



March 2012

## A Comparative Analysis of Indigenous Research Guidelines to Inform Genomic Research in Indigenous Communities

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### Recommended Citation

Taniguchi, N. K. , 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) . Retrieved from: <https://ir.lib.uwo.ca/iipj/vol3/iss1/6>

**DOI:** 10.18584/iipj.2012.3.1.6

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# A Comparative Analysis of Indigenous Research Guidelines to Inform Genomic Research in Indigenous Communities

## **Abstract**

**BACKGROUND:** Genetic research has potential benefits for improving health, such as identifying molecular characteristics of a disease, understanding disease prevalence and treatment, and developing treatments tailored to patients based on individual genetic characteristics of their disease. Indigenous people are often targeted for genetic research because genes are easier to study in communities that practice endogamy. Therefore, populations perceived to be more homogenous, such as Indigenous peoples, are ideal for genetic studies. While Indigenous communities remain the focal point of many genomic studies, some result in harm and unethical practice. Unfortunately, the harms of poorly formulated and unethical research involving Indigenous people have created barriers to participation that prevent critical and lifesaving research. These harms have led a number of Indigenous communities to develop guidelines for engaging with researchers to assist in safely bridging the gap between genetic research and Indigenous peoples.

**SPECIFIC AIMS:** The specific aims of this study were: (1) to conduct an international review and comparison of Indigenous research guidelines that highlight topics regarding genetics and use of biological samples and identify commonalities and differences among ethical principles of concern to Indigenous peoples; and (2) develop policy recommendations for Indigenous populations interested in creating formal policies around the use of genetic information and protection of biological samples using data from specific aim 1.

**METHODS:** A comparative analysis was performed to identify best research practices and recommendations for Indigenous groups from four countries: Canada, New Zealand, Australia, and the United States. The analysis examined commonalities in political relationships, which support self-determination among these Indigenous communities to control their data. Current international Indigenous guidelines were analyzed to review processes of how genetic research is conducted and the use of biological samples is handled with Indigenous peoples.

**RESULTS:** Results suggest the need for genetic and genomic research policies for the world's Indigenous people. Indigenous groups are most vulnerable to research exploitation and harm; therefore, identifying principles that work for Indigenous people will lead to best practices for all populations.

**CONCLUSIONS:** Development and implementation of best practices informed by research guidelines in Canada, New Zealand, Australia, and the U.S. may be helpful to advise Indigenous leaders, policy makers, and researchers to the proper conduction of genetic research within Indigenous communities. Comparative analyses are a useful tool for identifying areas for further work in developing genetic research policy for Indigenous communities.

**OUTCOME:** The outcomes of this analysis are relevant and useful to Indigenous communities and inform the development of community-based genetic research guidelines. The recommendations can be used in designing appropriate policies for future genomic research with Indigenous peoples.

## **Keywords**

genetic research, genomic research, Indigenous communities

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### **Acknowledgments**

Partial funding support was provided by the National Institutes of Health, National Cancer Institute: Knowledge, Attitudes, and Practices on Biobanking among Native Hawaiians, U54 CA 153459-01 (Chong). I would like to thank Dr. Maile Taulii and Dr. Jay Maddock for their direction, assistance, and guidance. In particular, Dr. Taulii's recommendations and suggestions have been invaluable for this research.

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## **A Comparative Analysis of Indigenous Research Guidelines to Inform Genomic Research in Indigenous Communities**

Population-based research attempts to address the unknown causes of health disparities among population groups by assessing risk factors and identifying interventions to prevent or treat disease and, ultimately, lead to the development of methods for protecting a community's health (Taylor & Johnson, 2007). Genetic information has been significant in identifying at-risk groups; for example, some groups have increased disease incidence due to a genetic predisposition with or without a definable environmental exposure (Khoury et al., 2000; Knoppers & Brand, 2008). Genetic research is generally disease-specific, which has implications for both rare genetic conditions and common diseases (Hawkins, 2010).

It is crucial to gain a better understanding of interactions between the genes that make up the human genome and the role of the environment on those genes to more clearly assess reasons for health versus susceptibility to disease (Knoppers, et al., 2010). Genetic research among population groups must not only provide health benefits, but must also serve develop strategies and create policies to protect historically disadvantaged groups from harm inherent in this type of research.

Currently, there is a high level of anxiety surrounding genetic research in Indigenous and minority communities (Freimuth et al., 2001; Humphery, 2001; Smith, 1999). The history and ongoing exploitive relationships between Indigenous and non-Indigenous peoples have severely damaged Indigenous peoples' trust in non-Indigenous societies. This lack of trust affects all research initiated by non-Indigenous people, including research that aims to improve Indigenous health. As Roderick McInnes (2011), President of the American Society of Human Genetics, noted in his 2010 Presidential Address, Indigenous peoples have "been left with a sense of mistrust, stigmatization, or weakened political authority" (p. 254). Consequently, many Indigenous people relate genetic research to their experiences of colonization, which makes genetic research a most controversial type of health research.

The extent to which existing research guidelines are successful at minimizing harms inherent in genetic research remains an issue among Indigenous groups. A comparative analysis of four countries (Canada, New Zealand, Australia, and the United States) was carried out to understand and identify ethical concerns surrounding genetic research with Indigenous peoples. This understanding will help to inform formal policy making around the use of genetic information and protection of biological samples for Indigenous communities.

### **Genetic Research**

Indigenous people are most strongly opposed to population genetics, a category within genetic research. Some Indigenous groups believe that genetic research into human population history threatens their cultural beliefs. For example, evolutionary accounts of history stated that Native Americans migrated to North America through the Bering Strait 15,000 to 45,000 years ago. This caused uproar among Native Americans because they believed their ancestors had always been in North American and did not "arrive" from somewhere else (Foster & Sharp, 2000). Native Americans have also refused DNA research on ancestral remains found on their lands (Tallbear, 2003).

In 2005, the National Geographic Society and International Business Machines (IBM) launched the "Genographic Project", a genetics research project targeting Indigenous populations (National Geographic, n.d.; Indigenous Peoples Council on Biocolonialism, 2000). The public was invited to send their DNA to National Geographic in order to study human migrations. This initiative attracted negative press very quickly, as the headline of a *New York Times* article read "DNA Gatherers Hit Snag: Tribes Don't Trust Them" (cited in McInnes, 2011). Pullman and Arbour (2009) suggested that findings from this project could "undermine cultural narratives about a people's origins that have been held for generations or centuries and could alter perceptions of who's in and who's out of particular cultural groups" (p. 257).

Further, two projects preceding the Genographic Project were the Human Genome Diversity Project (the HGDP) and the International HapMap, which were explicitly involved in genetic testing of Indigenous peoples for medical research. The aim of the HGDP was to record genetic profiles of endogamous populations to help explain why certain ethnic populations are vulnerable or resistant to certain diseases (Cavalli-Sforza, 2005). The HapMap Project was designed to study haplotypes, genetic markers that consist of closely linked groups of alleles that tend to be inherited together, and then develop a haplotype map of the human genome (International HapMap Project, n.d.). The HapMap intended to describe the common patterns of human DNA sequence variations in order to search for genes affecting health, disease, and responses to environmental factors. Indigenous groups voiced their opposition towards both of these projects because they felt as though they were being seen as mere sources of useful information.

In these instances, researchers failed to recognize the legal, ethical, and socio-cultural implications of genetic testing among their target research populations. The participatory research approach was not upheld. A common complaint among Indigenous peoples regarding research is that it benefits the researchers but not the population being studied. Laura Abour (2008) at the University of British Columbia stated that within our world's investigator-driven biomedical research model "the subjects have little voice in the research process, they waive rights of benefit sharing in general, the data and samples are 'owned' by the researcher, and the results go to journals and are not specifically ever directed back to or shared with the research subjects." Because Indigenous communities are often targets of genetic research, Indigenous peoples are becoming more cautious about data interpretation, data ownership, and involvement in research design.

Biobanks, essential to genetic research, collect human biological tissue specimens and related health data to answer research questions or test hypotheses (Hawkins, 2010). Banked tissue samples are used to help scientists and researchers identify diseases or conditions, to measure a patient's response to therapy, or to find appropriate treatments (National Cancer Institute, 2010). The main purpose of storing specimens for research is to identify genetic and environmental factors that predispose individuals to common diseases, such as heart disease, cancer, and mental illness. These storage banks are becoming increasingly valuable in health research. Their possibilities are numerous, and many remain unrealized (Research Advocacy Network, 2005). *Time Magazine* recently named biobanks as one of the "top ten ideas changing the world right now" (Park, 2009, p. 1). However, several concerns arise around the storage of specimens, including issues of confidentiality, transparency, and donors' rights to access and control over their own data (Godard, Marshall, Laberge, & Knoppers, 2004), which raises additional issues in the process of engaging in genetic research with Indigenous populations. These issues have been addressed to varying degrees among comparison countries.

### **Importance of Genomic and Genetic Research with Indigenous Peoples**

Genetic research can provide significant health-related benefits for Indigenous peoples. It is the homogeneity due to endogamy, norms that encourage reproduction within the group, among many Indigenous groups that is valuable in genetic studies (Mgbeoji, 2007). Increased homogeneity allows researchers to readily study a particular gene or loci of interest among affected and non-affected participants. For example, studies show greater prevalence rates of diabetes among Indigenous communities worldwide (Maple-Brown, Sinha, & Davis, 2010; Moy, Sallis, & David, 2010; White, Wong, Sureshkumar, & Singh, 2010). By looking at the DNA of particular groups, researchers hope to find genes that are relevant for understanding ailments, such as diabetes, heart disease, and infectious diseases. Finding these genes may lead to the development of new treatments or vaccines that will benefit the whole population. It may also allow for those at higher risk of contracting these diseases to be identified as targets for prevention and health promotion (Davey-Smith, 2007; Khoury, 2009).

### **Methods**

A comparative analysis of four countries – Canada, New Zealand, Australia, and the United States – was

conducted to synthesize research guidelines affecting Indigenous people. The research aims were to review existing international guidelines concerning genetic research; conduct a comparative analysis of the research guidelines in each of the four countries; and identify top priority concerns and topics within each country to further provide policy recommendations for Indigenous communities interested in creating formal policies around the use of genetic information and protection of biological samples. Countries with significant research guideline development specific to genetic research and a history of involvement in genetic research issues were chosen for analysis.

### Specific Aim 1: Comprehensive International Review and Comparative Analysis

A comprehensive international review of Indigenous research guidelines related to genetic research was conducted. Existing guidelines for Indigenous groups across the four countries – Canada, New Zealand, Australia, and the United States – were analyzed for this project. This research was carried out in partnership with the Native Hawaiian Epidemiology Centre, which provided relevant library resources. A critical analysis of research guidelines was conducted to look at common themes and identify notable voids in the four countries studied.

### Specific Aim 2: Matrix

Based on the guideline analysis in Specific Aim 1, a matrix was created highlighting top ethical concerns and priorities across the four countries to provide a framework for other Indigenous communities interested in developing formal policies around the use of genetic information and protection of biological samples.

## Results

### Aim 1: Comprehensive International Review and Comparative Analysis

The following section outlines research guidelines developed in Canada, New Zealand, Australia, and the US. Table 1 illustrates a historical timeline of Indigenous research guidelines developed in each country.

Table 1. Timeline of Indigenous Research Guidelines in Comparison Countries

Country	Title	Date	Author
United States	<i>Indigenous Research Protection Act</i>	2000	Indigenous Peoples Council on Biocolonialism (IPCB)
Australia	<i>Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research</i>	2003	National Health and Medical Research Council (NHMRC)
Canada	<i>Guidelines for Health Research Involving Aboriginal People</i>	2007	Canadian Institutes of Health Research (CIHR)
New Zealand	<i>Guidelines for Researchers on Health Research</i>	2008	Health Research Council of New Zealand (HRCNZ)

**Canada: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Guidelines for Health Research Involving Aboriginal People.** The Nuu-chah-nulth, a tribe on the west coast of Vancouver Island in British Columbia, made significant contributions to the development of Canadian guidelines on research with Indigenous populations (Dalton, 2002; Canadian Institutes of Health Research, 2007; Pullman & Arbour, 2009). In the early 1980s, Dr. R. H. Ward at the University of British Columbia approached tribal leaders to undertake a search for HLA alleles that may have been linked to arthritis in this tribe (McInnes, 2011). Leaders and all individuals in the community gave informed consent for the study. After 900 participants failed to demonstrate a linkage, the DNA was moved to other research

centers without the tribe's consent and was used for research that had not been authorized in the original agreement. The Nuu-chah-nulth were particularly concerned that samples would be used for genetic ancestry studies, an area of genetic research that is controversial for a number of culturally specific reasons, including spiritual beliefs about the manipulation of biological materials, oral traditions of origins or population history, and issues surrounding race and identity (Bolnick et al., 2007; Royal et al., 2010). Genetic ancestry studies, such as the Genographic Project, utilize five problematic narratives: (1) "we are all African"; (2) "genetic science can end racism"; (3) "Indigenous peoples are vanishing"; (4) "we are all related"; and (5) the Genographic Project "collaborates" with Indigenous peoples (T'Allbear, 2007).

Further, the DNA was not returned to the Nuu-chah-nulth until 20 years after the samples were collected. As a result, the tribe felt betrayed and mistrusted researchers. The elected Chief formed a committee to establish conditions that researchers would be required to follow if they wished to conduct future research with their community members. Consequently,

Canada's three federal agencies, known as "the Agencies" – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) – created the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) (CIHR, NSERC, & SSHRC, 1998). This policy was created to guide Canadian researchers in the ethical conduct of research involving humans. Section 6 of the TCPS states:

There is growing recognition that some research involving Aboriginal individuals may also involve the communities or groups to which they belong. The Agencies affirm that in developing ethical standards and practices, Aboriginal peoples have rights and interests that deserve recognition and respect by the research community. (CIHR, NSERC, & SSHRC, 1998, p. 6.1)

Unfortunately, Section 6 was left incomplete due to the Agencies' lack of consultation with the Aboriginal people, organizations, and researchers involved. To redress this, the Ethics Office of CIHR prepared the *Guidelines for Health Research Involving Aboriginal People* to assist researchers and institutions in conducting ethical and culturally sound research involving Aboriginal people (CIHR, 2007). These guidelines are outlined in Chapter 9 of the second edition of the TCPS (TCPS2) (CIHR, NSERC, & SSHRC, 2010).

Chapter 13 of the TCPS2 (containing Articles 13.1 to 13.7 inclusive, which are reproduced in Appendix A) concerns the use of genetic information for research. Genetic information has implications that extend beyond the individual since it may reveal facts about biological relatives and others with whom the individual shares genetic ancestry. Researchers may sometimes seek to conduct genetic research with family members or communities to look further into the social and cultural contexts in which participants live. As a result, concerns arise around participant recruitment, the consent process, privacy, and confidentiality.

CIHR's (2007) *Guidelines for Health Research Involving Aboriginal People* considers the use and storage of biological samples in sections 2.12 (containing Articles 12.1 to 12.5 inclusive) and 2.13 (Article 13). These sections are relevant to genetic research, as the guidelines set forth basic principles for the collection, disclosure, use, and transfer of data and biological samples (see Appendix B).

Much of the criticism directed towards research involving Aboriginal populations relates to the loss of control over data or biological samples collected from Aboriginal people. In addition, serious concern has been raised over the inappropriate use of stored biological samples, including DNA and cell lines, for unauthorized research. It is crucial for researchers to understand that ownership of traditional and sacred knowledge should always remain with the community.

Safeguards protecting the privacy and confidentiality of data and biological samples should be specified in a research agreement. If there is to be a transfer of the data or biological samples to a third party, consent must be obtained by researchers from the individual participants and community. If the third party wishes to

engage in secondary use of the transferred data or samples, then further consent must be obtained. In every case, secondary use of the data or biological samples requires new consent unless specified in the research agreement. Lastly, individuals have the right to access data about themselves (CIHR, 2007).

The following section introduces the concept of “DNA on loan”, which enables research to be carried out yet protects the interests of the individuals, families, and communities involved (Arbour & Cook, 2006).

**Biological samples on loan.** Article 13 states that “biological samples should be considered ‘on loan’ to the researcher unless otherwise specified in the research agreement” (CIHR, 2007, p. 6). According to Kowal, Rouhani, and Anderson (2011), Article 13 reflects Aboriginal philosophies regarding “full embodiment” whereby every part and product of the body is sacred and constitutes an essential part of the person. Most Canadian Aboriginal communities prefer a participatory approach to the collection, use, storage, and potential future use of human biological samples; hence, this should be negotiated as part of the research agreement. Researchers must have respect for the beliefs of the Aboriginal community being studied and realize that they are to be considered the stewards, rather than the owners, of any samples.

The research agreement and consent process should address the conditions of collection, place of storage, research lab or researcher involvement, industry roles, plans for governance, and potential future use of any samples collected. Unless samples have been destroyed or de-identified, requests by an individual to withdraw, return, or dispose of samples should be accommodated in accordance with the terms of the research agreement and any applicable law. In the case of existing tissue banks, the community and the individuals should be consulted to determine under what circumstances the samples could be used for future research (CIHR, 2007).

**New Zealand: *Guidelines for Researchers on Health Research Involving Maori.*** New Zealand has been the site of an incredible amount of research ranging from genetic engineering to genetically modified foods and crops to genetic testing and research. With genetic research technology becoming more widespread, there is an increasing demand to conduct genetic research on Maori populations; however, such research has become an extremely controversial issue amongst Maori. A number of Maori critiques, such as those concerning intellectual property rights, provide examples of how genetic research impacts Maori and Indigenous peoples. Maori are being subjected to a form of colonization through the control over their cultural and intellectual property. Although Maori have long argued strongly against the erosion of their cultural values, knowledge and rights, the misappropriation of Indigenous knowledge and resources is an ongoing issue (Gardiner, 1997; Gillett & McKergow, 2007; Hudson, Annabel, Ahuriri-Driscoll, Marino, & Lea, 2007; Mead & Mead, 2003). In Wellington, New Zealand, genetic epidemiologist, Rod Lea, at the Institute of Environmental Science and Research, told a genetics conference in Australia that Maori men were twice as likely as European men to carry monoamine oxidase (MOA), the warrior gene (Lea, 2006). The epidemiologist stated that the gene had been linked to risk-taking behaviors, such as smoking and gambling, and his remarks highlighted the overrepresentation of Maoris in violence statistics. Maori leaders were outraged and proclaimed that the statement only served to reinforce cultural stereotypes. Further, a Maori academic argued that linking the MOA allele with high levels of violence among Maori is scientifically unsound, effectively making being Maori a “disease” and possibly leading to genetic and racial discrimination by insurance companies (Hook, 2009).

The Health Research Council of New Zealand (HRCNZ) prepared the *Guidelines for Researchers on Health Research Involving Maori* (HRCNZ, 2008), which includes a section on genetic studies involving Maori participants. These guidelines enhance the research process by framing Maori ethical issues in a way that meets expectations of Maori communities. As summarized by Kowal and colleagues’ (2011) in their review of *International Guidelines for Indigenous Genetic Research*, the Maori guidelines propose the following:

- **Research within paradigms of a Maori worldview:** Genetic research sparks debate amongst many Maori. Researchers should become familiar with the issues outlined in the 1995 HRCNZ Consensus Development Conference report, *Whose Genes Are They Anyway?* (Baird, Geering,



Saville-Smith, Thompson, & Tuhipa, 1995). At the conference, Maori expressed “support for genetic research that enhances quality of life for Maori as defined by Maori... [if that research occurs] within the paradigms of a Maori worldview” (p. 3).

- **Community engagement:** Genetic studies require access to both *whakapapa* (genealogical) knowledge and blood or tissue samples. Such studies require cooperation between the research team and participating *whanau* (family) along with consultation with the *imi* (clan) to which the *whanau* belong. Thorough consultation will ensure commitment of all parties to the project and minimize potential difficulties. Genetic research projects involving Maori require the approval of the *imi* or *hapu* (sub-clan) organizations representing the *whanau* involved. This approval can be obtained in a *hui* (meeting) of the representative body following discussion of the project and should be documented in writing.
- **Collective consent:** Informed consent for research should, in many cases, be obtained from more than just an individual. It is also important for researchers to be aware that, even though they may have received consent to gather *whakapapa* knowledge and/or blood, hair, saliva, tissue, or other human samples from a *whanau* member, *whanau*, or even *hapu*, the resulting findings from research are not generalizable to the Maori population at large (HRCNZ, 2008, p. 19).

**Australia: Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.** There have not been significant levels of controversy surrounding Indigenous genetic research in Aboriginal and Torres Strait Islander communities. However, this may be due to fewer genetic research studies taking place with Indigenous populations in Australia. Both the *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* and the *National Statement on Ethical Conduct in Research Involving Humans*, produced by the National Health and Medical Research Council (NHMRC, 2003, 2007), apply to all health research involving Aboriginal and Torres Strait Islander Peoples.

The *Guidelines for Ethical Conduct* document (NHMRC, 2003) does not address genetic research or provide guidance on the use and handling of biological samples; however, it does highlight it as an issue that needs to be discussed. On the other hand, the *National Statement*, to which all genetic research in Australia must comply, specifically addresses human genetic research in Section 3.5 (also relevant are sections on databanks, also known as biobanks, in Section 3.2 and human tissue samples in Section 3.4) (NHMRC, 2007). The *National Statement* proposes that ethical issues arise in genetic research for two reasons: 1) many genes are shared with close genetic relatives (commonly called “blood relatives”) and with unrelated people in the population, and 2) genetic research can reveal information about predispositions to disease. Although people with such a predisposition may not develop the disease, the information may have implications for individuals and blood relatives when accessing employment, education, benefits, or services, including financial services, such as banking, insurance, and superannuation (NHMRC, 2007).

To manage the risks inherent in genetic research, the *National Statement* advises that researchers follow certain measures: 1) construct a plan for researchers to manage a situation where previously unknown paternity or maternity or non-blood relationships to siblings is detected in the course of the research; 2) ensure that data is held securely and participants are made aware of any statutory requirements to disclose information; and 3) ascertain that only personnel qualified in clinical genetics and/or genetic counseling provide genetic information to research participants (NHMRC, 2007).

Several aspects of the *National Statement* are particularly relevant to Indigenous research (Kowal et al., 2011). Firstly, “when complex socially significant characteristics or the genetic characteristics of communities are being investigated, there is a risk that the research may be misrepresented or misused in ways that lead to prejudice, disrespect, or other harm to participants or communities” (NHMRC, 2007, p. 43). Secondly, “genetic information can sometimes be misused to stigmatize people or to discriminate against them unfairly” (NHMRC, 2007, p. 43). Lastly, researchers must seek community, as well as individual, consent where: a) researchers propose to collect genetic material and information from individuals who are chosen because of their membership in a particular community; b) the research involves sensitivities for that community; and c)

there is known to be a culturally relevant community structure involved in such matters (NHMRC, 2007).

The *National Statement* also outlines how researchers should clearly describe their processes for data collection, storage, usage, and disclosure when planning a databank. These considerations include the following: ensuring that identifiers are removed from the data when used in the research; deciding how to make data results available to participants, taking into consideration the participant's wellbeing; denying or restricting access to some or all of the data for uses that may be detrimental to those to whom the data relate; and ensuring that researchers seek specific, extended, or unspecified consent for future research (NHMRC, 2007).

**United States: *Indigenous Research Protection Act.*** American Indian and Alaska Native (AI/AN) communities have an extensive history of research involvement, which unfortunately includes instances of group harm. One example of harmful research in Indian Country is described in the 2004 Havasupai Tribe lawsuit brought against researchers at Arizona State University when discovering that samples donated for diabetes research were used for other purposes (Dalton, 2004). Researchers were using the Tribe members' samples to look at human migration patterns, inbreeding, and genes related to schizophrenia without their permission. The court case ended in a large settlement for tribal members and resulted in many AI/AN communities seeking new ways of regulating research in their communities.

Native Hawaiians also have a long history of being "subjects of research." In the 1800s, citizens of the Kingdom of Hawai'i who had Hansen's disease were exiled to Kalaupapa, a remote peninsula on the northern island of Moloka'i. Dr. Edward Arning, a government physician, conducted unethical studies on this population looking for the mode of transmission of leprosy (Arning, 1886). The negative research experiences encountered by Native Hawaiians have continued into the 21<sup>st</sup> century. In one case, a family in a rural island community submitted blood samples for research hoping to obtain findings regarding a rare genetic condition (Santos, 2008). However, informed consent was not upheld and follow-up was not provided to participants. A Native Hawaiian health organization advocated on the family's behalf and required researchers to confirm their findings of the rare genetic disease. Researchers did not provide any means for genetic counseling, treatment, or testing for the family. The burden of care was instead left to local health providers who had limited capability to address this rare disease (Chang & Lowenthal, 2001). In 2003, the University of Hawaii proposed patenting the Native Hawaiian genome to provide both economic and health-related benefits for the Native Hawaiian people (Singeo, 2007). In another instance, the university also intended to genetically modify *kalu* (taro), a traditional staple food of the Hawaiian diet, culturally recognized by Native Hawaiians as being an ancestor (Malo, 2006). The Native Hawaiian community strongly opposed these intentions (Azambuja, 2008; Niese, 2007) and viewed these activities as acts of biopiracy and biocolonialism (Paoakalani Declaration, 2005).

Unfortunately, there are no formal U.S. research policies that exist for the conduct of health research in Native American communities; although the Indigenous Peoples Council on Biocolonialism (IPCB) has developed a model research code known as the *Indigenous Research Protection Act* (IRPA) (IPCB, 2000). The IPCB seeks to help AI/AN communities protect themselves from harm in genetic research. The Act intends to foster collaboration and sets the groundwork for tribes to allow some research to be done with their discretion. Section 5 of the IRPA (containing principles a-l inclusive, which are reproduced in Appendix C) details the guiding principles for the Research Review Committee (RRC) established under this Act. Section 11 (containing Articles 11.1 to 11.7 inclusive in Appendix C) concerns the use of biological samples.

## **Aim 2: Comparative Analysis**

Canada, New Zealand, Australia, and the United States have developed specific processes regarding research conducted in their countries. A comparative analysis characterizing specific commonalities and differences among guidelines from each of the four countries is presented in Table 2. In addition to outlining the specific findings for Aim 1, Table 2 also provides a foundation to meet the specific requirements of Aim 2, which are to highlight top ethical concerns and priorities across Indigenous research guidelines in the four countries and

to provide a framework for Indigenous communities interested in creating formal policies around the use of genetic information and protection of biological samples.

Standards have been developed by national and international organizations to assist researchers when consulting with communities about research. Table 2 has been constructed based on principles outlined by Richard Sharp and Morris Foster (2002) in *An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaskan Native Communities*. These principles were chosen to guide this analysis because Sharp and Foster have been widely cited throughout discussions addressing genomic research among Indigenous communities. The categories in Table 2 are divided into five principles: community consultation, sample collection and informed consent, use and storage of biological materials, prioritization of research uses, and post-research obligations. Guidelines are individually coded based on their inclusion or exclusion of 15 sub-principles. One axis of the table represents the 15 sub-principles, and the other represents research guidelines listed by country. This matrix applies Sharp and Foster's existing framework to the most recent guidelines developed for ethical research around the use of genetic information and protection of biological samples among Indigenous peoples.

Table 2. Comparative Analysis of Indigenous Research Guidelines Concerning Genomic Research Across Countries.

	Canada	New Zealand	Australia	United States
<b>Community Consultation</b>				
In protocol development	✓			
Before collection of samples	✓	✓		✓
Respect for cultural differences embodied	✓	✓	✓	✓
Formal community approval required	✓	✓		✓
<b>Sample Collection and Informed Consent</b>				
Done in a culturally sensitive manner	✓	✓	✓	✓
Possible collective harm (e.g. group discrimination) discussed as part of inform consent process	✓	✓	✓	✓
<b>Use and Storage of Biological Materials</b>				
Potential uses defined prior to sample collection	✓		✓	✓
Provision for withdrawal of samples (IW or CW)	IW, CW			CW
Discussion of secondary uses with contributors (DI or DC)	DI, DC			DC
Secondary uses require community approval	✓			✓
<b>Prioritization of Research Uses</b>				
Should benefit contributing population	✓			✓
Clear position on commercial applications	✓			✓
<b>Post-Research Obligations</b>				
Ongoing research updates to participating communities	✓			✓
Community review of study findings before release	✓	✓		✓
Need to develop local capacities	✓			✓

**Bolded terms** = Leading principles of concern to Indigenous peoples regarding genetic research

✓ = Identifies a sub-principle within a country's guideline

IW = Individual withdrawal

CW = Community withdrawal

DI = Discussion held with individual

DC = Discussion held with community

Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (CIHR, SSHRC, & NSERC, 2010) and *Guidelines for Health Research Involving Aboriginal People* (CIHR, 2007) encompass all sub-principles included in the table and, therefore, serve as the models for genomic research in Indigenous communities. The Canadian guidelines provided by CIHR (2007) includes a checklist of what researchers should understand when conducting research with Indigenous peoples. The guidelines address many of the concerns posed by Indigenous groups, such as re-consent for secondary or multiple uses of samples, protection of Indigenous rights, appreciation for intellectual property rights, and recognition of ownership and stewardship of biological samples (CIHR, 2007). Canada, alone, addresses the principle of community consultation during the design of research protocols. From principles of respect and cultural sensitivity to ensuring community participation throughout all stages of the research process, Canada has demonstrated a successful participatory approach to working with its Indigenous peoples and guiding health researchers in the values and ethics concerning genetic research within their communities.

New Zealand's *Guidelines for Researchers on Health Research Involving Maori* (HRCNZ, 2008) addressed principles of community consultation and informed consent specific to Indigenous peoples. These guidelines provide no direction on the use and storage of biological materials or priorities regarding research use; yet, they do require a community review of study findings prior to information release. Similarly, Australia's *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 2003), with its minor provisions specific to Indigenous research, acknowledges respect for cultural differences and addresses the principle of informed consent. It does not meet principles regarding the use and storage of biological materials; however, it does address that any potential use of samples needs to be defined prior to collection.

The United States' *Indigenous Research Protection Act* (IPCB, 2000) does not lag far behind Canada in addressing the concerns of Indigenous peoples; however, this Act functions more as a proposal than an official Act. It states that it "should be seen more as a cookbook than as a model to be adopted outright" (IPCB, 2000). The Act addresses provisions for community withdrawal of samples and discussions with communities regarding secondary uses of biological materials; yet, fails to consider the individual in both cases. This is unlike Canada's CIHR Guidelines, which recognize that community consent often precedes individual consent when conducting research with Indigenous peoples.

### Limitations

There are a few limitations to this study. One major challenge of the study was to extract key points from the guidelines of each of the countries. It is possible that this analysis fails to recognize significant crossovers due to wording and labeling differences. The formation of best practices of genomic research in Indigenous communities may be aided by coalescing the information from different countries and forming a homogenous set of basic genetic research guidelines.

This study is also limited due to the difficulty in assessing the relevancy and merit of guidelines within each country. Only Indigenous peoples can determine the effectiveness and appropriateness of principles presented in each of the guidelines. This comparative analysis is only able to review publicly accessible materials and highlight principles of concern that have long been identified by Indigenous groups. Further, the selection criteria for the guidelines included is limited to those created by English-speaking countries that specifically address genetic research with Indigenous populations.

### Discussion and Policy Implications

This review uses a comparative analysis to examine the development of community-based research guidelines concerning genetic research in Indigenous communities throughout Canada, New Zealand, Australia, and the United States. Genomic research is a growing field; one that involves collaboration between research communities and Indigenous groups. Indigenous communities have previous experience with abuse by researchers, which makes it important to develop ways of regulating research conducted with their people.

Unfortunately, regardless of established guidelines, Indigenous peoples continue to experience the negative impacts of research, giving these groups reason not to trust researchers or the research process. In addition, there are limitations in the guidelines of each country because they are merely guides without any repercussions when the terms are violated. The Havasupai, for example, still experienced deceit about the purposes of the research conducted, which led AI/AN groups to seek new ways of protecting themselves and controlling research that is performed in their communities (Dalton, 2004).

In the mid-1990s, guidelines rarely recommended community consultation as a leading principle for conducting research with Indigenous peoples; however, today's current guidelines published by government-run organizations highlight the need for individual and community approval on issues such as secondary uses of data and withdrawal of samples (Jacobs et al., 2010). An increasing number of guidelines also consider how to benefit participating Indigenous communities when research tends to commercialize data (Jacobs et al., 2010).

There are on-going concern over data sharing agreements, the use of biospecimens for commercial purposes, and the return of research results to the participating community. Another issue is whether there should be benefits provided to Indigenous communities for their participation in genomic and biobank research. Benefits of genetic research tend to be long-term, but more immediate benefits, such as providing health services and employment, should be provided to participating communities. Benefit sharing arrangements should be in place prior to the decision of whether or not to participate in a study. If provisions are made for benefit sharing prior to the research being conducted, patterns of harm experienced by Indigenous communities may be eliminated.

Community-based institutional review boards (IRBs) and community advisory boards are formal boards that function to oversee research performed in communities; however, they may be limited in their ability to enforce violations. Identifying best practices of Indigenous guidelines across four countries may help to inform the development of policies that could be implemented to protect Indigenous peoples from harm associated with genetic research. Furthermore, this is crucial to building trust, preventing future harm, and addressing the negative impacts experienced by Indigenous people.

The results of the analysis suggest the importance of establishing research principles that apply to genetics, as identified by Indigenous peoples in countries who share a long history of involvement with research issues. Providing a clearinghouse of guidelines and resources may help simplify the creation of formal genomic research policies for Indigenous communities. The comparative analysis comprises principles necessary to meet: 1) the ethical requirements of the research process and 2) the utilization and governance over information obtained from research. Upholding all the principles may assist Indigenous peoples in determining their own course in research. The use and storage of biological materials is a leading principle that, if addressed throughout all Indigenous research guidelines, ensures Indigenous peoples' governance over their data. This, in addition to principles of informed consent, risks, benefits, and confidentiality are critical components to not only genomic research, but to the biobanking process as well.

As research moves forward into the realm of genomic and biobank research, it is impossible to ignore the ethical and legal ramifications posed by informed consent requirements. For example, informed consent requires participants to have a thorough understanding of the research being conducted, but finding participants capable of providing this consent may be difficult given that it is a highly specialize and technical field of study. Another daunting task to genomic research and the emergence of biobanks is informing participants of the risks and benefits of participation. While research findings may be linked back to the individual or community, the misuse of this information can still occur, as in the case of the Havasupai and the "warrior gene" controversy in New Zealand. Since genetic material can provide information beyond individual participants, it is crucial to obtain community consent and establish provisions of control over how research will be reported back to the community.

The comparative analysis suggests that principles established for the use and storage of biological materials need to ensure that: 1) research is first carried out ethically; and 2) research participants are not harmed by involvement in a biobank. Unfortunately, many established biobank systems do not involve research participants in the decision-making process (Kaye & Stranger, 2009). For this reason, Aboriginal communities in Canada have proposed that blood and tissue accepted for research in their communities must be considered property of the donor or community involved. This essentially means that the samples are considered “on loan” to the researcher. The researcher becomes the warden holding DNA (or other biological samples) for the purpose of research, while ownership remains with the participant or community. The concept of “DNA on loan” enables research to be carried out, yet protects the interests of individuals, families, and communities involved (Arbour & Cook, 2006).

It is critical that all principles addressing research processes and ethics become an integral part of the utilization and governance of information obtained from research. The principles outlined in Table 2 are vital not only to genetic and genomic research, but to the overall governance structure of biobanks. A biobank governed by policies and guidelines that are engaged in ongoing dialogue with participants and the public stands the best chance for successful operation by maintaining public trust and support (Kaye & Stranger, 2009). Raising awareness and interest is crucial to advancing the capacity for future research that can improve population and community health in Indigenous peoples.

### Recommendations

Indigenous research guidelines of Canada, New Zealand, Australia, and the U.S. showcase common similarities and address present gaps that contribute to the research needs and concerns of Indigenous communities. While Indigenous communities in each country differ in numerous ways, the ethical principles outlined in Table 2 demonstrate a common concern voiced by all Indigenous groups – a need for principles regarding the use of genetic information and protection of biological samples.

To provide a framework for other Indigenous communities interested in creating formal policies around these research issues, recommendations include the following:

1. *Development of Indigenous research guidelines concerning the use of genetic information and protection of biological samples throughout New Zealand, Australia, and the U.S.*

New Zealand, Australia, and the U.S. have developed valuable research documents; however, each is missing vital components to ensure that genetic research is conducted properly within their Indigenous communities. Separate guidelines need to be created to specifically address the unique issues of genetic research among Indigenous peoples. Within these guidelines, the use and protection of biological samples should also be addressed. In this case, Canadian guidelines are helpful and may be used as a model. The Organization for Economic Co-operation and Development’s (OECD) document, *Guidelines on Human Biobanks and Genetic Research Databases*, was established through an international consortium, of which Canada, New Zealand, Australia, and the U.S. are member countries (OECD, 2009). This document established the importance of community engagement prior to conducting research with these groups. The guidelines also provide direction for the development of Human Biobanks and Genetic Research Databases (HBGRD). Genetic research inevitably involves the collection of biological materials and the use and storage of this data; therefore, governance should be established early to ensure Indigenous peoples share in the decision-making process and have control over their collective data. Canada, once again, has addressed this need in their concept of “DNA on loan.”

2. *Recognition of “trust” as a principle within Indigenous research guidelines.*

The concept of trust is vital to genetic research and has been discussed in the development of biobanking guidelines. Social, cultural, religious, and spiritual values and practices of Indigenous peoples should be recognized and protected. If a trust relationship has been established between

Indigenous groups and researchers, this may warrant greater participation by Indigenous peoples in genetic research. Researchers can achieve a high level of trust with other communities by studying and upholding the principles addressed within Table 2. Trust is a key element addressed in the *UK Biobank Ethics and Governance Framework* (UK Biobank, 2007). The *OECD Guidelines on Human Biobanks and Genetic Research Databases* also make reference to this concept (OECD, 2009).

3. *Implementation of a policy or law to enforce repercussive actions on those who violate the rights of Indigenous peoples through research.*

Consent is necessary in research and must ensure the respect and protection of research participants; however, providing informed consent has always been problematic with regard to biobanking. Indigenous populations may be unwilling to consent to future research that is unspecified for fear that research done would stigmatize their community. In the case of the Havasupai, a number of violations occurred, but failure of tribal members to provide informed consent was the one count charged since the law was upheld. Enforcing actions of repercussion will ensure that research communities conduct research in a way that is ethical and, also, prevent harm done to Indigenous groups.

The research environment continues to evolve as genomic research and biobanks emerge; however, these types of research may be unsuccessful if they fail to address the principles that Indigenous communities have identified as concerns. Canada's success in Indigenous research guideline development should be studied when considering the development of guidelines in other Indigenous communities. Research communities should apply the current knowledge and uphold the principles that concern Indigenous groups. Mahatma Gandhi states, "the measure of a country's greatness should be based on how well it cares for its most vulnerable populations." By identifying principles that work for Indigenous people, this will lead to best practices for all people.

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## Appendix A

### ***Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans***

#### *A. Application of Core Principles to Genetic Research*

*Article 13.1* – Guidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials, and other ethical guidance described in earlier chapters of this Policy apply equally to human genetic research

#### *B. Plans for Managing Information Revealed through Genetic Research*

*Article 13.2* – Researchers conducting genetic research shall

- (a) in their research proposal, develop a plan for managing information that may be revealed through their genetic research;
- (b) submit their plan to the REB; and
- (c) advise prospective participants of the plan for managing information revealed through the research.

*Article 13.3* – Where researchers plan to share findings with individuals, researchers shall provide participants with an opportunity to

- (a) make informed choices about whether they wish to receive information about themselves; and
- (b) express preferences about whether information will be shared with biological relatives or others with whom the participants have a family, community, or group relationship.

#### *C. Genetic Counseling*

*Article 13.4* – Where researchers plan to share results of genetic research with participants, the research proposal should make genetic counseling available at that time, where appropriate.

#### *D. Genetic Research Involving Families*

*Article 13.5* – Researchers who seek to recruit members of a family to participate in genetic research shall

- (a) ensure recruitment processes respect privacy and other personal interests of family members; and
- (b) seek consent from individual family members.

#### *E. Genetic Research Involving Communities and Groups*

*Article 13.6* – Where researchers intend to recruit participants for genetic research based on their membership in specific communities or groups, it may be appropriate for researchers to discuss the research with community or group members, and /or their leaders, in addition to seeking consent from individual participants. In these cases, researchers shall provide details to the REB about their proposed methods for engaging in discussion.

#### *F. Genetic Material Banks*

*Article 13.7*

- (a) Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings, and withdrawal by participants, as well as future contact of participants, families, communities, and groups.
- (b) Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.

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

## Appendix B

### *Guidelines for Health Research Involving Aboriginal People*

#### *2.12 Initial and secondary use, proprietary interest, and storage and transfer of data and biological samples*

*Article 12.1* – A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research

*Article 12.2* – Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies).

*Article 12.3* – Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if the research data or biological samples cannot be traced back to the individual donor then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required.

*Article 12.4* – Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use.

*Article 12.5* – Secondary use requires REB (Research Ethics Board) review.

Original Source: Canadian Institutes of Health Research. (2007). *CIHR Guidelines for Health Research Involving Aboriginal People*. Retrieved from <http://www.cihr-irsc.gc.ca/e/29134.html>.

## Appendix C

### *Indigenous Research Protection Act (IRPA)*

#### *Section 5. Guiding Principles for RRC*

- (a) *Principle of Fully Informed Consent After Full Disclosure and Consultation*  
 Research should not be conducted until there has been full consultation with all potentially affected Tribal communities and individuals, and each such community and individual has approved the research after full disclosure. Full disclosure is of the full range of potential benefits and harms of the research, all relevant affiliations of the person(s) or organization(s) seeking to undertake the research, and all sponsors of researcher(s).
- (b) *Principle of Immediate Risks and Benefits to the Tribal Community*  
 The research should be of immediate benefit to the Tribal community, and the risks associated with the research should be less significant than the benefits to be gained.
- (c) *Principle of Confidentiality*  
 This principle recognizes that the Tribe and local communities, at their sole discretion, have the right to exclude from publication and/or to have kept confidential any information concerning their culture, traditions, mythologies, or spiritual beliefs. Furthermore, researchers and other potential users shall guarantee such confidentiality.
- (d) *Principle of Respect*  
 This principle recognizes the necessity for researchers to respect the integrity, morality, and spirituality of the culture, traditions, and relationships of Tribal members with the world, and to avoid the imposition of external conceptions and standards.
- (e) *Principle of Communication*  
 This principle recognizes that communications should be carried out in the local language, using translators as necessary.
- (f) *Principle of Empowerment*  
 This principle recognizes that empowerment is the sharing of power and is premised on mutual respect. Empowerment means that each affected party feels that their needs are being met through a fair and equitable manner. Empowerment also means that research authorship must be shared between the Tribal community and the researcher.
- (g) *Principle of Equity*  
 This principle recognizes that equity is a sharing of resources. Both the researchers and the tribe must bring equity to any research contract, agreement, or understanding. Each of the participants in a good research agreement must evaluate such equity in relation to the research. Finance or money is only one form of equity. Community knowledge, networks, personnel, and political or social power are other forms of equity useful to the project. Each of these commodities has value and must be shared between the researchers and the Tribe if a good agreement is to be formulated. The parties must continuously review equity over the duration of a research agreement.
- (h) *Principle of Mutual Respect*  
 This principle recognizes that, in order to develop a good research agreement, the researchers and the Tribe must generate respect for each other. Respect is generated by understanding the social, political, and cultural structures of the other party. The researchers and the Tribes cannot assume that they believe in the same things or share the same goals and expectations. Good communication is required if a proper research agreement is to be generated. Cultural sensitivity training for the researchers and Tribal awareness presentations will help develop a mutual understanding in conducting the research project. Definitions and assumptions must be clarified and questioned by each side and set forth in an agreement. The Tribes and the researchers must listen to each other with open minds.
- (i) *Principle of Prior Rights*  
 This principle recognizes that indigenous peoples, traditional societies, and local communities

- have prior, proprietary rights and interests over all air, land, and waterways, and the natural resources within them that these peoples have traditionally inhabited or used, together with all knowledge, and intellectual property, and traditional resource rights associated with such resources and their use.
- (j) *Principle of Self-Determination*  
This principle recognizes that indigenous peoples, traditional societies, and local communities have a right to self determination and that researchers and associated organizations will acknowledge and respect such rights in their dealings with these peoples and their communities.
- (k) *Principle of Inalienability*  
This principle recognizes the inalienable rights of indigenous peoples in relation to their traditional territories, and the natural resources within them, and associated traditional knowledge. These rights are collective by nature but can include individual rights. It shall be for indigenous peoples to determine for themselves the nature and scope of their resource rights regimes.
- (l) *Principle of Traditional Guardianship*  
This principle recognizes the holistic interconnectedness of humanity with the ecosystems of our Sacred Earth and the obligation and responsibility of indigenous peoples to preserve and maintain their role as traditional guardians of these ecosystems through the maintenance of their cultures, mythologies, spiritual beliefs, and customary practices.

#### *Section 11. Regulation of Biological Samples*

*Article 11.1* – Any researcher who seeks to collect, acquire, or analyze any biological samples must agree and abide by the following conditions with regard to research with biological materials.

*Article 11.2* – The Tribe may, at any time, decide to withdraw from the research project, or any portion thereof, and request the return of all biological samples. The researcher, and any other parties, must comply.

*Article 11.3* – Upon completion of the research project, or termination or cancellation of the project at any time prior to completion, the biological samples must be completely and fully returned to the possession of the Tribe.

*Article 11.4* – No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully informed written approval of the Tribe.

*Article 11.5* – If the Tribe permits any biological samples to be stored in any other locations, the researcher shall maintain at all times a complete list thereof. The list shall include a description of the sample or data, source, specific use or purpose of each item, responsible person(s) at the location, where the item is housed (e.g., in a “gene bank” or on a specific computer), and any relevant timelines with regard to use, disposition, return, or destruction of the samples or data. The researcher shall provide an updated copy of the list to the Tribe whenever changes are made. The updated list shall include identification of changes made since the last copy of the list was provided to the Tribe.

*Article 11.6* – Any situation where biological samples will leave the possession or control of the researcher will require a separate agreement between the Tribe and the external party in accordance with this Act.

*Article 11.7* – No entity may seek to patent or commercialize any biological materials obtained from the Tribe, from the Tribe’s jurisdiction, or under the authority of the Tribe. This includes genetic samples, any copies of the original genetic samples, any cell lines containing copies of the original genetic samples, and data derived from these samples.

Original Source: Indigenous Peoples Council on Biocolonialism. (2000). *Indigenous Research Protection Act*. Retrieved from <http://www.ipcb.org/publications/policy/files/irpa.html>.