Tissue Act (2008), Health and Disability Commissioner Act (1994), *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes* (Ministry of Health, 2007), Code of Health and Disability Services Consumers' Rights, the Privacy Act (1993), and the Health Information Privacy Code (1994) and regulations, provide the relevant legislative framework for researchers and biobanking. However, a recent Law Commission Report observed that this current legislative framework is not very coherent and requires review (Office of the Privacy Commissioner, 2013).

Internationally, the emergence of consortia conducting collaborative genetic population research involving large-scale data sharing has highlighted a number of challenges for governance, and inadequacies and conflicts between this existing legislation and research ethics, policy, and practices. In New Zealand and more widely, this is particularly evident in the context of ownership, privacy, and consent as these principles are commonly considered by researchers in relation to the individual rather than to a population or a community.

Biobanks and issues of privacy. The New Zealand Bill of Rights Act (1990) does not provide an express right to privacy. However, the Privacy Act (1993) does contain regulations applicable to health information. The relevant regulation, the Health Information Privacy Code (1993), was issued in as a regulation under the Privacy Act (1993) and is administered by the Privacy Commissioner. Ultimately, if there is a breach of the specific privacy principles, a complaint can be made to the Privacy Commissioner and the Human Rights Review Tribunal.

The Health Information Privacy Code regulates how health agencies collect, hold, use, and disclose health information about identifiable individuals. There are two key concepts in the code. First, the purpose: Agencies must know why they are collecting health information and collect only the information they need. Once health information has been collected from a patient for a particular purpose, it can be used or disclosed for that purpose without additional consent. Second, openness: Agencies need to inform patients how their information is going to be used and disclosed so the patients can make decisions about whether to provide it. The Health Information Privacy Code contains various rules relating to the purpose of collection of health information, source of health information, collection of health information from an individual, manner of collection of health information, correction of health information, storage and security of health information, access to personal health information, retention of health information, limits on use of health information, sufficient safeguard against potentially controversial research, and limits on the disclosure of health information and unique identifiers.

These rules came into force before the emergence of large-scale biobanks, and the applicability and fit of these privacy rules to biobanking and protecting health information is at best tenuous. Areas of concern include the lack of discretion between basic and research health information, the current limits on the use of health information, the discretion of biobanks to disclose information to third parties, and the restriction on the use of unique identifiers (Lee, 2012). The interplay between various documents and mechanisms, such as the *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes* (Ministry of Health, 2007) and the Code of Health and Disability Services Consumers' Rights that seek to protect health information may provide added protection for donors, other than that set out in the Health Information Privacy Code (1993).

Biobanks and issues of ownership. Internationally, it is not uncommon for the ownership of stored specimens to be a matter of litigation (Moore v. Regents of the University of California, 1990), and various efforts to clarify the ownership of physical samples and custodial rights within a legislative framework have been pursued. In 2008, Iceland promulgated legislative provisions[3] (Act on Health Sector Database, 1998) to capture the ownership of physical samples stored by biobanks. Ownership was retained by the donors whilst the custodial rights were vested in the Icelandic government. The legislation provided for the establishment of a database to store the present, past, and future health information of the Icelandic population. This database encompassed a separate bank to store DNA and another to store genealogical information.

The intention was that this super biobank would provide a research tool for the entire population of Iceland. However, when a single license was granted to a commercial operator and subsequent court cases (Gudmundsdottir R v. The State of Iceland, 2003) highlighted the movement away from informed consent, the automatic inclusion of participants, and no right of family members to opt out on behalf of deceased family members (Lee, 2012), the Icelandic super biobank failed (Palsson, 2008). For similar reasons, biobanks in Tonga and Estonia, where the ownership was to be vested in the government with legislation providing protections to the donors, also failed. The UK Biobank is the first successful DNA biobank and is subject to the oversight of an Independent Ethics and Governance Council that adheres to the comprehensive UK Biobank Ethics and Governance Framework (UK Biobank, 2007).

There are a number of biobanks in New Zealand that store a variety of human tissue and samples. These are relatively small scale and held by clinicians and research groups for the purpose of researching a particular disease. Although New Zealand has yet to establish a legal framework that adequately addresses issues of ownership for biobank samples, a raft of legislation, regulations, and codes collectively apply to biobanking and privacy, and also to consent and ownership issues.

Biobanks and issues of consent. In New Zealand, the Code of Health and Disability Services Consumers' Rights (Health and Disability Commissioner Act, 1994) provides that no health care procedure shall be performed without informed consent. Rights 5[4], 6[5], and 7[6] of the Code reflect the elements of informed consent. A biobank provides a service to promote health together with protecting health and preventing disease for populations over an extended timeframe and, in these terms, can be classified as a health care provider for the purposes of the Code and the Rights that relate to informed consent.

Whether or not a biobank complies with the Code of Health and Disability Services Consumers' Rights regarding informed consent is complex, primarily because the nature of the research can be difficult to determine and foresee, and the elements that form the basis of the informed consent are also complex and not universally agreed upon. If the biobank takes all reasonable steps to give effect and comply with the Code of Health and Disability Services Consumers' Rights then this effectively provides an escape clause[7] when it is not possible to obtain informed consent without compromising the scientific value of the biobank (Caulfield, 2007). In this regard, Mongoven and Solomon (2012)

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[3] On December 17, 1998 the Health Sector Database Act was passed.

[4] Right to Effective Communication.

[5] Right to be Fully Informed.

[6] Right to Make an Informed Choice and Give Informed Consent.

[7] Clause 3 of the Code.

suggest donors are not really "informed" since the specific goals, risks, and benefits of future research are not known at the time of tissue donation. Further, since decisions regarding the specific use of samples ultimately will be made by the biobank, donors are not really providing "consent."

Ethical Oversight of Research in New Zealand

The *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes* issued by the Ministry of Health is intended to provide guidance for ethics committees when considering applications involving human tissue research (Lee, 2012). These guidelines sit below the Statement of Procedures for Ethics Committees (previously the Operational Standards for Ethics Committees) and guide the Health and Disability Ethics Committees when considering applications for research.[8] This combined guidance is flexible and creates a standard that is amenable to future research. However, compliance with the guidelines does not always result in ethics approval because the ethical review process considers the balance of potential benefits from the research against the potential risks to the participant or donor.

Together, the Code of Health and Disability Services Consumers' Rights and the Statement of Procedures support biobanking and the use of human tissue for unspecified research. However, the absence of any legislative framework to directly address the range of issues noted above means that the Health and Disability Ethics Committees do not have the degree of clarity to enable them to deal consistently and robustly with research involving the use of tissue from established biobanks.

This broad concern is compounded by the changes to the Health and Disability Ethics Committee (HDEC) structure and process introduced in July 2012 after a government assessment of the 2010 report from the Health Select Committee (Health Select Committee, 2011), who were investigating the means to potentially expand the number of clinical trials in New Zealand. The resulting changes included: a reduction in the number of committees from seven to four, a reduction in the number of members from twelve to eight, the development of new Statements of Procedure (SOP) to replace the previous Operational Standard, a loss of responsibility for peer review, the removal of the requirement for student research less than doctoral standard to have ethical review, and the introduction of an online application system. More important has been the introduction of the 35-day clock, which is aimed at speeding up the review process, but with the potential that adherence to this requirement becomes the prime focus in the work of committees. SOPs provide procedural guidance only and are intended to be read in conjunction with two other guideline documents published by the National Ethics Advisory Committee: *Ethics Guidelines for Observational Studies*; and the *Ethics Guidelines for Intervention Studies*, both of which were revised in 2012 to align them with the new HDEC structure (National Ethics Advisory Commitee, 2012a, 2012b).

Of more serious concern in the context of biobanking and genetic research is the requirement for HDECs to focus their attention on the ethics and not the science of research application. This ignores the fact that, commonly, the most serious ethical matters arise from the way in which proposed methodologies are applied in practice. The interaction among the research question, the process of data collection, and method of analysis is directly related to the outcomes the study produces. As Māori and Indigenous communities are particularly interested in cultural protocols for data and tissue collection as well as the outcomes and potential benefits of the project, the research

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[8] See section 11 of the New Zealand Health and Disability Act 2000, which contains provisions for the Minister of Health to establish an Ethics Committee and terms of reference.

methods need to be rigorously scrutinised (Hudson, Milne, Reynolds, Russell, & Smith, 2010). A second concern is the sense that, in the latest iteration of the HDECs, issues of relevance to Māori are being "dropped off the agenda." This is primarily because the matter of Māori membership is not explicitly defined even though the Ministry of Health's (informal) view is that this element of membership is still considered to be an important dimension in the composition of ethics committees. In summary, these changes have resulted in the perception that the degree of protection afforded research participants by the ethics review process is now not as robust as it once was (Gillett & Douglass, 2012). A manifestation of this perception is that key organisations in health, such as District Health Boards (DHBs), are setting up parallel structures (such as Māori Research Review committees) as a way of reducing this "risk quotient" to the organisation while drawing attention away from the risk associated with being a participant or donor.

In summary, the environment of ethical oversight has become more structurally complex and the current HDEC system has been somewhat disempowered. This makes it critical that issues around the relationships between Māori and the agencies involved in genetic research and biobanking are clarified through the development of cohesive guidelines that protect Māori interests and marry these with the goals of the health researcher community.

Engagement with Māori in the Ethics Review Process

The perspective held by many Māori, especially those involved in health research and including those who sit as Māori members on ethics committees, is that engagement with Māori should be a requirement except in very specifically defined circumstances. However, the view that instances of non-consultation should be rare is one that provokes a range of reactions within the health research community at large. The negative reaction to this tenet is generally couched in terms of criticism of the added cost and time arising from the supposed difficulty of finding suitable parties with whom to consult and then having to wait for responses that are said to be slow in coming. The extent of the general relevance of this process is also questioned. One possible solution is that consultation would only be required as a part of the ethics approval process when the research is clearly "Māori centred." Alternatively, if research participants are recruited from the general population, then an ethics committee could be asked to deal with this category of research on paper much as is the practice now.

This perspective is a long way from the opinion regarding Te Tiriti o Waitangi ("the Treaty") responsibilities that softening the requirements for Māori consultation should be the exception and never the rule (Treaty of Waitangi, 1840). Such a position is derived from the view that, in terms of the Treaty, all health research will be of relevance to Māori. Whilst approaches described in applications to HDECs lie somewhere between these two stances, the annual reports from these committees express concern about the way researchers deal with Māori consultation and cultural matters generally, which suggests that HDECs tend to favour a more broadly defined consultation requirement. Comments such as "some researchers pay no more than lip service to the cultural requirements" confirm a degree of dissatisfaction with the status quo (Northern Y Health and Disability Ethics Committee, 2008, p. 17). Moreover, a related argument also points to the concern that any relaxation of the requirement to consult with Māori may potentially reduce the amount of research activity focused on Māori issues, particularly in the area of personal and population health.

Moreover, the current system is not consistent in the way it deals with issues pertaining to Māori, and because there is an absence of nationally sanctioned guidelines (notwithstanding the utility of Te Ara Tika) ethics committees have been left to improvise in dealing with matters of relevance to Māori. This situation may lend itself toward a focus on cultural dimensions while ignoring critical issues such as impact on Māori and the reduction of health inequalities. The *modus operandi* regarding Treaty responsibilities has not been observed to have changed over the past decade but, more importantly, has been made possibly worse in the latest iteration of the ethics review system. A statement which describes this approach can be found in the Annual Report of the Multi-region Ethics Committee (2006) where it is suggested that:

> More often than not where consultation has occurred, it is framed around the need for cultural sensitivity and understanding with much less energy given to exploring the possible paradigmatic and research issues relating to Māori that may be implicated in the project. While matters of culture are important in the research process, there is a need for greater thought to be given to conceptual issues and questions, along with the shape of research outputs, if the results from health research are to contribute more positively to the health status of Māori. (p. 8)

Currently, researchers are required to outline: (a) how their study might benefit Māori; (b) what the main cultural issues are that Māori may face if they participate in the study; and (c) whether they have read the Health Research Council's *Guidelines for Researchers on Health Research Involving Māori* (which contains Te Ara Tika as an appendix). Unfortunately, the responses to these questions, and how a study might impact health inequality, historically and consistently have been answered poorly. The uni-dimensional focus along with the uneven stance taken by the current ethics committees in respect to these questions does not augur well for the creating of ethics review processes that keep Māori participants safe in the context of genetic research and biobanking.

Engagement with Māori Through Research Partnerships

A recent comprehensive international review and comparative analysis of Indigenous research guidelines in New Zealand, Australia, Canada, and the United States (US) identified a number of areas of concern and a need for further work in developing research policy that promotes respectful engagement with Indigenous communities (Taniguchi, Taualii, & Maddock, 2012). In New Zealand, Australia, and the US, there is currently no direction to seek community engagement during the development of research protocols as there is in Canada, although all countries did provide some guidance in other areas of community consultation (Taniguchi et al., 2012). And unlike Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Canadian Institutes for Health Research, National Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, 2010), New Zealand's *Guidelines for Researchers on Health Research Involving Māori* (Health Research Council New Zealand, 2008), does not provide guidance on the use and storage of biological materials, prioritization of research uses, or post-research obligations (other than community review of study findings before release).

More specifically, New Zealand research guidelines do not stipulate a requirement to define potential uses prior to sample collection, to make provision for individual or community withdrawal of samples, to discuss secondary uses with contributing individuals or communities, or to obtain community approval for secondary uses of material or the resulting genetic data (Taniguchi et al., 2012), although researchers may opt to do so. Furthermore, there is no direction around prioritization of research uses such that the research should benefit the contributing population, or a requirement that a clear position on commercial applications be disclosed.

Thus there is much to learn from the experiences of Indigenous people in other countries. The National Congress of American Indians (NCAI) Policy Research Center (PRC) has made an important commitment to education through the provision of specific resources that address unique considerations in conducting research with American Indian and Alaska Native (AI/AN) communities. Toolkits are freely available to communities and individuals who may have questions about genetic research including frequently asked questions; common concerns regarding stigmatization, data sharing, and strategies for addressing these concerns; and sample consent forms and research agreements for tribal communities (National Congress of American Indians, 2014a). Information is also available to researchers who have questions about how to effectively partner with AI/AN communities covering information about Indigenous knowledge, ethics, research policies, and protocols, and negotiation of research relationships with communities (National Congress of American Indians, 2014b).

In Canada, tribal governments have the legal authority to regulate research that is conducted on their lands and with their citizens (Deloria, 2003) and tribes as a result have employed a variety of research review processes (Sahota, 2007). These range from the involvement of Tribal Councils to the establishment of tribal research review boards and/or partnerships with others to review protocols that are presented to the community. If an AI/AN community does develop formal guidelines for research that is undertaken with their tribal members, researchers may be required to provide a written commitment to abide by these policies. Penalties may also be applied if researchers conduct unapproved research or violate other agreed terms for conducting research (Sahota, 2007). This is not currently the case in New Zealand.

Engagement with Māori in the Policy Development Process

In terms of satisfying Crown responsibilities under the Treaty, it is pivotal that Māori, in partnership with the Crown, participate meaningfully in any policy or legislation that would shape the context of biobanking and genetic research for Māori in a way that augments potential benefits while controlling the level of risk and giving protection to taonga. The Treaty can be viewed as "the founding document of New Zealand" (McDowell & Webb, 2006) and "a constitutional document" (Palmer, 2002), that many Māori see as "the most important document in New Zealand's history" (Cooke, 1990). It provides principles that include protection, partnership, and participation; however, there is no reference to the Treaty or the principles of the Treaty either within the Privacy Act (1993) or the Health Information Privacy Code (1993). There is also insufficient provision to adequately support and promote Māori approaches within the decision-making around these issues.

The Treaty clearly recognises the right of self-determination or tinorangatiratanga for Māori.[9] Kaitiakitanga (a way of managing the environment) is inherently linked to rangatiratanga (the right to exercise authority, autonomy, self-determination, self-management, and ownership) and rights of action over those taonga as they are used in genetic research (Treaty of Waitangi, 1840). In this way, Māori should be involved in the governance and regulation of biobanks and in the development of ethical standards for research and biobanking practices. This concept has been increasingly brought

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[9] See the Māori text that enables continuing rangatiratanga of Māori tribes over their possessions and taonga and asserts that the Crown would protect that rangatiratanga. This includes the right of self-determination and the right of development. The Crown receives the right to govern, a delegated power, subject to continuing Māori authority.

into New Zealand public policy on trusteeship or guardianship, especially in relation to environmental and resource controls under the Resource Management Act (1991, see section 7A).

While it has been acknowledged that Māori have an individual right to participate in biobanking and genetic research, the collective may assert its authority to protect their whakapapa as a taonga under Article 2 of Te Tiriti o Waitangi (Henagan, 2006). By paying regard to the benefits that could be associated with biobanking, this hurdle could be surmounted through creating a practical balance between the rights of the individual and those of the collective.

The United Nations (2008) Declaration on the Rights of Indigenous Peoples confirms the right of Māori to maintain control and protect their genetic resources. Article 31 provides:

> 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
>
> 2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights. (p.11)

Intellectual property is also of relevance to the protection of Māori interests in biobanking and genetic research. The World Intellectual Property Organization (WIPO) is the global forum for intellectual property services, policy, information, and cooperation. The WIPO Inter Governmental Committee (IGC) was established by the WIPO General Assembly in 2000 to provide a forum for States to discuss intellectual property issues in relation to traditional knowledge (TK), genetic resources (GRs), and traditional cultural expressions (TCEs or "expressions of folklore"). In 2009, the WIPO General Assembly authorized the IGC to undertake negotiations with the intention of reaching an agreement on the text of an international instrument to protect traditional knowledge, genetic resources, and traditional cultural expressions. The WIPO IGC is currently drafting three texts to encapsulate and control the use and dissemination of TK, GRs and TCEs. If the text on GRs is ratified, by the General Assembly of States, this could potentially become binding on New Zealand and provide further protection for Māori (WIPO IGC, n.d.).

In summary, Te Tiriti o Waitangi and the United Nations Declaration on the Rights of Indigenous Peoples provide clear support for Māori, as Indigenous people, to govern their own process of collection, storage, and use of genetic material. Whether Māori participate in existing biobanks in New Zealand or seek to govern their own, it is important for Māori that their agency in processes that affect them is enhanced, in order to achieve population-level health outcomes (Fullerton, Knerr, & Burke, 2012).

Moving Forward

There are a number of steps Māori could take to protect individual participants and communities participating in biobanking and genetic research. Based on the “gaps” in the framework of current legislation, policy, and practice in New Zealand, a number of practical recommendations of international relevance are suggested to afford protection to Māori who choose to engage in biobanking and genetic research.

1. Engage Māori, the medical, and the scientific community and government agencies to inform the development of cultural guidelines for biobanking and genetic research in New Zealand and elsewhere to ensure culturally safe interactions with participants and communities can occur.

2. Make educational resources available to researchers about how to effectively partner with Māori communities covering information about Indigenous knowledge, ethics, research policies and protocols, and negotiation of research relationships and priorities with communities. This information could be available on a website for the scientific community at a national and international level.

3. Support Māori communities to develop their own research strategy; criteria for the assessment and evaluation of research proposals; and formal guidelines for research that is undertaken with them, which could include restrictions on the future use of biospecimens collected for specific research projects.

4. Provide "toolkits" for Māori, available collectively and individually, about biobanking and genetic research including frequently asked questions, common concerns regarding data sharing, and strategies for addressing these concerns. Sample consent forms and research agreements and contracts should also be made available to communities.

5. Communities may consider applying penalties (for example, rejection of future research requests with Māori communities) if researchers conduct unapproved research or violate other agreed terms for conducting research. This notion could be extended to ethics review and research funding mechanisms.

6. Promote forums for Māori communities to share best practice examples of how communities are already participating in genetic research and biobanking to effectively build capacity and to ensure Māori interests are better protected.

Moving forward, "next-generation" regulation that provides more cohesive policies and legislation will be needed to inform the development of national and international systems equipped to deal with the challenges of biobanking and associated large-scale, population-level genomic research. Beyond continued engagement in the ethics review process, accompanying sustainable mechanisms that enable Māori participation in policy development and build trust, support and effective research partnerships between Māori communities and researchers must be established and sustained. A strong commitment to education that bridges cultural and communication differences and builds the capability of all stakeholders will be required.

References

Ahuriri-Driscoll, A., Hudson, M., Foote, J., Hepi, M., Rogers-Koroheke, M., Taimona, H., & Symes, J. (2007). Scientific collaborative research with Māori communities: Kaupapa or Kupapa Māori? *AlterNative: International Journal of Indigenous Scholarship, 3*(2), 60-81.

Auckland District Health Board. (2003). *Tikanga recommended best practice.* Retrieved from http://www.adhb.govt.nz/researchoffice/mrrc/tikanga_-_rbp.html

Barlow, C. (1991). *Tikanga whakaaro: Key concepts in Māori culture.* Auckland, NZ: Oxford University Press.

Boulton, A., Hudson, M., Ahuriri-Driscoll, A., & Stewart, A. (2014). Enacting kaitiakitanga: Challenges and complexities in the governance and ownership of rongoā research Information. *The International Indigenous Policy Journal, 5*(2), 1. Retrieved from http://ir.lib.uwo.ca/iipj/vol5/iss2/1

Canadian Institutes of Health Research (CIHR). (2012). *Guide to knowledge translation planning at CIHR: Integrated and end-of-grant approaches.* Ottawa, Canada: Author.

Canadian Institutes for Health Research, National Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2010). *Tri-council policy statement: Ethical conduct for research involving humans.* Ottawa: Author.

Caulfield, T. (2007). Biobanks and blanket consent: The proper place of the public perception and public good rationales. *King's Law Journal,* 18, 209-226.

Cheung, M. (2011). *Cellular and cultural studies of human neurodegenerative diseases* (Unpublished doctoral dissertation). University of Auckland, Auckland.

Cheung, M., Gibbons, H., Dragunow, M., & Faull, R. (2007). Tikanga in the laboratory: Engaging safe practice. *MAI Review,* 1, 1.

Cooke, R. (1990). Introduction. *New Zealand Universities Law Review, 14*(1), 1-8.

Cram, F., Pihama, L, & Barbara, G. (2000). *Māori and genetic engineering.* Auckland: International Institute for Māori and Indigenous Education.

Cram, F., Phillips, H., Tipene-Matua, B., Parsons, M., & Taupo, K. (2004). A 'parallel process'? Beginning a constructive conversation about a Mäori methodology. *Journal of Bioethical Inquiry,* 1, 14-19.

Deloria, P. (2003). *The role of tribal government in regulating research.* Portland: Northwest Portland Area Indian Health Service Institutional Review Board.

Du Plessis, R. (2007). *Biobanking in Aotearoa New Zealand: A case study of the New Zealand Rare Disease Biobank operated by the NZ Institute for Rare Disease Research Ltd* (Report No. 11). Christchurch, NZ: University of Canterbury.

Fullerton, S., Anderson, N., Guzauskas, G., Freeman, D., & Fryer-Edwards, K. (2010). Meeting the governance challenges of next generation bio repository research. *Science Translational Medicine*, *2*(15), 1-4.

Fullerton, S., Knerr, S., & Burke, W. (2012). "Finding a place for genomics in health disparities research." *Public Health Genomics, 15*(3-4), 156-163.

Gillett, G., & Douglass, A. (2012). Ethics committees in New Zealand. *Journal of Law and Medicine, 20*(2), 266-272.

Gudmundsdottir R v. The State of Iceland. (2003). No. 151/2003 Icelandic Supreme Court.

Health Act, No. 65. (1956). Retrieved from http://www.legislation.govt.nz/act/public/1956/0065/latest/DLM305840.html

Health (Cervical Screening (Kaitiaki)) Regulations (1995) SR 1995/29. Pursuant to sections 74A and 117 of the Health Act, 1956. Retrieved from http://legislation.govt.nz/regulation/public/1995/0029/latest/DLM198873.html

Health and Disability Commissioner Act, No. 88. (1994). Retrieved from http://www.legislation.govt.nz/act/public/1994/0088/latest/DLM333584.html

Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations, (1996). SR 1996/78. Pursuant to section 74(1) of the Health and Disability Commissioner Act 1994. Retrieved from http://www.legislation.govt.nz/regulation/public/1996/0078/latest/whole.html

Health Information Privacy Code (1994). Retrieved from http://privacy.org.nz/health-information-privacy-code

Health Research Council New Zealand. (2008). *Guidelines for researchers on health research involving Māori.* Auckland, NZ: Health Research Council NZ.

Health Select Committee. (2011). *Inquiry into improving New Zealand's environment to support innovation through clinical trials* (1.6F). Presented to the House of Representatives. Retrieved from http://www.parliament.nz/resource/en-nz/49DBSCH_SCR5154_1/19f143ece9bbafc1f5970397e5d92a582e003faa

Hemara, W. (2006). *Tikanga Māori, mātauranga Māori & bioethics: A literature review.* Report to the Bioethics Council. Mauriora ki te Ao Living Universe Ltd. Retrieved from http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf

Henagan, M. (2006). *Choosing genes for future children: Regulating pre-implantation genetic diagnosis.* Dunedin, NZ: University of Otago.

Hope, F., Molster, C., & O'Leary, P. (2009). Persistent disagreement about biobanks and the impact on public policy arising from public and consumer group engagement. [Abstract 182] *Journal of Twin Research*, May.

Hudson, M. (2004a). Māori perspectives on ethical review in (health) research. *Proceedings of Tikanga Rangahau, Matauranga Tuku Iho Research Ethics & Traditional Knowledge Conference* (pp. 57-76). Auckland, NZ: Nga Pae o Te Maramatanga, Auckland.

Hudson, M. (2004b). *He matatika Māori. Māori and ethical review in health research* (Unpublished Master's thesis). Auckland University of Technology, Auckland.

Hudson, M. (2009). Think globally, act locally: Collective consent and the ethics of knowledge production. *International Social Science Journal, 60*(195), 125-133.

Hudson, M., Ahuriri-Driscoll, A., Lea, G., & Lea, R. (2007). *Whakapapa - A foundation for genetic research?* Paper presented at the Bioethics Conference, February 10, 2006, Dunedin. Retrieved from http://www.ncaiprc.org/research-regulation-papers

Hudson, M., Allan, C., Bedford, K., Buckleton, J., & Stuart, K. (2008). The impact of Māori cultural values on forensic science practice in New Zealand. *Journal of Forensic Sciences, 53*(2), 380-383.

Hudson, M., Milne, M., Reynolds, R., Russell, K., & Smith, B. (2010). *Te ara tika: Guidelines for Māori research ethics: A framework for researchers and ethics committee members*. Auckland: The Health Research Council of New Zealand on behalf of the Putaiora Writing Group.

Hudson, M., Roberts, M., Smith, L., Tiakiwai, S., & Hemi, M. (2012). The art of dialogue with Indigenous communities in the new biotechnology world. *New Genetics and Society, 31*(1), 11-24.

Human Tissue Act, No. 28. (2008). Retrieved from http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html

Hutchings, J. (2009). A transformative Māori approach to bioethics. *Matariki, 1*(3), 173-194.

Hutchings, J., & Reynolds, P. (2007). Māori and the 'McScience' of new technologies: Biotechnology and nanotechnology development. *Matariki, 1*(1), 81-111.

Icelandic Act on Health Sector Database, No. 139/1998 (1998).

Jones, R. (2000). Rongoä Mäori and primary health care (Unpublished masters thesis). University of Auckland, Auckland, New Zealand.

Jones, R., Crengle, S., & McCreanor, T. (2006). How tikanga guides and protects the research process: Insights from the Hauora Tane Project. *Social Policy Journal of New Zealand*, 29, 60-77.

Lee, J. Y. (2012). The laws of privacy and consent and large-scale DNA biobanking in New Zealand (Thesis, Master of Laws). University of Otago. Retrieved from http://hdl.handle.net/10523/2604

McDowell, M., & Webb, D. (2006). *The New Zealand legal system: Structures and processes* (4th ed.). Wellington, New Zealand: LexisNexis.

Mark, G.T., & Lyons, A.C. (2010). Māori healers' views on wellbeing: The importance of mind, body, spirit, family and land. *Social Science and Medicine, 70*(11), 1756-1764.

Marsden, M. (2003). Kaitiakitanga: A definitive introduction to the holistic worldview of the Māori. In T. A. C. Royal (Ed.), *The woven universe: Selected writings of Rev. Māori Marsden* (pp. 54-72). Ōtaki: The estate of Rev. Māori Marsden.

Maschke, K. J. (2005). Navigating an ethical patchwork – Human gene banks. *Nature Biotechnology*, *23*, 539-545.

Mead, H. (2003). *Tikanga Māori: Living by Māori values.* Wellington: Huia Publishers.

Ministry for the Environment. (2002). *Report of the Royal Commission on Genetic Modification.* Retrieved from http://www.mfe.govt.nz/publications/organisms/royal-commission-gm/

Ministry of Health. (2007). *Guidelines on the use of human tissue for future unspecified research purposes.* Wellington: Ministry of Health.

Ministry of Health. (2014). *National Kaitiaki Group.* Retrieved from http://www.health.govt.nz/our-work/populations/Māori-health/national-kaitiaki-group

Mongoven, A. M., & Solomon, S. (2012). Biobanking: Shifting the analogy from consent to surrogacy. *Genetics in Medicine, 14*, 183–188.

Moore v. Regents of the University of California. (1990). 51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479 Supreme Court of California.

Multi-Region Ethics Committee. (2006). *Annual report.* New Zealand: Author.

National Congress of American Indians. (2014a). *American Indian and Alaska Native Genetics Resource Center. For tribes.* Retrieved from http://genetics.ncai.org/for-tribes/

National Congress of American Indians. (2014b). *American Indian and Alaska Native Genetics Resource Center. For researchers.* Retrieved from http://genetics.ncai.org/for-researchers/

National Ethics Advisory Committee. (2012a). *Ethical guidelines for observational studies: Observational research, audits and related activities* (Revised ed.). Wellington: Ministry of Health.

National Ethics Advisory Committee. (2012b). *Ethical guidelines for intervention studies* (Revised ed.). Wellington: Ministry of Health.

New Zealand Bill of Rights Act, No. 109. (1990). Retrieved from http://www.legislation.govt.nz/act/public/1990/0109/latest/DLM224792.html

Nikora, L. W., Masters, B., & Te Awekotuku, N. (2012). Final arrangements following death: Māori Indigenous decision making and tangi. *Journal of Community & Applied Social Psychology, 22*(5), 400-413.

Northern Y Health and Disability Ethics Committee. (2008). *Annual report.* New Zealand: Northern Y Health and Disability Ethics Committee.

Office of the Privacy Commissioner. (2013). *New Zealand Law Commission privacy review.* Retrieved from http://privacy.org.nz/the-privacy-act-and-codes/privacy-law-reform-resources/new-zealand-law-commission-privacy-review/

Palmer, G. (2002). *Constitutional conversations: Geoffrey Palmer talks to Kim Hill on National Radio 1994-2001.* Wellington: Victoria University Press.

Palsson, G. (2008). The rise and fall of a biobank: The case of Iceland. In H. Gottweis, & A. Petersen (Eds.), *Biobanks governance in comparative perspective* (pp. 41-55). London: Routledge.

Pihama, L., Cram, F., & Walker, S. (2002). Creating methodological space: A literature review of Kaupapa Māori research. *Canadian Journal of Native Education, 26*(1), 30-43.

Privacy Act, No. 28. (1993). Retrieved from http://www.legislation.govt.nz/act/public/1993/0028/latest/DLM296639.html

Port, R.V., Arnold, J., Kerr, D., Glavish, N., & Winship, I. (2008). Cultural enhancement of a clinical service to meet the needs of indigenous people; genetic service development in response to issues for New Zealand Māori. *Clinical Genetics, 73*(2), 132-138.

Resource Management Act, No. 69. (1991). Retrieved from http://www.legislation.govt.nz/act/public/1991/0069/latest/DLM230265.html

Roberts, M., & Fairweather, J. (2004). *South Island Māori perceptions of biotechnology* (Report No. 268). Christchurch: Lincoln University.

Roberts, M. (2005). Walking backwards into the future: Maori views on genetically modified organisms. *World Indigenous Nations Higher Education Consortium Journal.* Retrieved from http://www.win-hec.org/docs/pdfs/Journal/Mere%20Roberts.pdf

Sahota, P. C. (2007). Research regulation in American Indian/Alaska Native communities: Policy and practice considerations. Washington, DC: National Congress of American Indians Policy Research Center. Retrieved from http://ncaiprc.org/files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf

Smith, L. (1998). *Decolonising methodologies: Research and Indigenous peoples.* New York: Zed Books.

Taniguchi, N., Taualii, M., & Maddock, J. (2012). A comparative analysis of Indigenous research guidelines to inform genomic research in Indigenous communities. *The International Indigenous Policy Journal, 3*(1), 6. Retrieved from http://ir.lib.uwo.ca/iipj/vol3/iss1/6/

Tawhara, K. (2005). *Attitudes of Māori towards genetic research.* Prepared for the Māori Indigenous Health Institute (MIHI), and the Cardioendocrine Research Group, Christchurch School of Medicine and Health Sciences. Dunedin: University of Otago.

Te Momo, O. H. (2007). Biotechnology: The language of multiple views in Māori communities. *Biotechnology Journal, 2*, 1179–1183.

Tipene-Matua, B. (2006). *Having honest conversations about the impact of new technologies on Indigenous people's knowledge and values.* In J. S. Te Rito (Ed.), *Mātauranga taketake: Traditional knowledge Indigenous indicators of well-being: Perspectives, practices, solutions* (pp. 155-166). Retrieved from www.maramatanga.ac.nz/sites/default/files/TKC-2006.pdf

Treaty of Waitangi (1840). Retrieved from http://www.treatyofwaitangi.maori.nz/

Tupara, H. (2012). Ethics and health research: Decision making in Aotearoa New Zealand. *AJOB Primary Research, 3*(4), 40-52. doi: 10.1080/21507716.2012.714834

UK Biobank Ethics and Governance Council. (2007). *Workshop report: Involving publics in biobanks.* United Kingdom, UK Biobank Ethics and Governance Council. Retrieved from http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf

United Nations. (2008). *United Nations Declaration on the Rights of Indigenous Peoples.* Retrieved from www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf

World Intellectual Property Organization (WIPO). (n.d.). *Intergovernmental Committee.* Retrieved from http://www.wipo.int/tk/en/igc/

Appendix

Summary of Legislation, Policy and Ethical Protection in Biobanking and Research

Māori

- Te Tiriti o Waitangi (the Treaty of Waitangi) (1840)
- United Nations Declaration on the Rights of Indigenous Peoples (2008)
- Guidelines for Researchers on Health Research Involving Māori (2008)

Guidelines for Research with Māori

- Health Research Council New Zealand Guidelines for Researchers on Health Research Involving Māori (2008)
- Te Ara Tika: Guidelines for Māori Research Ethics—A Framework for Researchers and Ethics Committee Members (2010)

Privacy

- Privacy Act (1993)
- Health Information Privacy Code (1994)

Informed Consent

- Health and Disability Commissioner Act (1994)
- Code of Health and Disability Services Consumers' Rights (1996)

Ethical Approval for Research

- New Zealand Public Health and Disability Act (2000)
- Operational Standard for Ethics Committees (2006)
- National Ethics Advisory Committee Ethical Guidelines for Observational Studies (2012a)
- National Ethics Advisory Committee Ethical Guidelines for Intervention Studies (2012b)

Biobanking and Research

- Health Act (1956)
- Human Tissue Act (2008)

- Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes (2007)