Governing Cross-Border Sharing of Genetic Data:

A New Border Frontier

by

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Abstract

Introduction

Since the sequencing of the first human genome, nations have relied on collaborations with foreign and non-state actors to conduct genomics research to deliver clinical benefits to citizens. Genomics research has the potential to one day cure and prevent some of the most devastating diseases and disorders known to humans. In order to continue on this exciting trajectory of medical discovery, researchers must have access to large and diverse sets of genetic data. Currently in British Columbia, public-private partnerships are developing under projects such as the BC Digital Technology Superclusters to solve resource challenges and remain at the forefront of genomic research and precision medicine.

The information contained within an individual's DNA is arguably the most intimate form of information which uncovers a person's past, present and future. Such information is valuable not only to medical researchers and health care providers but also law enforcement, private for-profit organizations, insurance providers, financial institutions and employers. The risk of misuse and discrimination resulting from the inappropriate sharing of genetic data poses serious risks to human rights. Additionally, rapid advances in technology have enabled the digitization and near instantaneous sharing of personal information creating a novel environment for cross-border sharing. Data breaches and the abuse of citizen data by organizations such as Facebook, Cambridge Analytica and a number of retailers, and financial institutions has brought public awareness to the mass collection of personal data and the lack of infrastructure to manage these new developments.

In light of the benefits to sharing genetic data and the potential risks, clear and effective frameworks must be in place to enable the safe management of data that preserves the privacy of individuals and enables valuable data sharing between organizations around the world. Internationally, various approaches are utilized to address the sharing of personal information, some more restrictive while others more permissive. The primary problem this thesis seeks to explore is the challenge of governing genetic data in a manner that preserves privacy, autonomy and supports appropriate access between organizations, with a particular focus on cross-border data sharing.

Methodology and Methods

This thesis was a qualitative study that employed a human rights framework outlined in the United Nations Education Scientific and Cultural Organization (UNESCO) Declarations. A review of grey, academic and legal literature was conducted to identify governance mechanisms and frameworks

employed for the management of genetic data. The results from this review informed which cases would be most appropriate to conduct a comparative case study analysis. Three distinctly different governance models employed by the European Union (EU), China and a non-for-profit international consortium known as Global Alliance for Genomics and Health (GA4GH) were selected for further analysis. Additional research was conducted on each case study using primary and secondary sources of data. Primary sources of data included interviews with those related to each case study model, provincial and federal governments; subject matter experts in privacy, genomics and legal scholarship.

To address the relationship between data and cross-border sharing, a border theory lens was applied to gain a nuanced understanding of how to best manage data in extra-territorial spaces created by technology. This was achieved through border seminars, interviews and reviewing border theory scholarship.

Key Findings

The research indicates that governance mechanisms exist in the form of declarations, guidelines and principles established by international non-governmental organizations which provide a human rights framework for the collection, use and disclosure of genetic data. However, the operationalization of such principles within jurisdictions varies with mixed results. While various bodies contribute to the regulation of data sharing, research suggests that the state plays a central role in the governance of genetic data which is achieved primarily through legislation.

Two common legislative approaches utilized are either omnibus privacy legislation which addresses the use of all personal data or health sector specific legislation which only addresses personal health information. Within these frameworks, genetic data may be singled out as “exceptional” or have stand-alone legislation stipulating specific practices around the collection, use and disclosure of genetic data. A key consideration for determining which approach is the most appropriate for a jurisdiction is the consideration of context such as culture, community, health care system, legal structure, and geography.

Genetic data as a case study for border theory suggests that a re-bordering and de-bordering may be occurring simultaneously. Legislation as a governance mechanism creates new borders around genetic data which may contain provisions for sharing thus also contributing to a de-bordering. Within this approach, states may utilize a territorial approach limiting the sharing of genetic data to the physical boundary lines of the state or they may utilize a functional approach that enables the cross-border flow of genetic data through principled sharing in agreements or legislation. Functional borders may be more

conducive to facilitating valuable data sharing for research and health care than territorial borders while still providing privacy protection.

Based on the research findings, due to the complexities of genetic data and the requirement to link with other forms of personal data to conduct analysis, omnibus legislation such as the EU's *General Data Protection Regulation* (GDPR) may be the most effective approach to appropriately protect privacy while remaining adaptive to the continuous evolution of genetic data usage. However, when considering BC's context, health sector specific legislation may be the most appropriate fit within a federated Canadian system that possesses public and private sector privacy legislation. Finally, current aspects of BC's privacy framework may create sharing challenges due to the territorial nature of the data residency provision under the *Freedom of Information and Protection of Privacy Act* (FOIPPA). The movement towards a more functional model that relies on agreements and legal sharing provisions may safely remove barriers without endangering privacy.

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1.0 Introduction

Since the sequencing of the human genome in 2003, genomic research has uncovered valuable insight into the development and treatment of diseases and disorders (Yang, 2019). It is predicted that by 2025, 60 million genomes will be sequenced for health-care related purposes (Birney, Vamathevan, & Goodhand, 2017, p. 5). These discoveries benefit patients diagnosed with illnesses such as cancers and autoimmune disorders and are playing a role in preventative medicine. However, in order to continue to conduct meaningful research with high clinical utility, research projects rely on collaboration between multiple organizations to produce substantial data sets (Dove, 2015; Middleton, 2018). The cost of sequencing, conducting analysis and securely storing genetic data, makes genomic research expensive and difficult to conduct on one's (Schwarze, Buchanan, Fermont, et al., 2020). As a result, there is a reliance on partnerships with private bodies, governments and international organization to provide the necessary technology and resources to access a diverse population and undertake advanced analysis.

Despite the benefits derived from sharing genetic data for the purposes of medical research and providing health care, there are important considerations for sharing such sensitive information. Genetic data is the most personally identifying form of data (Naveed et al., 2015) that has the potential to reveal an individual's past, present and future. Unregulated access to and use of genetic data may have negative consequences for individuals, their family and community in the form of privacy breaches and inappropriate use which may result in discrimination (Otlowski, Taylor & Bombard, 2012). Inextricably linked to genetic data are human rights concepts such as the right to provide or revoke consent, the right to non-discrimination, the right to privacy and the right to access one's own data and benefit from the resulting research which are evident in the United Nations Education Scientific and Cultural Organization's (UNESCO) *International Declaration on Human Genetic Data*. An effective governance framework is essential to establish safe and ethical sharing of genetic data between organizations and participants that preserve these rights (Global Alliance for Genomics and Health, 2014).

Nations around the world have varied approaches to regulating the collection, use and disclosure of genetic data. While there are some commonalities such as recognition of privacy rights (Townend, 2018, p. 658), the expression of such concepts into practice may vastly differ due to state intention and context such as health care systems, political will, culture and ideology (Interviews 1, 2, 4). What results is the inconsistent treatment of genetic data which may conflict with agreed upon practices in the nation where the data originated. Fear of abuses and inconsistent application deters the sharing of genetic data by participants (Peterson, et al., 2002) and organizations who are custodians of such data; potentially

creating barriers to conducting valuable research that may improve the quality of life or the delivery of cutting-edge medical care (Otlowski, Taylor & Bombard, 2012).

This challenge is particularly evident when data crosses borders and becomes subject to new practices, policies and legislation in foreign jurisdictions. On a national level, Canada maintains a framework that enables the sharing of genetic data evident in its leadership in initiatives such as the International Cancer Genome Consortium and the International Human Epigenome Consortium (Thorogood, 2018, p. 596). However, scholars such as Thorogood warn that there are external factors such as cloud technology, new European legislation (GDPR) and an increasing public desire to control personal data which may restrict the open sharing of genetic data for research in Canada (Thorogood, 2018).

In Canada, the federal government sets the requirements for the provision of health care, however the planning and operationalization of health care is administered on a provincial level, which may differ from one jurisdiction to the next (Martin et al., 2018). This disparity also leads to an inconsistent application of privacy policies between provincial and federal governments (Thorogood, 2018, p. 596). Some scholars contend that a nationalized approach to data governance while vital, is not a current reality (Morin and Flegel, 2017). Currently within British Columbia (BC), there is a patchwork of controls in the form of legislation, policy and organizational practices that also differs between public and private bodies. Consequently, genetic data in BC may remain underutilized and vulnerable to privacy breaches that could compromise the publics' trust in medical institutions and willingness to participate in and support genomic research.

This thesis seeks to examine the critical elements of effective genetic data governance across jurisdictions to identify viable approaches for BC's context. The thesis employs a border theory framework to examine cross-border data sharing using human rights-based principles as the benchmark for appropriate data management. The following thesis begins with a problem definition, background information, an examination of the relevant border theory and governance literature, as well as explores common practices and challenges. The literature findings are applied to the comparative case study of three jurisdictions' genetic data management frameworks, the European Union (EU), China and Global Alliance for Genomics and Health (GA4GH). Each case study is examined using a human rights perspective as defined by the United Nations *Universal Declaration of Human Rights*. This data is examined further using interviews with subject matter experts which intends to provide a nuanced and granular understanding of the frameworks. The final section includes data analysis which utilizes border theory to identify potential genetic data governance approaches for BC as well as attempts to identify what the digitization of genetic data as a case study may be able to contribute to the field of border theory.

1.1 Defining the Problem

Genetics explores the heredity or the transmission of characteristics from generation to generation through the sharing of DNA (The Jackson Laboratory, 2019). Genetics generally examines a single gene or limited set of genes within a genome (genome being the entire genetic makeup of an organism). As a result, genetics focuses specifically on the heredity of certain diseases such as Huntington's or Cystic Fibrosis which are attributed to one gene (National Human Genome Research Institute, 2018). Meanwhile, genomics is the study of the genome in its entirety, and how genes interact with one another (National Human Genome Research Institute, 2018). Consequently, genomics is utilized for the study of disorders such as cancer or asthma which may be attributed to numerous genes and environmental factors (National Human Genome Research Institute, 2018).

For the purpose of this project, genetic data will be defined according to the definition employed under the European Union's *General Data Protection Regulation* (GDPR) as:

> personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained. (2016, Recital 34)

Consequently, the terms genetic and genomic data are used interchangeably, and this thesis will consider all personal data resulting from analysis of genetics within the scope of this research. The primary problem this thesis seeks to explore is the challenge of governing genetic data in a manner that preserves privacy, autonomy and supports appropriate access between organizations with a particular focus on cross-border data sharing.

Rapid technological innovation has enabled scientists to examine genes and obtain information from them to develop tailored approaches to medical treatment for the individual and the population at large known as precision medicine (National Cancer Institute, 2017). While this technology has the potential to provide significant benefits to patients around the world, genomic information may also be used for nefarious purposes that causes significant harm to people and communities (Otlowski, Taylor & Bombard, 2012). Consequently, governance of genetic data must be conducted in a way that prevents misuse.

In order to produce research that will result in high clinical utility, large volumes of genetic data must be amassed and linked with other sources of data (Dove, 2015, p. 677; Middleton, 2018). Townend explains that "data sharing in genomic research is about linking data held in silos such as institutions, research

projects, biobanks, hospital records, general practitioner records, consumer companies and other collections lifestyle data" (Townend, 2018, p. 658). Indeed, today's internet of things (IoT) such as technical wearable devices that track activities, nutrition, blood sugar levels, sleeping patterns and heart rate (among other data), contribute to the collection of big data. Big data provides vast amounts of information about individuals that may be valuable for genomic research (Andriukaitis, 2017). Combining data in this way makes the anonymization of information difficult and contributes to a high risk of reidentification when such data sets leave the protected environment (Schadt, 2012). It is not just genetic research that will require data linking but also the application of precision medicine (Townend, 2018, p. 660).

Given the limitations on access to large and diverse populations and resources in the form of technology and expert personnel, obtaining sufficient amounts of data and conducting cutting edge analysis cannot be done alone (Middleton, 2018). Indeed, the Human Genome Project (HGP) is an example of how international collaboration is essential to creating robust and meaningful research. Currently, around the world, varying approaches exist to regulating genetic data. While there are global organizations that seek to create a standardized process, the literature identifies that there continues to be varying approaches to managing genetic data, resulting in disparate practices and standards relating to privacy protection, patient autonomy and equitable access. Such discrepancies not only challenge the human rights of patients and research participants, but also create barriers to data sharing that are essential for research and patient care.

Opportunities for genomic research are unfolding in BC, however as one of the only provinces in Canada without health information legislation, BC does not have a clear legislative framework for managing health data let alone genetic data. A lack of framework results in confusion among researchers and health care providers, discourages sharing and creates gaps in privacy protection (Interview 4). This is compounded by the presence of two separate acts, the *Freedom of Information and Protection of Privacy Act* (FOIPPA, 1996) which applies to public bodies and the *Personal Information Protection Act* (PIPA, 2003) which governs the private sector. While both pieces of legislation share many provisions, there are fundamental difference between them. FOIPPA is an authority-based model that compels the collection of personal information for the purpose of providing publicly provided services such as health care. PIPA employs a consent model, as it primarily manages the data sharing of for-profit entities. To complicate matters further, BC is part of a universal health care system where public bodies that collect personal health information (PHI) such as the Ministry of Health, Health Authorities and, BC Cancer Agency (among others) are subject to FOIPPA., while physicians who provide public health care services are considered private providers when operating out of clinics making them PIPA bodies. The same physician

may treat PHI differently when working in a hospital than the PHI collected in her own clinical practice. Additionally, FOIPPA and PIPA approach the cross-border sharing of PHI differently from one another. The data residency requirement under section 30.1 of FOIPPA stipulates that public bodies may not store personal information or allow it to be accessed outside of Canada except in limited circumstances. Exceptions include if the individual has consented to their information being stored or accessed outside of BC (s. 30.1(a)). This restricts the way information may be collected, from whom and which technology is available for public sector use. Such requirements do not apply to private bodies and may make international collaboration difficult. As a result, interoperability and consistency in sharing health information (including genetic data) is currently a challenge in BC.

1.2 Project Objectives and Research Questions

This thesis seeks to identify the most optimal governance framework and regulatory instruments essential for the safe and effective cross-border sharing of genetic data.

The primary research questions are as follows:

- What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?
- What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?

Secondary questions:

- What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving health care while preserving human rights to privacy, autonomy and access to data?
- Based on the above, what are potential approaches for the BC context?

1.3 Background

The united efforts of Celera Genomics, the United States, United Kingdom, France, Germany, Japan and China led to the completed sequencing of the human genome (Lander, Linton, Birren, et al., 2001, p. 860) The Human Genome Project (HGP) created a road map to the susceptibility and development of diseases allowing scientists, medical professionals, and patients to gain valuable information on inheritable traits, and aging (National Human Genome Research Institute, 2018). Since the completing of sequencing in 2003, genomics has not only improved our knowledge of genetic diseases and diagnostic capabilities but

has also led to the development of new health care strategies such as precision medicine, the practice of tailoring health care to the genes of patients for the purpose of treatment, management and prevention (Yang, 2019).

The HGP working group established and administered processes and policies that governed and developed shared vision and standards for the manner in which genomics research would be approached. For example, the Bermuda Principle employed by the working group determined that genomic data would be made globally accessible (Knoppers et al., 2011, p. 1). As the group sequenced data, it was made rapidly available to the public (Lander, Linton, Birren, et al., 2001, p. 865). Such a policy practice acknowledged the value genetic research contributes to society, the shared ownership of genetic information and the need to facilitate global cooperation to further genomic research. The policy also signaled the development of governance structures within the field of international genomic research. Indeed, organizations such as Genome Canada require project teams to adhere to the timely dissemination of data, enable access to research publications and respect intellectual property as a requirement for receiving funding (Simard et al., 2016, p. 1). Genomic research organizations and the global nature of genetic information may play a significant role in challenging traditionally held notions of what constitutes borders and reshapes our conceptualization of territoriality. This new paradigm is evident in the employment of group membership, technological borders, and the practice of data sharing that may be in contravention of protocols held by many nation states (Cook-Deegan & McGuire, 2017, p. 897).

The benefits that arise from genomics research have the potential to substantially increase the welfare of human life. Sequencing and further research is dependent on the contribution of many individuals to provide the volume and variety of genetic data required to achieve accurate sequencing and analysis. Access to genetic data may be considered a human right as it originates from and is held by each individual. Arguably, the benefits that may be realized from this knowledge have been classified as a global public good (Knoppers et al., 2011, p. 1). Certain frameworks enable greater access to research benefits, for instance, sequencing conducted by the HGP under the Bermuda Principle resulted in a greater number of diagnostic tests than patented sequencing conducted by Celera Corporation whose publication of findings also decreased by up to 30% (Williams, 2013, p. 1).

The governance of genetic data presents a new regulatory challenge for jurisdictions around the world. A struggle to establish regulatory frameworks that balance the need for privacy protection and civil liberties with data sharing and medical innovation to improve the lives of citizens is an ambitious endeavour. Currently, there is a lack of consensus within nations on how to define genetic data (Varga et al., 2012) and best practices for its collection, use and disclosure. For example, genetic data may be classified as a

unique form of personal identifying information due to its inability to be fully anonymized, its capacity to provide both current and future information and potential to reveal data on kin (Naveed et al. 2015). Such challenges make genetic data incredibly valuable and equally as volatile, warranting careful consideration for regulation and policy development (Gauvin & Wilson, 2012).

Regulation of genomic information in Canada and BC occurs through various instruments ranging from general privacy legislation, *Human Rights Codes*, the *Canadian Constitution* (1982) to best practices and policies established by numerous bodies in public and private sectors. The Federal *Genetic Non-Discrimination Act* was enacted May 4, 2017 and prohibits the requirement for individuals to undergo genetic testing or disclose the results of genetic tests as a condition for receiving services or engaging in contractual agreements (s.3(1)). The legislation resulted in amendments to the *Canada Labour Code* (1985), protecting employees from mandatory genetic testing or being compelled to disclose test results among other protections. The *Canadian Human Rights Act* (1985) was also amended to prohibit discrimination on the ground of genetic characteristics. However, on December 21, 2018, Quebec's Court of Appeal deemed the legislation unconstitutional, as it did not fall under the jurisdiction of criminal legislation (*Genetic Non-Discrimination Act*, 2018 QCCA 2193). A month later, the Canadian Coalition of Genetic Fairness filed a notice of appeal to the Supreme Court of Canada (Gagné, Jospé, Shortt, & Douville, 2019). The future of genetic non-discrimination and the role it may or may not play as part of the governance scheme in BC is yet to be determined.

The *Personal Information and Protection of Electronic Documents Act* (PIPEDA, 2005) applies to the cross-border sharing of information in the private sector and while PIPA has been deemed substantially similar, once data crosses provincial or national borders, PIPEDA has supremacy (Office of the Privacy Commissioner of Canada, 2017). PIPEDA is based on an accountability model which dictates that organizations who have "possession or custody" over personal information remain responsible for ensuring the appropriate management of the data even once transferred to a third body (Schedule 1, Principle 4.1.3). This is modeled after the Organization for Economic Cooperation and Development (OECD) approach which enables sharing with all bodies (Thorogood, 2018, p. 598). In contrast, the EU employs an adequacy model which only permits the transfer of personal information to a list of predetermined jurisdictions which have been deemed to have similar legal frameworks to that of the EU (European Commission, 2019).

In addition to applicable Federal legislation, each province has its own domestic legislation. As previously mentioned, BC has FOIPPA, which governs the way public bodies manage personal information in the province. FOIPPA is considered to be authority based, as public bodies require access

to individuals' information in order to provide services such as health care. As a result, FOIPPA compels the collection, use and disclosure of information as obtaining consent directly from individuals in a public system would pose significant operational challenges. Nevertheless, there are stringent regulations in place to help ensure that personal information is managed by bodies in an appropriate and secure manner. For example, personal information may only be collected, used or disclosed for specified purposes that are consistent with the purpose for which they were collected. Furthermore, under section 4, bodies are required to provide individuals with access to their information upon request and employ reasonable security measures (s.30). With few exceptions, section 30.1 of FOIPPA requires that storage and access of personal information remains within Canada. However, on October 31, 2019, *Bill 35 – 2019 Miscellaneous Statute Amendments*, received Royal Assent. Section 22 of *Bill 35* amends s.33.1(1) of FOIPPA to include two new subsections which enable a limited amount of disclosure of personal information outside of Canada. Amended provisions enable the temporary disclosure of personal information outside of BC if it is necessary for the processing of data that is not accessed by another individual; is necessary for system instillation, repair or management; or it is metadata that is generated by an electronic system describing how individuals use that system.

The amendments enable public bodies to utilize cloud technologies as well as other technical tools that may have some degree of disclosure or access from outside of the country. Despite this softening of the data residency requirement, the amendments do not include data that falls under the *E-Health* (*Personal Health Information Access and Protection of Privacy) Act* (2008) or the *Pharmaceutical Services Act* (PSA, 2012).[1] Both the *E-Health Act* and PSA govern the collection, use and disclosure of personal information in public health repositories which include the Client Registry, Provider Registry, Provincial Laboratory Information Solution and PharmaNet. This means that various health sector bodies will need to continue to adhere to the data residency provisions. The data residency provision seeks to protect personal information from being exposed to foreign demand. For example, the *US Patriot Act* (2001), requires that data held by American companies be turned over to authorities upon demand (Treasury Board of Canada Secretariat, 2006). However, the requirement may create challenges for sharing genomic data for direct patient care by limiting international collaboration and the utilization of innovative and new technology for analyzing and managing patient data.

BC's private sector legislation, PIPA is consent based and does not contain provisions for using data for secondary purposes such as quality improvement or evaluation unless consent is obtained directly from individuals. FOIPPA may apply to a custodian in one circumstance, while PIPA applies in other

[1] As per section 18(2) of the *E-Health Act* and section 23(2(a) of the *PSA*.

circumstance, contributing to confusion and inconsistent governance of personal data, including genetic information. This challenge is not unique to BC, but also exists in jurisdictions such as the EU (Interview 6). Numerous provisions exist to support the sharing of patient data for health care purposes; however, sources have suggested that many health care providers struggle with interpreting and applying the appropriate legislation (Interview 4 & 6).

Currently, in BC, cross-border sharing of genomic data is enabled by obtaining patient consent as per s.33.1(1)(b) of FOIPPA. This is also the case for research participants where researchers must go through research ethics boards. In essence, there is no single coordinated requirement for the collection, use and disclosure of genetic data. As a result, BC's piece-meal approach to genetic data regulation presents challenges for future projects such as the BC Digital Technology Superclusters where public and private bodies will be sharing genetic data amongst themselves.

TABLE 1 - BC GOVERNANCE CURRENT STATE

Body	Federal	Provincial	Local
Public	Privacy Act Human Rights Code, Constitution	FOIPPA BC Ministry of Health policies and procedures	Research Ethics Boards – based on institution/organization
Private	PIPEDA Human Rights Code Constitution	PIPA College Standards of Practice	Research Ethics Boards – based on institution/organization

National Projects and Initiatives

In the Canadian context, Genome Canada is a not-for-profit organization whose work it is to support the translation of genomics research to solve current health, agriculture, forestry, aquaculture, energy and mining challenges by bringing together the public and private sectors to find innovative uses for genomics (Genome Canada, 2016, p. 4) . This is achieved through generating funding and developing innovative models of public private partnership to "pool resources and expertise, reduce the duplication of efforts and mitigate early stage risks" (Genome Canada 2017, p. 14). Recently, BC was awarded one of the $950 million federally funded Digital Technology Superclusters (Government of Canada, 2019a). Phase one will work to develop a secure health and genomics platform for cancer treatments, infrastructure for analytics to support precision medicine and improve health care by enabling patients and their health care

providers to access patient information (Canada's Digital Technology Supercluster, 2017, p. 7). The cross-industry project includes Genome BC as well as various academic institutions such as the University of British Columbia, Simon Fraser University, and the University of Victoria, Providence Health Care, agencies and foundations, research institutes and private corporations such as Telus and Shoppers Drug Mart, in addition to over 500 organizations and post-secondary institutions (Canada's Digital Technology Supercluster, 2018).

Key participants in many genomic research projects around the globe coordinate efforts not only between international governments, non-for-profits and non-governmental organizations, but also for-profit corporations, demonstrating the development of a complex global infrastructure. Indeed, academics such as Bunton and Peterson contend that governance has the capacity to cross nation state divides by operating on various levels and concentrating efforts on activities within a network of actors seeking common and at times conflicting objectives (Bunton & Petersen, 2005, p. 4). Bunton and Petersen take this conceptualization further by arguing that today's modern society is organized by more than the state (Bunton & Petersen, 2005, p. 4). The presence of for-profit corporations who endeavour to secure patents, may be at odds with governmental and non-for-profit research organizations who seek to increase accessibility of genomics as a common good. Such a dynamic undoubtedly influences the design and function of governance frameworks and could provide additional insight into the complex relationship between governments and corporations as well as the way they influence the traditional state border.

Multi-state and private collaborations have allowed for the shaping of governance structures that exist outside the traditional sovereign state model. The Human Genome Organization Ethics Committee, UNESCO's guidelines, and the OECD's *Principles and Guidelines for Access to Research Data from Public Funding* have all played a significant role in establishing frameworks for research (Chen & Pang, 2014, p. 115). However, Knopper's et al., counters that the aforementioned organizations are not supra-national in nature and therefore lack enforcement capabilities, a characteristic that nation states possess (Chen & Pang, 2014, p. 115). Despite this, a current example that may challenge this notion is the EU, argued by some to be a global regulating power (Young, 2015). The EU has the infrastructure and authority to facilitate data sharing between multiple sovereign states. In 2018, the EU announced the signing of a declaration of thirteen member-states to create secure cross border access to national and regional genetic data banks (European Commission, 2018a). The willing participation of Member States to commit to prescribed data sharing practices suggests a softening of the traditional state border that governs the practices of nations. Conversely, there are existing examples of centralization, that reaffirms territoriality within legal boundaries such as the governance structure of China's regulation over genetic data and research (Chen & Song, 2018).

1.4 Organization of Report

This thesis will first outline a literature review examining the development and current state of collaborative genetic research and the data sharing activities, existing governance frameworks and current challenges to sharing. The thesis will then address the conceptual framework using the UNESCO Human Rights Frameworks and the associated governance mechanisms utilized to achieve privacy rights.

The methodological approach and the use of qualitative methods will be outlined including the strategy used for data analysis. Finally, the thesis will identify the findings resulting from research including the main themes resulting from the case studies and the interviews. This will be followed by discussion and analysis including the application of border theory for understanding the benefits and drawbacks to the themes that contribute to an overall framework. Finally, the thesis will suggest potential approaches for BC's governance of genetic data and what this may suggest for the understanding of border theory.

2.0 Literature Review

2.1 Genetic Data, Privacy & Borders

As this project attempts to address the governance of cross-border flows of genetic data, the following literature review may be broken down into three primary categories, literature addressing genetic data privacy, border theory and governance. Within each category, the main literature themes and paradigms are outlined in greater detail. This section will expand on how each body of literature is pertinent to the analysis of governing cross-border flows of genetic data.

2.2 Genetic Data Privacy Literature Review

Despite widely established security practices to protect personal data across jurisdictions, literature demonstrates that the unique characteristics of genomic data present challenges to these security approaches. For example, pseudo-anonymization entails removing information such as individuals' names or birth dates and those characteristics that may be quasi-identifiable (Naveed et al. 2015, p. 13). Even with the use of pseudo-anonymization, the phenotype (physical traits of an individual) may be uncovered potentially exposing an individual's genetic composition (Naveed et al. 2015, p. 13). Through publicly available information, individuals may be reidentified such as those individuals who took part in the Personal Genome Project (Sweeney et al. 2013). Along with patient records, aggregate genetic data is also vulnerable to being reidentified (Naveed et al., 2015, p. 14). For instance, research published in 2004 discovered that only 75 single-nucleotide polymorphisms are required to differentiate between genetic study participants (Lin et al. 2004). Numerous papers published by researchers such as Homer et al. have brought to light the various ways individuals may be reidentified using portions of their genetic data when combined with other easily accessible forms of data (Naveed et al., 2015, p. 14). This suggests that genetic data is vulnerable to privacy violations in ways that other personal data is not. In order to employ an effective data management framework, policy makers need to consider the unique privacy needs associated with protecting genetic data. What has resulted, is a number of competing paradigms that influence privacy approaches to genetic data. For example, countries such as China and the United States have genetic specific legislation which range in use restrictions. Meanwhile, Canada has attempted to enact genetic specific legislation and continues to address genetic data in separate public and private sector legislation. This suggests, there are diverse approaches not only around the globe but within Canada.

I. Privacy Protection versus Open Access

Researchers and policy makers have recognized the value of enabling access to genetic data in order to conduct valuable research. Given the revealing nature of genetic data discussed earlier in this paper and the existence of various interest groups such as the Canadian Coalition for Genetic Fairness, work is underway to ensure that there are privacy protections in place for patients and research participants. Privacy awareness has resulted in access restrictions being placed on who may access the genetic data, how and for what purpose. As a result, proponents of open access have raised concerns that such restrictions challenge the practice of open data sharing that is so essential to the development of beneficial research. (Greenbaum, 2011). However, unrestricted open access can have a detrimental impact on the privacy of individuals and result in legal and ethical implications as well as compromise the scientific integrity of research (Joly, Dove, Knoppers et al., 2012, p.1). What has transpired is a conflict between privacy protection and data sharing (Kaye, 2012).

The literature on data management discusses the common belief among organizations that a trade-off between privacy and innovation must be made. The notion that data protection comes at the cost of innovation which is dependent on unimpeded data sharing is prevalent among researchers (Zarsky, 2015). Conversely, data sharing is said to compromise privacy protection and as a result data custodian are required to choose between prioritizing data privacy or innovation. Consequently, those who place a higher value on medical innovation and research and its ability to save and improve lives often view privacy as a barrier to achieving research goals (Ingelfinger & Drazen, 2004, p. 1452). However, privacy professionals such as Ann Cavoukian, Ontario's previous Information and Privacy Commissioner, contend that privacy does not have to come at the cost of innovation if privacy is integrated into the infrastructure of systems and projects (Cavoukian, 2009, p. 14). Indeed, Cavoukian developed the concept of "Privacy by Design" in the 1990's as a way to tackle the impact of communication and data technologies on privacy (Cavoukian, 2011). The principled approach was formalized in a collaborative effort which included the Information and Privacy Commissioners of Ontario and the Dutch Data Protection Authority (Hustinx, 2010, p. 253). *Privacy by Design* is based on seven foundational principles that are embedded in the infrastructure of a system in order to protect data throughout its entire life cycle without impeding functionality of technology or the initiative (Cavoukian, 2011, p. 2). *Privacy by Design* has been utilized by organizations and countries around the world, most notably the employment of the principles in the recently enacted GDPR (2016, Article 25).

Privacy Solutions

A potential solution put forward by Joly et al. to address the problem of sharing and protecting data at the same time is to establish a multi-layered access approach whereby access remains open for data that

cannot be linked with other data elements that would re-identify individuals (Joly, Dove, Knoppers, et al., 2012, p. 1). Meanwhile, data that is considered sensitive, such as genome sequencing and it's resulting data, is restricted to those who have applied for access through a regulating body (Joly, Dove, Knoppers, et al., 2012, p. 1). While this approach may provide an additional layer of protection, it may also be onerous for researchers to complete and submit lengthy applications on top of existing requirements (Joly, Dover, Knoppers, et al., 2012, p. 4).

Naveed et al., highlight the use of technical solutions such as cryptography or obfuscation for ensuring privacy (2015, p. 9). However, the authors point out that cryptography may diminish algorithm proficiency, are computationally laborious and create barriers to data observation (Naveed et al., 2015, p. 9). On the other hand, techniques such as obfuscation decreases the accuracy of genomic data which in turn compromises its usefulness to those conducting research (Naveed et al., 2015, p. 9). There are various technical approaches that enhance the privacy and security of genetic data; however, the use of this approach is unlikely sufficient on its own.

Another approach posited by Naveed et al. in *Privacy in the Genomic Era*, is the employment of privacy policy or legislation, a method employed by countries around the world (2015, p. 9). Legislation will often regulate how the above mechanisms (limiting access and the application of technical solutions) are applied. A challenge for this approach is enforcement since it is argued that some uses of genetic data may go unnoticed and legislation is dependent on legal interpretation (2015, p. 9). Despite these drawbacks, there is substantial literature that addresses legislative and policy approaches for managing genetic data which will be examined further in the following section.

II. Genetic Exceptionalism

Literature addressing the privacy of genetic data is primarily divided between two data management approaches. The first approach states that genetic data is uniquely identifying personal information that is more sensitive than any other form of personal data and as a result should not be openly shared (Rothstein, 2005; Naveed et al., 2015). The term "genetic exceptionalism" originating from the earlier label of "HIV exceptionalism", and was adopted by Thomas Murray (Rothstein, 2005, p. 27). Canada's Ann Cavoukian outlines that while *Privacy by Design* is applicable to all personal information, particular attention should be given to sensitive information, for example financial or medical information (2011, p. 1). Additionally, privacy approaches should be proportionate with the sensitivity of the personal information (Cavoukian, 2011, p. 1). Interestingly, Canada's federal legislation as well as provincial health information legislation has not taken a genetic exceptionalism approach.

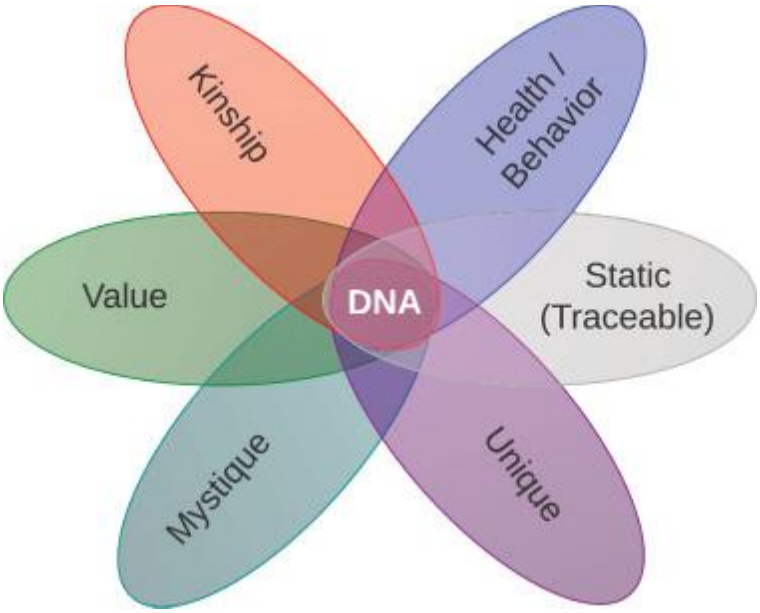

FIGURE 1 - GENETIC EXCEPTIONALISM

Figure 1 found in *Privacy in the Genomic Era*, by Naveed et al. aptly illustrates why genetic data may be exceptional compared to other forms of personal information (2015, p., 4). The authors contend that DNA reveals information about individuals' physical and mental well-being, remains unchanging (static) and is unique to that individual (unique) while revealing information about those they are biologically related to (kindship) and contains valuable information that does not diminish in value over time (value) (2015, p. 4). Finally, from a public perspective, DNA holds a degree of "mystique" as there remain many unknowns about what information DNA may hold (2015, p. 4). As a result of its inherently sensitive nature, genetic data is considered to require elevated privacy and security practices which differ from the approaches used for different types of personal health information. Genetic exceptionalism is commonly evident in legislative models.

Indeed, jurisdictions that employ this approach will often have stand alone genetic data legislation that specifically addresses the management of this information or at a minimum calls out genetic data in general legislation as sensitive and requiring special management. Such an approach is not much different than the approach used for other forms of personal health information such as mental health disorders and HIV status that have been subject to additional protection (Rothstein, 2005, p. 30). The sensitivity of personal data is based on contextual factors and circumstance rather than explicitly called out as sensitive under Canadian privacy legislation (Thorogood, 2018, p. 597). Nevertheless, oversight bodies and Canadian courts have often categorized genetic data as sensitive (Thorogood, 2018, p. 597). Indeed, in British Columbia, genetic data is categorized as personal information under PIPA and FOIPPA, however the Office of the Information and Privacy Commissioner for British Columbia, has classified it as "highly

sensitive personal information" (Office of the Information and Privacy Commissioner of British Columbia, 2017, p. 4)

The competing paradigm to genetic exceptionalism is the notion that all forms of personal information are the same. This is to say, that genetic data is no more sensitive than any other type of personal information and should be subject to the same privacy and security standards (Rothstein, 2005). Rothstein, who recognizes the value of genetic exceptionalism, disagrees with the concept as a public policy contending that it is a challenge to implement separate management of genetic data which is often found in combination with other health information (2005, p. 29). For example, it would be unfeasible to separate genetic information from the rest of a health record or to restrict disclosure of health information to elements which are not related to genetic information (Rothstein, 2005, p. 29). Furthermore, Rothstein among others contend that creating genetic specific legislation may further promote stigma and discrimination of genetic disorders and fail to address the associated social problems that reinforce the need for privacy protection (2005, p. 30).

Indeed, the recent amassing of personal data over the last decade and the technical capability to link these data sets creates an environment where information that once was considered benign, now when combined with other available information may reveal more personal information about an individual (Schadt, 2012). Thus, determining which data element may be key to unlocking more revealing information poses significant challenges when custodians cannot identify all the possible data elements personal information may be combined with. What the literature on genetic exceptionalism suggest, is that this approach may be employed to alleviate public privacy concerns, however given data networks and technology, it is unlikely to provide any more protection. The challenges to developing an effective framework for the governance of genetic data may be further complicated when genetic information crosses borders. To better understand this aspect of governance, a border theory literature review is outlined below.

2.3 Border Theory Literature Review

Border theory studies has gained momentum over the last two decades as an interdisciplinary study involving not only geographers and historians but also economists, anthropologists, sociologists, and political scientists among others (Brunet-Jailly, 2005, p. 634). Borders as boundaries to sovereign nation states are a relatively new concept that took hold after the Treaty of Westphalia in 1648, marking the end of the Holy Roman Empire and the beginning of what is commonly understood as the sovereign state (Krasner, 2001, p. 17). Throughout history borders continually shifted from feudal systems to nation states, merged and broke down; reaching the pinnacle of stability during the Cold War (Haselsberger,

2014, p. 507). Indeed, over the last 100 years, as few as ten European nations have maintained the same borders (Wallace, 1992 as cited by Haselsberger, 2014, p. 506). While globalization is said to have contributed to more permeable borders, it is also argued to have resulted in the establishment of more borders, a concept that is addressed in the following literature review.

While border studies have traditionally focused on the physical delineated border, the discipline has grown to include the non-tangible aspects of borders including the influence of the "physical and human environment", thus making states, culture and markets valuable for analysis of borders (Brunet-Jailly, 2005, p. 634). Borders are complex and dynamic spaces that do more than purely keep people and things out (Haselsberger, 2014). Indeed, Haselsberger contends that it is no longer enough to examine borders as merely ways to define physical space (2014, p. 505). Scholars now recognize that while borders are fortifications, they also facilitate the access to people and goods. Through the classification and control of various process such as economics, culture and politics, borders also have the capacity to affirm when groups are "othered" as well as separate and group those that belong together (Haselsberger, 2014, p. 505). This is an important point when considering the application of borders around goods and services. For example, genetic data crosses borders not only when individuals travel, but when information is exchanged for research, medical treatment, or commercial purposes. Data repositories containing the DNA of citizens from around the world can be found in research institutes, hospitals, public and private labs as well as law enforcement agencies (Schadt, 2012). Thus, the genetic data of citizens who reside within different bordered regions is consolidated into a new space that may differ from its original location. This new space has its own borders that subjects the data to unique regulations and activities that it may not be subjected to in its place of origin.

Technology has had a significant impact on the traditional border's ability to control the movement of goods such as data and communication technology (Castells, 1997). Indeed, technology has created its own digital borders by enabling or restricting access to global social media platforms, markets, online publications and applications by creating its own space and membership. In an effort to control this space and address some of the rising issues (privacy concerns or illegal activity), states are denying (e.g. China's firewall) or restricting access to these spaces or attempting to regulate the behavior within them. Data repositories are increasingly being held in cloud technology or on servers across the world, providing examples of what Castells refers to as "spaces of flows" (Castells, 1997). The literature from scholars such as Castells suggests that the ability for various bodies regardless of geographical location to access genetic data in these repositories exemplifies the way in which spaces of flows challenge the notion of physically bounded territorially demarcated and delineated states.

The use of genetic testing companies such as 23andMe or Ancestry.ca, have enabled individuals to obtain information from their own DNA without relying on physicians or the health care system. Consumers send their DNA samples to companies often located out of their country of residence, or citizenship and receive information regarding their ancestry or inherited traits. As a result, genetic data is no longer restricted to the secure environments of research and medical institutions regulated by bordered states but is also obtained and retained by international corporations with differing regulatory approaches. There are now data repositories around the globe that contain vast amount of personal data sets which are analyzed for numerous purposes, often out of the control of individuals whose data it belongs to. Citizens and private bodies are now playing a leading role in driving cross-border flows of genetic data sharing. From the perspective of this study, the relationship between genetic data and the borders it crosses can provide valuable clues for governance approaches. Genetic data may also prove to be a unique and revealing case study for border theory as it challenges the traditional notion of the territorial boundary and the ability for physical spaces alone to contain and manage resources and protect the privacy of its citizens.

I. The De-bordering versus Re-bordering Paradigms

DE-BORDERING PARADIGM

In the field of border scholarship, two main opposing paradigms exist. The first paradigm contents there is a global trend towards de-bordering whereby the borders of the state either become more permeable or fade away due to globalization and the rise of global actors such as multi-national corporations and not-for-profits. Indeed, multi-national corporations have increasingly been able to circumvent regulation or play a key role in influencing its development (Dahan, Doh & Guay, 2006). Ohmae argues in, *The End of the Nation State*, that the state is largely becoming an obsolete actor that is being supplanted by global corporations (Ohmae, 1995). Ohmae contends that forces such as investment, industry, information technology and the individual consumer have displaced the "market making" role of the state (1995, p. 4). Valaskakis also contends that new sub-national and international bodies undermine the once central role of the state (Chapter 3, 2001, p. 57). As outlined in the introduction to this section, the power of the state and its sovereignty has over time established a deep connection to the strength of its borders. Thus, the deterioration of state power may also be considered a deterioration in borders or vice verse.

Indeed, scholars have identified that borders have been reshaped by factors such as globalization, communications, international free trade agreements and politics (Ohmae 1995; Castells 1997; Knippendberg & Markusse 1999; Shulz 1999; Van Houtum 2000; Blatter & Clement 2000; Perkmann & Sum 2002, p. 3-24, as cited in Brunet-Jailly, 2004, p. 1). The erosion of state borders may in turn impact the role of the sovereign nation as a regulating power both with regards to domestic matters as well as for

cross-border activities. The concept of information technology as challenging the role of the state is particularly relevant for the analysis of cross-border flows of genetic data which are often in digitized form and may not be stored or accessed solely in their country of origin. This can be seen with servers housed outside of Canada that contain Canadians' personal information or the use of cloud technology. Data that is in transit does not necessarily stay within national boundaries but may be routed outside of the country before reaching its storage destination. The same data may be accessed by out of country third parties who are providing maintenance services for information technology. Activities involving non-state actors and frequent cross-border sharing may challenge the traditional role of territorial boundaries and in turn the state's role as gatekeeper for the entry and exit of goods. In this way, technology may work to degrade the border and in turn state power.

This paradigm may be challenged in that technology may also enable the creation of a functional border which will be examined further in the following section. Brunet-Jailly contends that among goods, capital and skilled labour, information moves across physical spaces as if there are no borders suggesting a deterioration in the delineating power of boundaries (2004, p. 2). In light of the frequency and ease of cross-border flows of goods, Brunet-Jailly suggests a type of "functional evolution" is occurring to meet the new global environment that favours movement and sharing but also exclusionary access (2004, p. 2). Indeed, the increasing permeability of boundaries may not come at a detriment to state power but is rather an intentional adaptation by the state to improve access to technology and markets around the world. For example, given the substantial costs of developing and operating such technological infrastructure, there is a growing reliance on corporations to enable public bodies to access such information technology in order to provide essential services such as health care. The BC Digital Technology Superclusters is a timely example of how public-private partnerships are being developed to facilitate genomic research and access to precision medicine. Such partnerships and infrastructure may either lead to more border permeability and challenge the traditional role of the state or lead to the development of what Borders in Globalization academics detail in their research as functional regulatory borders (University of Victoria, 2019). Such borders can be born in Canada and impose a specific standard outside the country or they can make Canada porous to unfettered data transfers resembling a wild west of information technology.

RE-BORDERING PARADIGM

Scholars such as Newman contend that a borderless world is not possible, as borders play a critical function in establishing order through compartmentalization (Albert et at., 2001; van Houtum and van Naerssen, 2002, as cited in Newman, 2006, p. 143). What this suggests, is that there is state reliance on maintaining borders in order to retain the state's influence as a primary regulator. The connotation that borders evokes is often one of siloed and closed interactions between state actors. However, the continual

existence of borders does not necessarily indicate a closing off of states, rather as Chen posits, borders are a nexus for openness and may act as a conduit for international activities (Chen, 2005, p. 23). For example, while the 20th century witnessed the creation of more borders than the previous century, the world has never been more open (Chen, 2005, p.22). In essence, borders are more than merely physical barriers that deny or enable entry into another sovereign nation, but rather play a functional role that facilitates and promotes certain activities such as commerce, or in the case of this thesis, an exchange or transfer of data for the purpose of medical care or research.

Indeed, the borders developed in the field of genomics research have the potential to act as a bridge and facilitate the unobstructed flow of genetic resources that will enable collaborative research. However, as will be outlined further in this paper, relying on territorially based borders to govern genetic data may create barriers to data sharing that is essential to health care and research.

FUNCTIONAL VERSUS TERRITORIAL BORDERS

Border studies scholars tend to agree that borders are complex, dynamic and come in a variety of forms most of which are meant to serve a purpose based on social constructs (Brunet-Jailly, 2004). As a result, borders possess different functions and bordering processes. The OECD document *Redefining Territories: The Functional Regions*, defines functional regions in the OECD as;

> territorial unit resulting from the organisation of social and economic relations in that its boundaries do not reflect geographical particularities or historical events. It is thus a functional sub-division of territories. The most typical concept used in defining a functional region is that of labour markets (Cattan & Organisation for Economic Co-operation and Development, 2002, p. 11).

Haselsberger examines the processes around bordering and the different functions and components of borders using a "dynamic border interpretation framework" which is a consolidation of border theory literature summarizing the attributes of borders put forward by scholars (Haselsberger, 2014, p. 506). The model is broken down into four groupings; geopolitical boundaries, sociocultural boundaries, economic boundaries and biophysical boundaries (2014, p. 512). Each group is then examined based on the functions, framings of borders and discourses, and bordering processes are examined through perceptions and interpretations (2014, p. 513).

For the purpose of this thesis, economic boundaries may be the most relevant lens for analyzing the cross-border flow of genomic data and impact on functionality and bordering processes. Scholars tend to agree with the notion that functional spaces have their own rational and as a result may not parallel spaces that

are political, administrative or environmental in nature (Davy, 2002 as cited by Haselsberger, 2014 p.518). As such, understanding the unique properties of functional borders is critical to developing effective governance strategies. While borders will not necessarily always enable or restrict access in every scenario (Haselsberger, 2014, p. 517), retaining permeability gives borders functionality and supports or limits certain activities. Consequently, Haselsberger urges planners (and in the case of this thesis, policy makers and legislators) to understand the dynamics associated with functional and environmental spaces (2014, p. 517).

The utilization of border theory provides a new lens for examining the extra-territorial impact of technology on personal data. However, in order to gain an understanding of how to develop an effective framework to regulate the cross-border sharing of genetic data, an overview of governance approaches will be explored in the following section.

2.4 Governance Literature Review

In *Governing Complex Societies*, Pierre and Peters illustrate the competing governance paradigms by highlighting key arguments made by scholars. For example, scholars such as Osborne and Gaebler describe the concept of governance as "the business of government", while Rosenau and Czempiel contend that the evolving international sphere has challenged governments' ability to manage policy direction (Gaebler, 1991; Czempiel, 1992, as cited in Pierre and Peters, 2005, p. 2). There are also scholars such as Rhodes (1997) who argue that while governments provide a legal framework which allow other bodies to carry out activities, the public sector has little ability to exert control over these bodies (as cited in Pierre and Peters, 2005, p.2).

Pierre and Peters agree that the power of public bodies has diminished, however governments still play a critical role in governance, particularly the notion of "democratic governance" (Pierre and Peters, 2005, p. 3). Furthermore, a lack of consensus within nations on how to approach policy problems may in part be due to a lack of political will to take a position on contentious or complex issues. This may then impact the coordination of international efforts to create consistency and interoperability. Indeed, the preface to the 1980 OECD *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data*, cautioned that a lack of alignment across nations' laws would create barriers to the cross-border flow of data (Dove, 2015, p. 681). At the global level, levers generally employed at the sub-national and national levels in the form of democracy, law enforcement and government administration are not typically present (Frenk & Moon, 2013, p. 937). The absence of these levers creates obstacles for establishing a consistent framework to support consensus on enforcement, coordination of efforts, policy development and responsibility (Frenk & Moon, 2013, p. 937). The varied approach or complete lack of approach to

addressing the appropriate collection, use and disclosure of personal information, particularly by private corporations may contribute to breaches and misuse of personal information evident in the cases of Facebook and Cambridge Analytica.

After World War II, multilateral institutions were created to harmonize what Frenk and Moon describe as "shared social objectives" (Frenk & Moon, 2013, p. 937). The existence of NGOs, such as the World Health Organization (WHO), contribute to the presence of a global framework for coordinating health care (2013, p. 937). Indeed, 194 Member States share in the work of the WHO to address health care issues around the world (Frenk & Moon, 2013, p. 937). A shared global framework may help to support a joint vision between organizations worldwide which includes the activities of non-government organizations.

Non-government bodies, such as for-profit companies, play a role in driving and shaping policy but experience greater challenges in instances where there is a lack of consensus (Pierre and Peters, 2005, p. 3). An additional challenge or draw back to network driven governance is a lack of accountability and a reliance on governments to create instruments that enforce and hold private bodies accountable (Pierre and Peters, 2005, p. 3). Alternatively, private bodies may be held accountable through consumer power; citizens as consumers have buying power that is akin to voting. Negative publicity may not necessarily result in losses to revenues; however, they may incentivize private bodies who are in the business of selling products and services to behave in a way that consumers believe to be appropriate (King, 2011). Furthermore, technology such as social media platforms, may create accountability outside of formal government structures by providing citizens the opportunity to vocalize their concerns (Mills, 2017). Such an example may be seen with consumer boycotts on Uber, American Airlines, or Chic-fil-a in the United States (Mill, 2017). The consumers' choice to vocalize disapproval of a business's conduct or activities may regulate behavior through the use of protest which influences markets (King, 2011).

In essence, the governance literature has highlighted five relevant considerations for the governance of cross-border sharing of genetic data; the state's decline as a regulator due to globalization, intra state challenges to addressing policy problems, the role of international organization, the influence of the private sector and issues of accountability. Finally, the absence of a coordinated approach may impede access to health care evident in the challenges to the secure cross-border sharing of genetic data and the fragmented approach to privacy legislation across Canada and within British Columbia.

2.5 Summary

The above literature is relevant to three key aspects of this study; the privacy and sharing of genetic data, the relationship between genetic data and borders and what governance mechanisms may be employed by states to ensure the secure and uninhibited flow of the data.

The literature highlights that there are challenges to regulating genetic data; whether access to data should be restricted or open, and if genetic data is an exceptional form of personal information that requires special treatment to ensure privacy. This is further complicated when considering the use of big data and technology which can make certain approaches such as genetic exceptionalism impractical to implement. Potential approaches to addressing privacy protection include; multilayered access, technical solutions that conceal data and legislative approaches that regulate activities associated with genetic data. These approaches are often found in combination as part of a larger governance strategy.

Border theory literature highlights that borders have evolved from being mere demarcations of space to playing a role in creating and regulating "spaces of flows" for all types of functions and activities. While softer more permeable borders are considered by some to be a sign of a weakening state, these borders may be indicative of functional borders which regulate activities and enable international partnerships, a favourable feature for genomic research. The application of a border lens to the cross-border governance of genetic data is valuable to understanding the impact non-tangible goods and services such as data may have on borders as well as provide a more comprehensive understanding of how data may be impacted when crossing into different spaces.

Finally, governance theory literature provides a view of governance challenges for governments, particularly in light of rapid technological changes and the inclusion of non-state actors. The growing demands on governments to provide citizens with access to essential services such as health care has strained the resources of the state (Theodoulou & Roy, 2016). As a result, there is a growing reliance on public private partnerships to meet the needs of populations by creating access to expert personnel and technical resources. The growing role of the private sector as well as the presence of multi-national corporations has created a networked environment where states can no longer act in a vacuum but must consider all impacts on citizens and their data. The increasing involvement of the private sector has revealed a regulatory void. Indeed, literature has identified a need for greater accountability on the part of private bodies to align with appropriate data practices which preserve the privacy and autonomy of individuals.

On a global scale, creating consistency and alignment across international boundaries that both protect and enable access to genetic data is particularly challenging given the number of actors (state and non-state) and the need to align various jurisdictions. Multi-lateral institutions such as the UN and OECD may play a critical role in guiding policy direction across jurisdictions that are consistent and enable data sharing while setting a high standard for privacy protection.

TABLE 2 - RESEARCH QUESTIONS AND THE LITERATURE

Question 1	Question 2	Secondary Question 1	Secondary Question 2
What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?	What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?	What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving health care while preserving human rights to privacy, autonomy and access to data?	Based on findings, what are potential approaches for the BC context?
Literature Suggests	Literature Suggests	Literature Suggests	Literature Suggests
The movement of genetic data in research across borders as well as the inclusion of multiple state and non-state actors challenges the notion of the traditional territorial border.	The bordering of genetic data may not create silos but rather act as a conduit for data sharing by creating what Castells calls “spaces of flows” that regulate the handling of genetic data by certain bodies.	International infrastructure exists in the form of declarations, guidelines and principles that consistently address human rights, privacy and enabling access to data.	International declarations, guidelines and principles are already being employed in Canada on a federal level. The continued employment on a provincial level could support interoperability both within Canada and internationally.

3.0 Methodology and Methods

The purpose of the study is to determine what may be the most appropriate approach to regulating the cross-border sharing of genomic data within British Columbia. How appropriate a framework is for the BC context is determined by its ability to protect the privacy of individuals, preserve participant autonomy and enable secure and appropriate access to data. A primary objective of the framework is to support scientific and medical innovation to improve the health of BC citizens without compromising human rights. The following section will outline methodology, methods and interview processes that were undertaken to complete this project.

3.1 Methodology

To understand what approaches exist for governing the management of genetic data, the project utilized qualitative research in the form of primary and secondary data which was triangulated to conduct a comparative case study of three jurisdictions, the European Union (EU), China and Global Alliance for Genomics and Health (GA4GH). The case studies were selected due to their governance approach, organization type (e.g. public, private, national, supranational and global), and what their data practices mean for privacy and the sharing of genetic data.

The governance of genomic data is examined through the human rights framework as set out by UNESCO's Human Rights Declarations, in particular the *Universal Declaration on Human Genome and Human Rights, International Declaration on Human Genetic Data*, and the *Universal Declaration on Bioethics and Human Rights* (known as the Declarations going forward). The Declarations establish the guiding principles for genomic data governance such as the right to privacy, the right to access data, and the requirement to obtain consent from patients and research participants. The project assessed how each case study employed the genomic human rights framework and whether these principles were realized in practice.

Through academic and grey literature, common global governance mechanisms were identified; they include the UNESCO Declarations, OECD *Guidelines on Human Biobanks and Genetic Research Databases* and the Bermuda Principles. In addition to this, legally enforceable mechanisms in the form of supranational bodies, constitutions, and privacy legislation are compared across the three case studies to identify the operationalization of genomic governance strategies and their impact on cross-border sharing of data. The objective of the project was to develop a comprehensive analysis of what governance structure may most effectively protect the integrity and privacy of personal information while enabling its movement for health care research and delivery in BC.

3.2 Methods

Timeline

Research and background analysis occurred from January until March which included the submission of a proposal and ethics approval under the Borders in Globalization project (Ethics Protocol Number 18-1035). The case study research and analysis occurred from April until June and identified additional areas of research required to complete the comparative case study analysis. It was recognized that primary data collection would be needed to answer outstanding research questions not provided in the literature and was best achieved through interviews. Approval of interview questions was received prior to contacting interviewees and conducting interviews. The preparation for interviews, interview requests and conducting interviews took place from July until September. Triangulation of the data and analysis was conducted throughout September and October with the final first draft of the project completed in November.

Case Study Selection

Each case study was selected due to its unique context and structure while still employing a common set of regulatory mechanisms. This was determined after conducting a jurisdictional scan of states and global organizations that play a leading role in genetic data governance. China was selected due to its state-centred approach which implements genetic specific legislation. The EU was selected for its supranational framework which employs the *General Data Protection Regulation* (GDPR). GA4GH is an international non-for-profit organization that began in 2013 under the direction of a group of leading researchers with a purpose to enable global data sharing to support the development of science and medicine (Kosseim et al., 2014, p. 5). As a result, GA4GH was selected because it is a global consortium that spans public and private as well as state and non-state actors across numerous countries.

Methods

Academic databases were utilized to search journals that focused on medical, scientific, legal, privacy, security, policy and governance. Google Scholar was used to conducted key word searches for subject matter involving genomics data sharing, genetic privacy, genetic exceptionalism, health care privacy, patient autonomy, direct to consumer genetic testing, international genomic research collaboration, governance of genetic data, and regulation of genomic research. Research notes outlined key bodies in the field of genomics, landmark accomplishments, current projects, common governance practices, challenges and potential solutions. Spreadsheets were created to organize key governance mechanisms for genomic data to identify which bodies utilized them and map relationships.

The University of Victoria's, Borders in Globalization project hosted seminars which included presentations from subject matter experts in the field of border studies and provided insightful discussion on border topics including governance, networks, security and the cross-border flow of goods. Academic journals such as the *Journal of Borderlands Studies*, was utilized to develop a foundational knowledge of border studies, history of the field, developments and current paradigms that provide a lens for the analysis of genetic data governance.

Research included attending workshops, seminars and conferences. Privacy and security conferences as well as workshops and sessions on genetic data privacy and health data governance. Seminars on privacy and policy hosted by government communities of practice were also attended and utilized to assist in the direction of research by identifying subject matter experts, new genomic projects and developments in genomic research and technology.

In person conferences and seminars also provided opportunities to connect with professionals who were later approached for interviews. Interviews contributed to the collection of primary research data which were used to triangulate secondary data collection. Interviews were able to provide context and granular data that academic and grey literature could not provide. Interviewees had expertise in privacy, security, legal and or genomics and were able to identify undocumented governance practices, potential strengths, weakness, and challenges of such approaches.

3.3 Interviews

A total of eight interviews were conducted as part of the research. Interviews were conducted with personnel from Canadian provincial and federal governments, provincial regulatory body, and an EU Member State Data Protection Agency. Additionally, academics specializing in health law, EU and Chinese legislation, and policy development for GA4GH were interviewed for their expertise. Interviews were approximately 60 minutes in length and each participant was provided a package containing the research thesis background, project and supervisor contact information, a consent form and sample questions. Consent was obtained prior to conducting the interview and participants were informed they could request that interviews not be recorded. No personal information was requested during the interview process and any personal information that may have been collected was destroyed.

While there was a general theme and consistent nature to the interview questions (see Appendix 1), each session was tailored to the expertise of the interviewee in order to obtain granular detail about their organization's governance approach, experience with specific regulation, governance framework or the specifics of research and published works. Questions were tailored to fit the jurisdiction of the

interviewee (Canada, China, European Union, and global), the level of governance (international, national, provincial), the role of the interviewee (scholar, oversight/regulating body, government body, non-government organization, scholar/legal/analyst). Interviewees were selected based on their knowledge in the area of genomic data governance and involvement in the field or experience with each case study (the EU, China and GA4GH). Interviews were conducted with the intent to uncover themes regarding type of regulations, formal and informal processes, privacy approaches, degree of state involvement, culture and context, interoperability of regulations across borders, privacy rights of individuals and communities, and enforcement capabilities. Outlined below are points that were used to guide discussion along with specific questions.

1. Application of human rights concepts in governance approach
2. Consistency in approach across jurisdictions to concepts of:
    i. privacy
    ii. data sharing
3. Reliance on a particular structure (e.g. the state or a supranational body as an enforcement mechanism)
4. Reliance on a particular mechanism (e.g. national legislation or supra-national legislation)
5. The presence of general privacy laws versus sensitive data categories or genetic exceptionalism
6. Adequacy versus accountability approaches

Initial interviews were used to identify themes, key words and consistent ideas or paradigms. The final four interviews were used to address the identified themes from earlier interviews and explore the concepts further by having specific questions regarding these topics. A range of topics were discussed in one-on-one interviews, however reoccurring topics and themes arose across all interviews which included the following; context, community rights, trust, data ownership, process formalization, role of the state and legislative approaches. Once interviews were completed, recordings were transcribed along with interview notes to identify common themes and key words using an excel spreadsheet. Common language and themes were examined using the research questions that focus on human right to privacy, the impacts on sharing and the relationship with border theory.

While there was an effort to connect with private sector actors such as private sequencing and communications companies, no interviews were scheduled with any for-profit organizations. There would

be value in conducting further research on the desired governance strategies from the private sector perspective (e.g. the continuation of public-private partnerships, business needs, public relations, etc.).

3.4 Analytical Framework

The following section will provide information on common governance mechanisms employed with a particular focus on four instruments, UNESCO Human Rights Declarations, OECD Guidelines, Bermuda Principles, national legislation and judicial interpretation as a measure for protecting privacy rights and supporting appropriate data access. These instruments provide an analytical framework to conduct a comparative analysis of the EU, China and GA4GH case studies.

Tools employed to operationalize governance principles are often legal or quasi-legal instruments that may be employed at an international, regional or a local level. Andorno, contends that while international organizations may establish a standard of principles or "optimization commands", national governments are the bodies that implement the principles into action (Alexy, 1994 as cited by Andorno, 2013, p. 18). Enabling the flow of genomic data while preserving privacy rights is dependent on national interests, relationships, priorities, and level of economic stability and development. The environment in which regulation takes place influences the instruments that are used to achieve governance goals. Numerous scholars list some of the following instruments as vehicles for implementing governance principles.

There are a number of informal levers that citizens and interest groups may leverage to influence governance frameworks. This may include boycotting for-profit organizations by revoking consent for the use of genetic data or avoiding the purchase of related services. The scientific community's voice is crucial in condoning research or condemning the actions of colleagues, institutions and state actors and may result in poor public relations leading to the potential failure of associated projects. An example of this is pressure applied by Chinese geneticists on the government to respond to a case of unethical use of genetic data by Harvard researchers, resulting in the development of the *Interim Measures for the Administration of Human Genetic Resources* (Chen & Song, 2018, p. 607). Additional methods of regulation may occur through the allocation of funding. For example, the *Fort Lauderdale Agreement* stipulates that a condition of project funding should include the unrestricted release of data to public databases to ensure free access (Wellcome Trust, 2003, p. 3). Finally, patients and professionals may influence governance by establishing special interest groups that petition on behalf of communities, such as the Canadian Coalition for Genetic Fairness. Citizens may act on their own to raise awareness through mainstream media as well as social media platforms to disseminate information, create awareness and advocate for specific regulation.

UNESCO Human Rights Declarations

A human rights paradigm is an approach that may effectively address the principles of privacy, consent, security, access, and equity. Andorno has argued that the instruments developed by both UNESCO and the Council of Europe have resulted in comprehensive guiding principles, demonstrating the development of international biomedical law which was born from international human rights legislation (Andorno, 2013, p. 13). These principles are considered foundational to biomedical ethics and are consistently considered among ethics boards who review and approve scientific research projects. As a result, biomedical ethics falls within the scope of the framework considered in this thesis. While the principle of non-discrimination is closely connected to the notion of human rights, it is not the chief focus of this paper and may be more adequately addressed in a separate thesis.

Since 1945, the United Nations Educational, Scientific and Cultural Organization (UNESCO) has worked to create peace through global co-operation of education, sciences and culture (UNESCO, 2019). Comprised of 193 Member and 11 Associate Members, UNESCO's Constitution enables it to make "conventions and recommendations" which may be considered a form of soft law (Harmon, 2005, p. 28). Despite this, the Declarations may be a point of reference for the development of national, transnational and supranational governance frameworks by establishing what have been argued as universally accepted ethics and human rights principles on which governance is based (Levitt & Zwart, 2009). Taylor has suggested that instead of signifying international agreement, the Declarations are a path to the potential creation of enforceable instruments by facilitating dialogue (Taylor, 1999, p. 511). This suggests that the instruments have not solved the challenge of disparate policy approaches to genetic data sharing but rather have played a critical role in generating awareness and facilitating discussion on the topic.

Background

In the preface of the *Proceedings of the First Session of the IBC* (UNESCO, 1994), Federico Mayor, the Director-General of UNESCO believed the organization had a role to play in coordinating international standards and legislation that would be "grounded on the essential values of mankind" (as cited by Harmon, 2005, p. 24). Such a framework would be based on the *International Bill of Rights* (IBR), including the *Universal Declaration of Human Rights* (UDHR), the *International Covenant on Civil and Political Rights* (ICCPR), and the *International Covenant on Economical, Social and Cultural Rights* (ICESCR) (Harmon, 2005, p. 24). Indeed, rapid advances in biotechnology would prompt the creation of "the first international instrument on genetics" (Harmon, 2005, p. 28). Developed by UNESCO's International Bioethics Committee (IBC) and finalized in 1998, UNESCO put forward the *Universal Declaration on the Human Genome and Human Rights* (UDHG). The supplemental *International*

Declaration on Human Genetic Data (IDHGD) was finalized in 2003 and the *Universal Declaration on Bioethics and Human Rights* (UDBHR) in 2005 (Andorno, 2013, p. 14). The three UNESCO Declarations (the Declarations) whose foundations were built with the IBR in mind provide a framework for autonomy, equity, consent, confidentiality and information sharing among others (Harmon, 2005, p. 43).

Limitations

Since their inception, three primary criticisms have been aimed at the Declarations. Accusations include the concern that the core values are not universally accepted, the development of bioethical frameworks is out of the jurisdiction of UNESCO, and provisions are too general and ambiguous to result in tangible action (Landman and Schüklenk 2005, iv). Indeed, UNESCO's statement that it is "desirable to set universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics*"* (UNESCO 2003) suggests that not only do universal values exist, but that they may be expressed consistently from one culture to the next. However, critics argue that UNESCO has imposed western ideology, primarily in the form of "European enlightenment philosophy" on non-western nations, resulting in skepticism that human dignity is an appropriate framework for bioethics (Landman and Schüklenk, 2005, iv). However, Levitt and Zwart point out that consultations with 67 states did indeed result in the inclusion of dignity as a common principle along with equality, non-discrimination and the notion of privacy (2009, p. 369).

From a practical standpoint, Harmon posits that due to the reconceptualization of sovereignty, non-state bodies such as UNESCO are appropriately placed to lead the way on novel challenges in fields such as genomics (Harmon, 2005, p. 28). Despite UNESCO lacking bioethical expertise, it is well versed in the development of frameworks and global collaboration, a critical factor in harmonizing data sharing practices. As a result, UNESCO has played a significant role in generating discussion on the challenges and opportunities of genomics and establishing a common point of reference.

Finally, the Declarations are said to be limited in their capacity to act as effective guidance tools (Harmon, 2005, p. 44). Despite possessing principles of consent and equitable sharing, there is little direction on how to achieve them, contributing to inconsistent application (Harmon, 2005, p. 44). Arguably, such a broad approach enables the Declarations to be flexible and adaptive, thus remaining relevant despite changes in time and culture.

Additional Categories of Analysis

In addition to UNESCO's right's based framework, the case studies for China, the EU and Global Alliance for Genomics and Health (GA4GH) will consider the presence of national legislation,

supranational legislation such as the Council of Europe *Convention on Human Rights and Biomedicine*, the *General Data Protection Regulation* (GDPR), and judicial interpretation of genetic case law that influence policies and procedures. Additionally, each case will be analyzed according to its adherence to and implementation of guidelines and recommendations put forward by global organization or international collaborations, namely the Organization for Economic Collaboration and Development (OECD) and the Bermuda Principles.

OECD Guidelines

The OECD includes the governments of 30 democracies whose purpose it is to assist in addressing challenges associated with globalization (Organisation for Economic Co-operation and Development, 2008, p. 7). The OECD endeavours to co-ordinate international and domestic policies and establish best practices in order to develop a global standard that is acknowledged and implemented around the world (Organisation for Economic Co-operation and Development, 2008). Recommendations put forward by the OECD in collaboration with members and stakeholders has been self-described as a "legal instrument…that is not legally binding, but through long standing practice of the member countries, considered to have a great moral force" (OECD, 2007, p. 7). Adoption of standards and principles commence when Member States make a political commitment to employing recommendations. The OECD explicitly refers to this as a soft law (OECD, 2007, p. 7).

For the purpose of this thesis, there are two guidelines developed by the OECD that are relevant to the governance of genetic data and its movement across borders, these include *Guidelines on the Protection of Privacy and Transborder Flow of Personal Data* and the *Recommendation on Human Biobanks and Genetic Research Databases*. In the late 20th century, the OECD recognized that bodies were developing new uses of personal data which showed signs of significant economic and social benefit (OECD, 2013). As a result, the OECD sought to develop guidelines to enable the flow of data between member countries while promoting the protection of privacy and the security of personal information. The guidelines include the following principles:

- Accountability
- Purpose specification
- Collection limitation
- Use limitation
- Data quality
- Security safeguards
- Openness

- Individual participation

The above principles would be used in the drafting of Canada's PIPEDA which would receive Royal Assent in 2000. In October of 2009, the OECD Council adopted the *Recommendation on Human Biobanks and Genetic Research Databases* to provide guidance on the "governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases (HBGRD)" (OECD, 2009, p. 1). OECD Guidelines of HBGRD address principles and best practices regarding privacy, consent, security, access, governance, management and oversight and custodianship among others (OECD, 2009, p. 1). Not unlike the UNESCO Declarations, the HBGRD document establishes the principle of access by recommending that genomic data is **"**rapidly and widely available to researchers so as to advance knowledge and understanding" (OECD, 2009, 1.C). Additionally, as per 1.H, research results are published in order to provide access. Principles of equitable access entrenched in the HBGRD, align with human rights principles that underpin the Declarations, national legislation, biomedical ethics boards, and policy (OECD, 2009, 1.D). Human rights principles are evident in section 4.B, addressing the requirement to obtain free and informed consent in order to protect individuals (OECD, 2009).

The HBGRD is perhaps one of the first instruments to address public private partnerships (P3) and the need for transparency regarding the P3 relationship, particularly as it pertains to informing citizens (OECD, 2009, 2.4). Further stipulations are outlined highlighting the importance of communicating the commercial outputs from research and disclosure regarding any benefits to participants.

Bermuda Principles

The Human Genome Project (HGP) included scientists across 20 institutions from six countries; China, France, Germany, Japan, the UK and the US (yourgenome, 2016b). In addition to the sequencing of the human genome, the HGP established a framework for the appropriate sharing of data that would occur between HGP members as well as the global medical and scientific communities. Chief within this framework was the Bermuda Principle which was established to make data publicly accessible within a 24-hour timeframe (yourgenome, 2016c). Francis Collins who led the HGP between 1993 and 2003 from the US National Institute of Health, insisted that sequencing of the genome was not information that should be kept a secret, but rather made readily available to scientists around the world (yourgenome, 2014). Collins would contend that "the most significant hallmark" of the HGP was the influence it had in changing the mentality of the scientific community toward open access to data (yourgenome, 2014). However, despite the establishment of the Bermuda Principle, resistance to sharing for the purpose of establishing patents for commercial profits would create challenges within the HGP. In 1998, Craig Venter launched Celera Genomics with the objective of completing the HGP as a private project

(yourgenome, 2016a). Additional scientists sought to patent certain genetic sequences for commercialization, such as Myriad Genetics who patented the genes related to breast cancer (BRCA 1 and BRCA 2) (yourgenome, 2016d). Indeed, the conflict between whether or not data should be freely accessed contributed to the early departure of James Watson (yourgenome, 2016d). Francis Collins, who firmly believed in open access would come to replace James Watson (yourgenome, 2016d). Years later in 2013, the US Supreme Court would prohibit the patenting of the human genome, rendering Myriad's breast cancer patents powerless (*Ass'n for Molecular Pathology v. Myriad Genetics, Inc*.) (yourgenome, 2016d). Undeniably, court decisions and the judicial interpretation of genetic and human rights legislation plays a critical role in the application of regulatory frameworks to various circumstances.

While the Bermuda Principle has a narrower scope and fewer participants than the UNESCO and OECD instruments which include consent, privacy and security, the Principle was instrumental in shifting the mentality of the scientific community towards the notion of equitable and open access. As a result, the Bermuda Principles will be a comparative point of reference in this thesis.

National Laws

Among the various instruments utilized to regulate genetic data, national laws may be the greatest expression of international principles applied within the environment of a state's culture and values. Interpretation of principles and their applicability within a society varies from nation to nation. Indeed, the Declarations were developed with the intent there would flexibility in their implementation so as to acknowledge the unique context of states (Andorno, 2013, p. 18). Nations may possess stand alone genetic legislation or genetic data may be addressed in various laws where genetic data may be applied such as labour, insurance, health care, forensic, diagnostic or carrier testing (Varga et al., 2012, p. 132).

Additional consideration will be given to national human rights laws which may exist in the form of constitutions that may address the right to privacy and autonomy (consent). By examining human rights legislation within each case study, insight may be gleaned as to the intended purposes behind any existing genetic data laws, for example, a focus on national security versus the rights of individuals to privacy.

Judicial Interpretation

While the Bermuda Principle establishes common values and their best practices for conducting genomic research, without the power of judicial enforcement, the agreed upon principles have little enforceability or recourse. Judicial interpretation regarding the restricted use of a discovery that resides in the genetic makeup of humans plays a critical role in not only framing regulation principles, but puts into action agreed upon principles – or delegitimizes them, and has the capacity to enforce adherence within the

nation state as well as across supranational bodies. This is a clear example of Alexy's "optimization commands", that are employed by national governments. Indeed, to achieve operationalization, principles put forward by the UNESCO Declarations need to be combined with national law and finally, applied by judges, the "natural intermediary" (Andorno, 2013, p. 18). The case studies will address what if any significant judicial decisions have taken place and their impact on the operationalization of regulations.

3.5 Summary

While the UNESCO Declarations are the primary point used for conducting the case study analysis of the EU, China and GA4GH, the OECD Guidelines, Bermuda Principles, national legislation and judicial interpretations will also be employed as measures of protecting the human right to privacy.

3.6 Data Analysis

The primary and secondary data collected was analyzed through multiple lenses, human rights and border theory. The governance of genetic data was examined through border theory, specifically the role of the state and whether the regulation of genetic data is undergoing a state decentralization resulting from international collaboration and public-private partnerships or whether there is a trend in increasing state control of genetic data as more attention is given to data privacy rights.

Interviews sought to identify recurring themes in governance strategies as well as challenges and outcomes of recently implemented regulatory structures such as GDPR. Interview findings supported the literature review of China, the EU and the GA4GH case studies. Final recommendations are made on what regulatory mechanisms may provide the strongest framework for enabling appropriate cross-border sharing in BC. The BC lens considered the province's diverse populations which is comprised of 200,000 Indigenous individuals (WelcomeBC, n.d.), nearly 1.3 million (28.3%) immigrants (Statistics Canada, 2017), and a public health care system comprised of multiple health authorities that is engaging in public-private partnerships to deliver services.

The concept of borders is integral to the assessment of governance frameworks since it is the shifting and evolution of borders that affects the way goods and services are shared. In this instance, it is namely data and the collaboration of the scientific community that is impacted by borders. The trickle-down effect of borders is felt by patients receiving health care or participating in research. As such, border theory may provide a new lens for analyzing the sharing of genetic data.

3.7 Project Limitations

Genomics research, technology and its regulation are evolving at a rapid pace. Indeed, over the course of this thesis, there were three revisions made in content due to changes in China's legislation, a court decision on the constitutionality of Canada's *Genetic Non-Discrimination Act* (2017) and amendments to BC's *Freedom of Information and Privacy Protection Act*. In addition to this, genomics research developments included the unsanctioned gene editing by a Chinese scientist as well as a number of other sequencing discoveries and applications. Many projects such as the BC Digital Technology Superclusters are currently in the early stages of development and as a result, providing a comprehensive analysis of the current state of genomic research and projects in BC as well as around the globe is challenging. Additionally, this thesis is only able to provide a snapshot of the state in the period of time in which the research took place based on available information. Nevertheless, it is felt that such an examination may still provide insight on how to manage the future of genetic data sharing in BC.

As a public servant for the province of BC, disclosure of information on the development of projects, legislation and policy is limited to information that is publicly available due to the issue of cabinet confidentiality. The author has previous experience and a background in the challenges and complexities associated with privacy and health information which could bias her. To address this, the author has made a deliberate effort to outline the benefits, drawbacks and opportunities of each approach and select interviewees with varied viewpoints on the approach to privacy and data sharing.

4.0 Findings

4.1 Comparative Analysis of Case Studies

Each case study examines the employment of privacy protection using a human rights lens outlined by the UNESCO Declarations and their implementation using OECD Guidelines, Bermuda Principles, supranational bodies, constitution, national legislation and jurisprudence. Finally, each case studies' motivations were examined to gain an understanding for the raison d'etre of each governance framework.

TABLE 3 - RESEARCH QUESTIONS

Question 1	Question 2	Secondary Question 1	Secondary Question 2
What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?	What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?	What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving health care while preserving human rights to privacy, autonomy and access to data?	Based on the findings, what are potential approaches for the BC context?

4.2 EU Case Study

Background

Along with the US, China, Japan and Canada, NGOs, not-for-profit organizations and academic institutions in European Member States, Germany, France, and the UK contributed to the Human Genome Project. Today, most Member States have various genomic research projects and programs which often involve engaging with national, international and global bodies. For the purposes of this thesis, the case study examining continental Europe will take an EU focused approach. While the EU is a supranational organization that may exert legal power over Member States, the Council of Europe, impacts the activities of European nations. All 28 EU Member States are members of the Council of Europe, but not all 47

Council of Europe members belong to the EU (Townend, 2016, p. 128). The chief difference between the two regimes is that the EU is primarily an economic vehicle that was implemented post World War II as a method to connect nations through free trade, while the Council of Europe has a democratic and human rights purpose (Townend, 2016, p. 128). Townend, contends these two regimes heavily influence the governance of genomic data and biobanking in Europe (Townend, 2016, p. 128). Nevertheless, governance across and within 47 nations does not occur in a vacuum and is subject to local, international and transnational factors that influence the way genomic data is managed.

International Influence

UNESCO Declarations

Most EU Member States are signatories to various international treaties such as the *International Covenant on Civil and Political Rights* (Middleton, 2018, p. R10) and all are signatories to the UNESCO Declarations. In fact, Europe may be credited with influencing the UNDBHR in particular. This influence is evident in the explicit reference to the Council of Europe Convention on Human Rights and Biomedicine in the UNDBHR preamble (Andorno, 2013, p. 15). Andorno highlights the significance of this uncommon reference to a localized tool as an indication that UNESCO recognized the thorough approach to bioethics that Europe had taken (2013, p. 15). This not only shows that a strong bioethical framework exists across Europe but suggests that aligning with the values and principles of global actors such as UNESCO may support consistency for cross-border sharing that enables open access and appropriate protection of privacy.

OECD Guidelines on Human Biobanks and Genetic Research Database

The majority of EU states are members of the OECD with exception to Bulgaria, Romania and Croatia. The Commission of the European Communities contributes to OECD projects, indicating a high level of EU involvement. Contribution and adherence to OECD frameworks further aligns the supranational state with that of global organizations who endeavour to establish consistent practices that promote appropriate data sharing and privacy protection.

Bermuda Principles

As previously mentioned, Germany and the UK accept the philosophy of open sharing put forward by the Bermuda Principles. The degree to which the Bermuda Principles are employed across within each Member State is unclear, however there are a number of factors that suggest a philosophy of data sharing. For example, in addition to a number of EU initiatives for furthering research and information sharing

between Member States, GDPR includes exemptions for specific types of data processing which will be discussed below. This suggests an inclination to enabling access to data in order to support genetic research.

Supranational Influence

The human right to privacy is a central concept for the processing of genetic data in the EU. This may be seen in in the legal instruments that protect individual privacy rights across the EU including Article 8 under the *European Convention on Human Rights* and Articles 7 and 8 in the *Charter of Fundamental Rights of the European Union* (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 196). The European Union possesses mechanisms for governing the flow of data within its boundaries as well as across them. A recent example of this is the GDPR which came into effect May 24, 2018. While the EU's *Directive 95/46/EC* was in place since 1995, GDPR has modernized privacy protection to address the digitization and commodification of personal data, thus providing an extensive regulatory framework for appropriate data processing in today's technology heavy environment.

Twenty-eight national agencies are required to enforce GDPR. Regulations under GDPR enable each member state to determine how requirements will be outlined and operationalized within its borders. Under Recital 34 of the GDPR (2016), genetic data is defined as:

> personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.

The processing of personal data that reveals genetic information, among others such as race and religious affiliation are prohibited with a few exceptions. Some exceptions include when explicit consent has been obtained from the data subject, information is essential for protecting data subjects, there is a public interest or for the purpose of conducting scientific, historical or statistical research (GDPR, 2016, Article 9). While GDPR defines genetic data as sensitive and requires special processing, equitable access to data and the interoperability of data sharing is out of the scope of GDPR. The GDPR mechanism addresses this paper's concern for the regulation of privacy, security and consent, but may not fully address equitable distribution of research or health care benefits resulting from genomics research. This may only be achieved through technical interoperability and collaboration which is based on equal benefit sharing between organizations.

EU Constitution

Most EU Member States possess a constitution outlining individuals' rights as citizens (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 196). Fundamental protections seen across Member States includes a right to vote, freedom of speech, movement, and assembly, as well as protection from arbitrary detainment, and torture among other elements. The 2009 *Treaty of Lisbon* granted the *Charter of Fundamental Rights of the European Union* legal binding force and is considered a primary source of law in the EU (European Parliament, 2019). Relevant freedoms to genetic data regulation, include the principle of dignity evident in the UNESCO Declarations as well as the right to privacy and protection of personal data and access to health care. The EU Charter applies to the Institution of the European Union and all Member States when applying EU law with exception to the UK and Poland who under Article 2 of Protocol No. 30, "shall only apply to Poland or the United Kingdom to the extent that the rights or principles that it contains are recognized in the law or practices of Poland or of the United Kingdom". This creates potential for inconsistency in the application of human rights as they apply to the management of genetic data. Differing rights around privacy, access, equity and security that may not align with the EU Charter, could create discrepancies in the management of genomic data.

National Legislation

Despite international instruments for regulation, nations may adopt international law in various ways. For instance, nations may adopt a monistic or dualistic legal approach when implementing international legislation (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 196). In the case of monistic law, international treaties are directly applied to national legislation which is treated as one legal system (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 196). Conversely, some Member States use a dualistic legal approach that treats international and national systems separately requiring an additional process for applying international treaties to national legislation (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 196). Despite international overarching regulation, there may be a disparity in the implementation of such mechanisms which is evident in Member States' application of supranational laws such as GDPR and the *Charter of Fundamental Rights of the European Union*. Indeed, such challenges may have a trickle-down impact on genetic data regulating instruments thus creating barriers to genomic information sharing and challenge consistent and commensurate privacy practices between nations.

The European Commission has the authority to make adequacy decisions and may determine whether a member state may transfer personal information to a third country based on whether data protection laws are equivalent to those in the EU, known as "adequacy" (European Commission, 2019). Currently,

Andorra, Argentina, Canada (with some exceptions), Switzerland, Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, Uruguay, United States and New Zealand are considered to have adequacy (European Commission, 2019). For those nations who are not listed, other instruments have been established to enable sharing such as the *US-EU Safe Harbor Agreement* (2000). The *Safe Harbor Agreement* only applies to organizations under the Federal Trade Commission and excludes non-for-profit organizations (Rothstein & Knoppers, 20016, p.168). Various factors influence data protection, as a result, such agreements rarely exist in perpetuity. On October 6, 2015, in light of Edward's Snowden's leak on the US National Surveillance Agency's operations, the European Court of Justice ruled in *Schrems v Data Protection Commissioner* (2015) that the *Safe Harbor Agreement* between the EU and US was invalid because it did not protect EU citizens (Rothstein & Knoppers, 2016, p.168). The Agreement has since been replaced by the *EU-US Privacy Shield Framework.*

GDPR provides an overarching framework for the processing of personal data and requires Member States to adopt its provisions with some room for derogations. However, many Member States possess stand-alone legislation that specifically address the collection, use and disclosure of genetic data.[2] What this demonstrates is that the EU is a *sui generis*, what Borry et al. refer to as a "multilevel system of governance" (Borry et al., 2012, p. 720). For example, France's Civil Code addresses genetic testing, Slovakia possesses legislation that regulates the use of DNA for identifying individuals, the UK has enacted genetic discrimination legislation and Bulgarian legislation regulates the application of genetics to health care (Varga et al., 2012, p. 131). Harmonizing legislation across states that have various ethical standards, priorities and approaches to adopting international laws is one among many challenges to establishing a genomic governance framework across multiple sectors.

Jurisprudence

Given GDPR's recent enactment, at the time of writing, no landmark genomic data privacy decisions came from the Court of Justice of the European Union. With time and increases in the use of genomic data, cases may come to light that potentially challenge the parameters of the new framework. Future cases that arise will have the capacity to influence domestic courts across the EU.

[2] For example, Portugal's *Personal Genetic and Health Information Law*, Greece's *Use of Genetic Data*, the Netherland's *Application of Genetics*, Estonia's *Human Genes Research Act*, the Austrian *Gene Technology Act*, among others (Varga et al., 2012, p. 131).

Cross-Border Approach: Towards Harmonization

Despite various regulatory mechanisms which may conflict or fail to address aspects of genetic data sharing, there is a general sentiment across the EU that genomic data should be readily shared. In 2006, the Council of Europe put forward Article 20(1) in the *Recommendation on Research on Biological Materials of Human Origin*, requiring member states to enable researchers to access population biobanks, their respective biological materials and associated data (Council of Europe, Committee of Ministers, 2006). Perhaps the most recent development for genomic data regulation that seeks to overcome harmonization challenges, is the signing of 20 EU Member States to commit to a collaborative genetic data sharing agreement. The initiative is also open to countries of the European Economic Area and the European Free Trade Association. The EU Declaration stresses that there are no financial obligation for the signatories, thus removing financial barriers to participation (European Commission, 2018b, p. 7). The EU Declaration was made public on April 10, 2018 with thirteen signatories, and has since included additional members, most recently Austria and Greece. At the time of writing, signatory states include Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, Spain, Sweden and the UK (European Commission, 2018a).

The EU Declaration aims to unify a currently fragmented infrastructure as well as utilize the contributions and investments of Member States in genetic sequencing data infrastructure (European Commission, 2018a). The main objective of the EU Declaration is to increase the scale of the available genomic data to enhance the effectiveness of clinical research with a goal of enabling access to one million genomes by 2022 (European Commission, 2018a). The aim is to break down silos and unify various national projects. The One Million Genome Initiative has a focus on enabling cross-border access to genomic databases and is part of the EU's agenda for the Digital Transformation of Health and Care (European Commission, 2018b). On September 12, 2018, the European Alliance for Personalized Medicine's (EAPM) announced that in partnership with the Austrian EU Presidency, it will move ahead to achieve the goal of one million genomes in what has been named the EAPM MEGA (Million European Genome Alliance) initiative (ESMO, 2018). By 2020, MEGA endeavours to connect new and old research, clinical programs and other forms of data sharing across territorial borders (Horgan, Romao & Hastings, 2017).

By coordinating mechanisms, the EU Declaration will develop a governance model outlining the responsibilities for the cross-border movement of genetic data (European Commission, 2018b). The aim is to support research by facilitating the development of technical requirements that will support the secure transfer of data between repositories (European Commission, 2018b). The EU Declaration endeavours to ensure the ethical use of personal information and implement appropriate measures to

protect privacy while clearly outlining data ownership (European Commission, 2018a). The long-term goal of the EU Declaration is to support the creation of research that has high clinical utility with the intent to benefit patients in the health care system.

The EU Declaration recognizes that the linking of health data and any collaborative work regarding MEGA, must be in compliance with GDPR. This suggests that while there is a move to create a governance framework for cross-border sharing of genomic data, there is an overarching framework that supersedes any provisions stipulated within the EU Declaration as it pertains to data privacy and security. In addition to GDPR, previously outlined EU and international declarations also require consideration and implementation. Despite GDPR's light touch on the regulation of genetic data, the regulation plays a significant role in establishing standards and harmonizes requirements among nation states as well as public and private organizations for the processing of personal information. Collection, use, disclosure, access, privacy and security requirements are extensively outlined in GDPR, including provisions for privacy breach notification (Article 33). A sizable portion of what would need to be outlined in a genetic data governance framework has already been established under GDPR. Outside of the EU, it appears there is no comparable overarching legal structure that regulates the processing of data across multiple sovereign states and organizations. It is perhaps this distinct factor that makes the EU case unique from China and Global Alliance for Genomics and Health.

There were significant delays in the adoption of the *Directive 95/46/EC* into EU members' national laws despite an implementation deadline of three years post adoption of the directive (Custers, Dechesne, Sears, Tani, & Van der Hof, 2018, p. 215). France, Luxembourg, the Netherlands, Germany and Ireland failed to meet this deadline. By the time France adopted the directive in 2004, applicable national legislation had undergone revision in many countries (Custers et al., 2018, p. 215). However, unlike the *Directive 95/46/EC* which is a legislative act stating a goal of EU adoption, GDPR is a binding legislative act (European Union, 2019). As a result, there may be a greater incentive to achieve compliance.

As of today, GDPR has only been in force for little over a year, it may take time to determine rates of compliance as well as its success as a legislative instrument. While the EU Declaration sets out intentions to enable access to one million sequenced genomes, the governance structure for the operationalization of the initiative is currently under development. The terms regarding consent models, appropriate uses such as analytics and types of research that may be conducted as well as ownership rights, will require outlining under the EU Declaration. Critical to the consistent implementation of a governance framework is the establishment of agreed upon definitions and their terms of use. Varga et al., identify a challenge in gaining consensus on definitions, currently various national legal documents fail to distinguish between

genetic testing and genetic information (Varga et al., 2012, p. 126). Indeed, studies have discovered substantial differences in how countries such as the UK, Estonia, Iceland and Sweden define key concepts regarding genetic databases and the material they contain (Varga et al., 2012, p. 126).

Currently, the signatories of the EU Declaration are limited to EU nation states, however, as has been highlighted, the private sector plays a significant role in advancing biotechnology and genomic research. Additionally, the presence of various patient advocacy groups and research organizations suggests a need to define the roles of NGO's and for-profit organizations acting on their own or in partnership with public bodies. Will private bodies be granted the same open access to genetic repositories as public bodies? If so, what rules will apply to the use of the data? Genomic research is more valuable when combined with other data elements such as health records, creating privacy issues for patients. What privacy and consent principles will be employed in the event citizens' health records are linked to genetic information? The recent case of Iceland's partnership with genomic corporation, DeCODE on the Health Sector Database and the Database for Genetic and Genealogical Information did not have a favourable outcome and resulted in a loss of public trust (Chen, 2013, p. 324).

Application of Border Theory

Throughout European history, state borders have been removed and recreated, and continue to undergo changes. Political environments impact the willingness to collaborate and even change the legal landscape for data sharing. Current developments regarding the UK's departure from the EU will provide a unique case study on the impacts to cross-border data sharing when a state is no longer under the umbrella of a union agreement (mentioned in previous section on adequacy approaches.). Currently, there is no agreement on how the UK will ensure the flow of data and access to datasets critical for conducting business and protecting the country (Hill, 2018). The UK, a current global leader in genomic research, may be at a disadvantage once separated from the EU. It remains to be seen how the Declaration may enable the UK to maintain a foothold in the European genomic data sharing community. A robust governance framework that retains membership despite fluctuating relationships and political dynamics is critical to the longevity and stability of consistent data sharing for public health benefits.

From a border theory perspective, the EU has developed borders that enable the sharing of genetic data based on a common legal framework, infrastructures and principles that are expressed in domestic legislation and practices of Member States. Arguably, this functionality extends outside of the EU evident in the establishment of agreements such as the *EU-US Privacy Shield Framework* and the adequacy framework which recognizes a number of non-EU nations as appropriate partners for data sharing. Common practices and principle-based sharing present in agreements and legislation act as a conduit

between sovereign nations that may not interact similarly if the data was a tangible object that crossed physical borders. Indeed, the EU case study may be understood as having functional borders. However, there continues to be aspects of territoriality with regards to data governance. State sovereignty remains relevant when considering that members may derogate from EU law and are left to determine their own legal approach, for example, the employment of a dualistic or monistic legal system. Additionally, states determine the manner in which genetic data is approached, such as the application of genetic exceptionalism which will impact the way data is shared from one Member State to the next and external EU partners. Finally, enforcement capabilities, which will be addressed in later sections identifies a continued connection to territoriality.

The EU case demonstrates that the sharing of genetic data is a priority that may not come at the expense of human rights. Functional borders are created between states to facilitate common sharing schemes, however there are still aspects of territoriality that contribute to a bordering of the data that parallels physical boundary lines of Member States. The employment of each jurisdictions' own definitions and policy approaches creates challenges to interoperability of data sharing, a problem not unique to the EU case study.

4.3 China Case Study

Background

China was instrumental in the success of the Human Genome Project (HGP) and is now a world leader in genomic sequencing (Cyranoski, 2016, p.462) Companies such as BGI in Shenzen and Novogene in Beijing have accelerated the pace of sequencing to 18,000 genomes per year since 2014, reducing the cost of sequencing (Cyranoski, 2016, p. 462). With over 1.3 billion people comprised of 56 different ethnic groups, China provides researchers with a unique and sizeable source of genetic information (Goldenberg & M.S., 2013, p. 2). China regards this data as a valuable resource to national security, population health and the economy. Because of this valuable pool of information as well as circumstances that arose from international misuse of Chinese genetic data, the Chinese government has established a framework to control the flow of genetic data within but especially across China's borders.

International Influence

UNESCO Declarations

China became a permanent UN member on October 24, 1945. Arguably by becoming a member, China would be poised to align with the principles put forward by the UN, thus sharing a consistent global approach to biomedical ethics and data management. However, China may be a case study in how the

culture and context of a nation as well as its political and economic position in the global arena influences the expression of the principles outlined in the UNESCO Declarations. While EU members subscribe to the same sets of principles (with some variation) outlined in the Declarations, the approach to data sharing, particularly across state borders differs from the more restrictive approach taken by China.

OECD Guidelines on Human Biobanks and Genetic Research Databases

Though China has participated in the development of OECD projects, it is not a member of the organization. However, in 2007, the OECD Council established an enhanced engagement program with China (in addition to Brazil, India, Indonesia, and South Africa) which may result in membership at some point in the future (OECD, 2019). There is potential that China's lack of OECD membership further distances itself from global alignment in genomic data regulation.

Bermuda Principles

China joined the Bermuda Principles in 1999. However, the degree to which China continues to embrace the open access philosophy is uncertain considering the development of legislation and stringent licensing regulations since the late 20th century. A movement away from the Bermuda Principles may negatively impact international sharing and the advancement and quality of genomic research.

Supranational Influence

China is a member of the Asia-Pacific Economic Corporation (APEC), however unlike the EU, the agreements pertaining to this supranational organization are not legally binding and do not restrict the sovereignty of the Chinese state. Incentives for adhering to supranational policies may be low if requirements do not align with national mandates and interests such as international competitive advantage, national security or the privacy of citizens.

National Influence

There are numerous levers utilized by the Chinese state that operate simultaneously to create an overarching framework for addressing the collection, use and disclosure of genetic data (Chen & Song, 2018). Principal levers include genomic specific legislation such as the *Interim Measures for the Administration of Human Genetic Resources* (1998), *draft Regulation on Human Genetic Resources* (2016), and the *Licensing Guide* (2015). In addition to specific instruments, there are applicable medical and health information legislation such as the *Medical Practitioner Law* (1998), *Tort Liability Law* (2009), *Provisions on Medical Records Administered by Health Institutions* (2013), *Population Health Information Measures* (2017) (Chen & Song, p. 606). Civil law which addresses the protection of

personal information in addition to tort liability preserve individual privacy rights using privacy principles such as consent (Chen & Song, 2018, p. 609). For example, under Article 62 of Chinese *Tort Liability Law*, informed consent must be obtained in order to treat a patient or disclose their medical data (Yu & Li, 2014). Cybersecurity laws address illegitimate uses of personal information but are primarily focused on national security versus individuals' rights. Quasi-legal or non-legal levers include research ethics boards (REB) and the self-regulation of biobanks. Biobanks which amass large amounts of genetic data also establish their own policies and procedures in accordance with legislation for the management of data (Chen & Song, 2018).

As of July 1, 2019, China adopted the *Management of Human Genetic Resources* to replace the *Interim Measures*, which have been in place for over twenty years. Changes in scientific and technological capabilities have been said to render the *Interim Measures* outdated and largely ineffective (Zhao & Jackson, 2019). The 2018 occurrence of the first gene edited babies garnered criticism from the international scientific community and likely played a role in the government's development of the new legislation (Zhao & Jackson).

China's Constitution

Under the *Constitution of the People's Republic of China* (Xianfa, 1982), citizens are considered equal before the law, and protection of human rights includes those commonly identified around the world. This includes rights and freedoms such as the right to vote, freedom of religious belief, assembly and speech (Xianfa, art. 34, art. 36, sec.1 and art. 35 respectively). The approach to the protection of privacy refers to privacy of citizen correspondence and outlines that no organization or individual may, "infringe upon citizens' freedom and privacy of correspondence", except for the purpose of security or criminal investigation (Xianfa, art. 40). All censoring of correspondence must be in accordance with procedures outlined under the law (Xianfa, art. 40). By contrast, European constitutions outline an inherent right to privacy, for example under Article 22 of Belgium's *Constitution* (1831), "everyone has the right to respect of his private and family life, except in the cases and conditions determined by law" (Art. 22, Const. coord.). Hungary goes further in its *Constitution* (1990) by expanding the right to privacy not just to private and family life but "the right to the protection of his or her personal data, as well as to access and disseminate data of public interest" (Art. VI.2). By comparison, China's approach to privacy rights under the Chinese *Constitution* is limited in scope to private communications (Xianfa art. 40). Such an approach may hint at the priority privacy protection is given and whether individuals have a fundamental right to privacy of their own data and persons.

Cross-border Approach: Towards Protectionism

In 1997, two epidemiologists from Harvard collected genetic data in the Anhui Province of China. Upon publication of the research, it was discovered that the scientists had failed to obtain informed consent from participants (Chen & Song, 2018, p. 607). Chinese geneticists called on the government to address the situation citing the incident as an act of biopiracy (Zhang & Zheng, 2017 as cited by Chen & Song, 2018, p. 607). The outcome was the development of the *Interim Measure for the Administration of Human Genetic Resources* (*Interim Measures*), a legal instrument for governing the management of Chinese genetic data (Chen & Song, 2018, p. 607). The *Interim Measures* were issued by the Ministry of Science and Technology and the Ministry of Health and proclaimed by the General Office of the State Council (Chen, 2013, p. 325).

The Harvard research incident is indicative of a common issue of research exploitation. India, Uganda and Tonga are among some of the nations that in the last decade have been exploited for commercial biomedical research (Chen, 2013, p. 324). Exploitation occurs when researchers conduct research in foreign nations in order to access large new populations of genetic data and circumvent ethics procedures.

The Harvard research incident was not the only motivation for developing genetic data regulations. The Chinese government sought to protect national security, enhance state competitiveness, and preserve benefits to public health that flow from the nation's human genetic resources (Chen & Song, 2018, p. 605). Advances in biotechnology and the development of new markets has resulted in the commodification of genomic data incentivizing the patenting of gene mapping and their functions (Goldenberg & M.S., 2013, p. 2). In response to this international competition, the *Interim Measures* attempted to establish clear ownership and global recognition of research publications by granting the Chinese research and development organizations sole possession rights over genetic data (Chen & Song, 2018, p. 607; Goldenberg & M.S., 2013, p. 2). Notably, there is an absence of the term privacy in the *Interim Measures*, *Licensing Guide* and only a minor mention in the 2016 draft *HGR Regulation* (Chen & Song, 2018, p. 610)). According to Chen and Song, this indicates that the primary concern of the state is not the protection of citizens' privacy but rather the collective protection of genetic material which is considered a state resource (Chen & Song, 2018, p. 610).

Another key tenet of the *Interim Measures*, was the condition that foreign researchers may only gain access to genetic resources in China by collaborating with domestic Chinese scientists (Chen, 2013, p. 326). According to Yuan (2017), this requirement may be in response to the peripheral role Chinese researchers have played when they have partnered with international researchers using Chinese genetic data (as cited by Chen & Song, 2018, p. 607). By requiring external researchers to collaborate with

Chinese researchers to gain access to Chinese genomic data, the Chinese government is ensuring that any research using their citizens' data has a domestic researcher attached to the project. In addition to keeping Chinese researchers at the forefront of genomic projects, this provision may also increase the publication rate of Chinese researchers (Chen & Song, 2018, p. 607).

The China Administration of Genetic Human Resources (CAGHR) which is under the purview of the Ministry of Public Health, supervises the "collection, storage and export" of human genetic materials (Chen & Song, 2018, p. 606). The Ministry of Science & Technology (MOST) interprets the *Interim Measures* and plays a key role in establishing policy that coordinates with local authorities. In 2004, the *Administrative Licensing Law* came into effect and it is a requirement for individuals to submit applications to partake in specific activities, thus creating an additional layer of control over data related activities (Chen & Song, 2018, p. 606).

Under the *Interim Measures*, consent was required to precede any project or initiative that processed human genetic information (Chen & Song, 2018, p. 609). In addition to individual consent, the *Interim Measur*es included the requirement to obtain familial consent for the collection, use and disclosure of a blood relative's genetic information (Chen & Song, 2018, p. 609). This notion of community rights may be a result of what Chen and Song describe as a "collectivist philosophy" (2018, p. 609). However, any further mention of familial or community consent is not evident and operationalization of such a principle is not clearly defined. As a result, it is unclear to what degree such principles are consistently applied (Chen & Song, 2018, p. 609).

Despite the logic of obtaining family consent with regards to shared information such as genetics, recognizing group rights alongside those of the individual is a concept that has not been adopted in Western nations such as Canada. The *Canadian Charter of Rights and Freedoms*, which prioritizes the rights of individuals over the group (with some group right exceptions), would face challenges were it to acknowledge the rights of a group over that of the individual. Nevertheless, the reality that communities are equally at risk when the genetic data of an individual is disclosed presents considerable ethical and human rights challenges that require attention. However, nations with legislative frameworks that seek to protect individual rights, would require a fundamental shift in their charters in order to avoid constitutional challenges (Hallinan & de Hert, 2017, p. 176).

As previously mentioned, new legislation has replaced the *Interim Measures*. Under the new *Regulations*, human genetic resources acquired in China for scientific research, will also need to be undertaken in collaboration with Chinese institutions subject to approval by the Ministry of Science and Technology (MOST) (Zou, McGinty, Zhou, & Xie, 2019, p. 2). A notable difference between the *Interim Measures*

and the new *Regulation* is the application of sanctions for non-compliance. For example, failure to collaborate with Chinese institutions may result in penalties ranging from RMB 1,000,000 and RMB 10,000,000 or 5-10 times of the amount illegally obtained if it is greater than RMB 1 million (Zou, McGinty, Zhou, & Xie, 2019, p. 4). Additionally, failure to acquire MOST approval will result in penalties from RMB 500,000 to RMB 5,000,000 or five to ten times the value of the illegal earnings (Zou, McGinty, Zhou, & Xie, 2019, p. 4).

In 2012, the draft *Human Genetic Resources Management Ordinance* (*draft HGR Regulations)* was released by China's State Council Legislative Affairs Office (Goldenberg & M.S., 2013, p. 2) and would undergo revision in 2016 (Chen & Song, 2018, p.607). The purpose of the *draft HGR Regulation* was to vet and approve activities involving the processing of human genetic data (Goldenberg & M.S., 2013, p. 2). Under the *draft HGR Regulation*, it is specified that participants should be informed of and consent to the purpose as well as understand the benefits and risks of the research being undertaken (Chen & Song, 2018, p. 609). Additionally, research subjects should be made aware that participation is voluntary and that they may withdraw from the research (Chen & Song, 2018, p. 609). Under Article 14 of the *draft HGR Regulation*, for consent to be meaningful, it is required that documentation provided to participants is commensurate with their level of education in order to ensure comprehension (Chen & Song, 2018, p. 609).

Henning has noted that openly discussing personal information with others in China is sensitive which may be further complicated by a potential lack of training physicians and researchers receive in addressing the interests of patients (Hennig, 2006, p. 851). Instead, physicians will often communicate issues with patients' relatives or in some cases, individuals whom patients are not related to (Henning, 2006, p. 851). Henning notes that such barriers compromise the integrity of obtaining informed consent and the patients' right to privacy (Hennig, 2006, p. 851). The inclusion of familial consent for the purpose of collecting genetic data may be a natural extension of current interactions with patients' relatives who serve as conduits for the transmission of culturally sensitive information.

What these examples suggest, is that the operationalization of privacy rights and consent models outlined in regulatory frameworks and adopted human rights frameworks may not be easily implemented due cultural or practical factors such as professional training or the comprehension of patients or research participants, particularly those in rural communities (Hennig, 2006, p. 854). The context and environment in which frameworks are employed requires consideration in order to account for variations in norms and social nuances.

The Chinese *Cybersecurity Law* came into effect June 1, 2017. While China had existing laws and regulations these primarily dealt with infrastructure security rather than personal data protection (KPMG, 2017, p.4). The recently enacted *Cybersecurity Law* has a primary focus on protecting personal information and the privacy of individuals by establishing the appropriate collection, use and disclosure of personal information. For example, organizations must obtain consent from data subjects prior to collecting personal information (Article 22). Under Article 76(5) of the legislation, the scope of what constitutes personal information has been expanded to include all types of information that may be "recorded through electronic or other means" which is capable of identifying a natural personal on its own or when combined with other types of information such as "name, date of birth, identification number, personal biometrics, address and telephone number" (KPMG, 2017, p. 6). The expanded scope of personal information includes individuals' biological data and would therefore have an impact on the way genetic data is managed across digital borders.

Similar to BC's FOIPPA data residency requirement to keep personal information within Canada, the *Cybersecurity Law* requires that sensitive data is stored in China. Both jurisdictions enable such information to leave the country when necessary under the condition that specific measures are taken prior to releasing such data. For example, BC requires public bodies to obtain consent from individuals and conduct a privacy impact assessment, while in China, a security assessment is conducted as per the requirements stipulated by China's cyberspace administration bodies and departments under the State Council (KPMG, 2017, p. 12). However, unlike BC's FOIPPA which only applies to public bodies, businesses that violate China's *Cybersecurity Law* are subject to penalties that range from having their business closed, activities or licenses suspended or receive fines up to RMB 1,000,000 (KPMG, 2017, p. 5).

Individuals have likened the Chinese *Cybersecurity Law* to that of EU's GDPR which was released for public consultation in April 2016 (Interview 2). Both pieces of legislation require breach notification, obtaining informed consent, the appointment of a contact person and financial penalties for non-compliance (Haden, 2019). However, others such as Daniel Wagner, have suggested it operates in contrast to that of the GDPR by requiring network operators to provide the Chinese government full access to any data in their possession by cooperating with Chine's crime and security investigators including submitting to undefined "technical support" (Wagner, 2019). Wagner suggests that the new legislation may result from two motivations. According to critics, the first motivation may be a move to suppress international competitors in the data management and telecommunications industry by requiring foreign organization to invest in servers located in China or obtain a local service provider (Wagner,

2019). The second motivation may be an attempt to corral data under China's jurisdictions in order to enhance prosecuting capabilities for violations under Chinese legislation (Wagner, 2019).

National Legislation

China's framework employs genetic specific legislation, general privacy and security laws, regulations and organizations such as academic and professional institutions that regulate the management of genetic data. This multi-framework is not unique to China. Indeed, the EU and as we will see Global Alliance for Genomics and Health, have a multi-faceted approach that leverages various mechanisms to create a regulating infrastructure. However, where China differs is the degree to which the state controls the cross-border flow of genetic data and the manner it is imposed on organizations. China is perhaps the most regulated out of the three case studies.

Notably, legislation and regulation in China, as with other jurisdictions, tends to be reactionary to international incidents, such as Harvard researchers' misuse of genetic data or the global reaction to the gene editing of babies. While China has signed *Human Rights Declarations* and has become involved in the OECD, there are various factors that may prevent harmonization of genetic data regulation between countries. Individuals interviewed for have cited geography as a barrier to interactions and communications between China and the West (Interview 2). Those nations who share boundary lines or geography may communicate with greater ease, are incentivized to interact and collaborate out of necessity and may share cultural practices and language (Interview 2). China's collective cultural philosophy may work to support a more state centered approach for the sharing and use of personal data as a valued resource to the state versus an individual proprietary approach favoured in Europe and North America (Interview 1). The political philosophy evident in a socialist regime and state involvement in the daily lives of individuals adopts a more restrictive governance approach which may be magnified by larger populations of individuals with varying levels of education and differing notions of privacy (Interview 2).

Despite the presence of prescriptive regulations, there are still challenges with local implementation, not unlike in the EU and GA4GH case studies. This suggest that the local context plays a significant role in operationalization of principles. There are benefits and drawbacks to this highly state controlled approach, for example, China may be able to prevent a reoccurrence of the Harvard research incident and ensure that participation with Chinese researchers and the use of Chinese genetic data is credited appropriately in publications.

China has developed a localized approach by assigning science and technology administrative departments within each province, regions, and municipalities (Goldenberg & M.S., 2013, p. 3). While the framework attempts to address familial privacy and consent ethics, the approach is fundamentally protectionist and creates barriers to international collaboration that may be detrimental to genomic research and clinical trials (Goldenberg & M.S., 2013, p. 2). On average, obtaining the appropriate approvals for international collaboration on genomics research in China takes approximately 9-12 months, and has been described as challenging (Goldenberg & M.S., 2013, p. 2). Despite the Chinese government's support of genomic research by citizens, barriers to non-Chinese collaboration may deter international researchers and challenge Chinese researchers' access to valuable resources and technology that could contribute to substantial gains in clinical medicine and biotechnology. While the state-centred approach enables stringent monitoring, approval and control over the use of genetic data by external bodies, it may obstruct critical information sharing between nations and transnational organizations.

China's framework, particularly the use of the *Administrative Licensing Law*, is an example of the genetic exceptionalism model (Chen & Song, 2018, p. 606). As outlined in the previous Governance Section, genetic exceptionalism is the belief that genetic information should be treated differently than any other form of medical information due to its ability to disclose sensitive information about a person as well as their family members. Genetic exceptionalism supports the development of a separate governance framework often including legislation to regulate genetic data. Arguably, the EU and GA4GH can be classified under the paradigm of genetic exceptionalism as they both have established separate frameworks for the management of genetic data. However, it is China's restrictive approach that differentiates itself from the other two models whose primary purpose it is to enable collaborative data sharing. Additionally, China's exceptionalism model only relates to the protection of genetic data as a state resource. Rather, the privacy of genetic data is only addressed under tort and civil law, demonstrating an absence of a privacy protection framework for cross-border flows of genetic information specifically (Chen & Song, 2018, p. 610). There is, however, some mention of privacy principles in the newly enacted *Regulations* that may develop further (Article 9).

As previously noted, despite China's involvement with the HGP which employed the Bermuda Principle to enable worldwide sharing of genetic sequencing, China has since become more protectionist over its data. From a border theory perspective, China has aligned its genomic data sharing principles with its physical borders. Conversely, the EU and GA4GH have created more permeable borders by attempting to harmonize policy and legislation on data sharing as well as creating interoperable technology that enables rapid access.

Judicial Interpretation

Three cases of unauthorized transfer or publication of sequenced genetic data occurred in 2018 involving a Chinese hospital and five companies, including research company, BGI based in Shenzhen (Cryanoski, 2019, p. 1). Government responses included warnings, compulsory destruction of data, and completion of data-privacy examinations prior to rejoining research projects (Cryanoski, 2019, p. 1). As of July 1, 2019, the *Interim Measures* have been formalized and include substantial penalties which are said to align with GDPR's penalties which may reach 4% of the offending organization's annual profits (Cryanoski, 2019, p.1). The impact the law will have on international research is speculated to depend on the way China will approach enforcement (Cryanoski, 2019, p. 1).

Additional Considerations

Perhaps a significant consideration is the context in which China operates in the global arena in comparison to the EU and participants in GA4GH. China's global status, economic reality and political history must be considered when examining its approach to genomic governance. Historically, China's relationship with the global community has been subject to tensions with various actors such as Japan, Russia, and Tibet. Relations with the West have frequently been marked with conflict, dating back to Britain's 1842 seizure of Hong Kong during the Opium Wars, the Boxer Uprising of 1900, the bombing of the Chinese embassy in Belgrade during the Kosovo conflict in 2000, and most recently political tensions between the US and Canada involving the extradition of Chinese Huawei CFO, Meng Wanzhou.

Application of Border Theory

The Chinese case study provides a revealing contrast to the EU case study in that it employs a more protectionist approach out of concern for intellectual property rights, market competition and national security rather than for the sole protection of individuals' privacy rights. China's model is highly centralized due to the government's role in the market and regulation of non-state actors which restricts the flow of genetic data within and across China's state borders. Various factors may contribute to this territorial approach such as differences in geography, culture and language which may create additional barriers, thus affirming the physical border which may act to separate the East from the West.

China's territorial approach is evident in the alignment between the physical state boundary and the restricted activity flow of genetic data. This may be a direct result from its prohibition on the external use of Chinese genetic data without a license and the requirement to partner with Chinese researchers. By tying external actors to domestic actors, the state may enhance its surveillance and enforcement capabilities. Indeed, China's regulator mechanisms, primarily legislation does not have a functional

intent, but rather a protectionist one bound to territory. Unlike the EU's use of agreements and adequacy model to enable the safe sharing of data, China's approach appears to restrict data use. Finally, the influence of supranational organizations such as APEC are not legally binding and therefore unlike the EU, China's intent may not be to create functional borders.

4.4 Global Alliance for Genomics and Health Case Study

Background

Global Alliance for Genomics and Health (GA4GH) is an international non-for-profit organization that began in 2013 under the direction of a group of leading researchers with a purpose to enable global data sharing to support the development of science and medicine (Kosseim et al., 2014, p. 5). Today, over 500 organizations and 2,000 subscribers across sectors in over 90 countries participate in GA4GH (Global Alliance for Genomics and Health, n.d.). Various bodies such as patient advocacy groups, researchers, life sciences and information technology organizations as well as academic institutions all contribute to GA4GH work (Global Alliance for Genomics and Health, n.d.).

International Influence

UNESCO Declarations

GA4GH is based on the *Framework for the Responsible Sharing of Genomics and Health-Related Data* (the Framework), founded on the principle of the human right to benefit from scientific advancements (Knoppers, 2014, p.1). GA4GH endeavours to develop and circulate standard regulatory approaches for the ethical and collaborative sharing of data as part of genomic research (Kosseim et al., 2014, p. 5). The standards embody principles of participant autonomy and responsible and secure sharing of data that reflects human rights legislation. Specifically highlighted is the 1948 *Universal Declaration of Human Rights,* Article 27 the right of every individual in the world to "freely participate…and share in the scientific advancement and its benefits" as well as "the right to the protection of the moral and material interests resulting from any scientific…production of which (a person) is the author" (Global Alliance for Genomics and Health, 2014, p. 1). The *International Covenant on Economic, Social and Cultural Rights* (UN 1966) Article 15 references similar principles that offer guidance. GA4GH summarizes in the Framework that there are various treaties, conventions and declarations that guide the work of GA4GH (Global Alliance for Genomics and Health, 2014).

Projects

GA4GH seeks to develop an umbrella organization that will provide infrastructure that not only has ethical, and regulatory infrastructure, but enables technical interoperability by providing practical and IT support (Middleton, 2018, p. R10). Operationalizing these objectives has resulted in the development of Connect, a five-year strategic plan to be completed by 2022 (Global Alliances for Genomics and Health, 2017). GA4GH will pilot its frameworks and tools (Work Streams) using existing genomic data projects or Driver Projects. (Global Alliance for Genomics and Health, 2018). Workstreams include:

1. large scale genomics projects,
2. data use and research identity,
3. data security,
4. cloud storage,
5. discovery (aggregating global data, harmonizing and redistribution),
6. regulatory and ethics,
7. genomic knowledge standards, and
8. clinical & phenotypic data capture.

Technical work streams will address current and relevant practices and working groups identify existing standards or as necessary develop new standards. Foundational work streams provide support to existing genomic research projects taking place around the world in the form of legal, ethical and security advice. A few current projects include cloud interoperability, data repository services, data ontology, development of secure interfaces, international participant values survey "Your DNA, Your Say", and researcher identity verification for federated cloud systems (Global Alliance for Genomics and Health, 2018). Connect includes a strong technological component that endeavours to harmonize data by employing federated internet databases as well as various projects to enhance secure access to data (Global Alliance for Genomics and Health, 2018, p. 5).

OECD Guidelines on Human Biobanks and Genetic Research Databases

In addition to the UNESCO Declarations, GA4GH utilizes OECD *Guidelines on Human Biobanks and Genetic Research Databases* as well as various other guidelines (*Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data*) in the development of the Framework.

Bermuda Principles

The Bermuda Principles are also utilized as a guidance tool for the Framework's development. Concepts of access are further supported through employment of the 2009 Toronto *Statement on Prepublication Data Sharing*, the 2007 OECD *Principles and Guidelines for Access to Research Data from Public Funding*, 2003 *Fort Lauderdale Statement*, and *Budapest Open Access Initiative*. The OECD Guidelines for example, aim to "promote the culture of openness and sharing of research data among public research as well as within and beyond" OECD member countries (OECD, 2007, p. 11). The utilization of various declarations, guidelines and agreements addressing open access provide a clear direction and intention on the sharing of data and that it is a Framework priority. Despite this, GA4GH emphasizes that data sharing should not compromise ethics and privacy requiring a balanced approach and a need for common standards.

Founding Principles

GA4GH has established four founding principles:

1. Respect individuals, families and communities,
2. advance research and scientific knowledge,
3. promote health, wellbeing, and fair distribution of benefits, and
4. foster trust, integrity and reciprocity.

GA4GH seeks to create a robust governance framework by addressing not just ethical and moral factors but the political and legal aspects involved in data sharing. This is done by considering the responsibilities of groups and institutions and promotes the notion that governments, industries, funders, publishers, and researchers will need to participate in the creation of a system that shares data responsibly (Global Alliance for Genomics and Health, 2014, p. 2). The core elements are implemented based on the environmental factors in which research is occurring and must take into account the communities involved and as a result the unique risks they present. GA4GH is clear that the regulatory Framework is to be applied to research data that was obtained through legitimate channels that involved appropriate ethics, consent, approval of appropriate bodies (ethics boards and governing bodies) and is compliant with subsequent use requirements (Global Alliance for Genomics and Health, 2014, p.3). Additionally, the Framework does not impede bodies from establishing policy and processes that address unique circumstances that involve vulnerable populations (children and marginalized communities), thus enabling context specific application that is tailored to each organization's needs (Global Alliance for Genomics and Health, 2014, p. 3). What this suggests is that GA4GH is establishing a minimum standard

that all bodies should strive to meet with the intention of implementing context specific policies to address the unique circumstances of the research and participants.

Under the Framework, core elements of responsible data sharing include transparency, accountability, engagement, data ownership and security, privacy, data protection and confidentiality, risk-benefit analysis, recognition and attribution, sustainability, education and training and finally accessibility and dissemination (Global Alliance for Genomics and Health, 2014, p. 4). Each element is broken down further to address specific goals within each category. For example, under the core element of transparency, there is a goal to "provide clear information on the purpose, collection, use and exchange of genomic and health-related data, including, but not limited to: commercial involvement" (among others) (Global Alliance for Genomics and Health, 2014, p. 4).

Supranational Influence

The Framework references the use the *Council of Europe Convention on Human Rights and Biomedicine* to guide its development. Furthermore, GA4GH supports adherence to GDPR requirements and has resources such as the GDPR Forum which provides discussion and information on various aspects of genetic data sharing and research under GDPR and how to ensure compliance with its requirements.

National Influence

GA4GH consistently messages to members the need to adhere to relevant legislative requirements and research ethics boards within each members' jurisdictions to ensure that data is being managed appropriately (Global Alliance for Genomics and Health, 2014, p. 2). A criticism of this approach may be that instead of providing a consistent and standalone framework, G4AGH defers to existing national structures which may be flawed and lack interoperability. However, this is by no means a way to avoid creating a robust framework. Rather, by disregarding national legislation, the Framework would fail to account for the functioning realities of organizations operating within each unique environment. Instead, G4AGH may support the use of additional security, privacy, consent or access measures that national legislation may fail to address or do so minimally. By providing access to resources, tools and a global community, GA4GH could potentially influence nations to adapt their legislation to meet the new global standard built upon the compilation of globally recognized instruments (UN, OECD, etc.).

A particular workstream undertaken by GA4GH is the translation of the Framework into as many languages as possible to improve accessibility and enhance implementation into local contexts (Global Alliance for Genomics and Health, 2014). Completed translations include; Greek, Arabic, Chinese, Korean, Japanese and Spanish. As previously mentioned, establishing agreed upon terminology and

definitions is a challenge in harmonizing governance approaches (Varga et al., 2012, p. 126). An integral component to this work is translating the governance approach so that terms and knowledge may be refined to more accurately reflect intentions. The creation of a shared lexis that supports consistent practice is a common challenge experienced in all three case studies.

GA4GH Constitution

In order to become a member of GA4GH, organizations must accept the terms and conditions outlined in the *Organization Membership Agreement* and the GA4GH *Constitution*. Member's must be legal entities with an "open and professional presence" whose "mission, operations and public statements align with the GA4GH *Constitution* and the *Member Agreement"* (Global Alliance for Genomics and Health, 2019). Additionally, there is a requirement for the organization to clearly state their ownership, governance, funding, and leadership (Global Alliance for Genomics and Health, 2019). As per Article 27 of the *Universal Declaration of Human Rights*, the Framework is grounded in the fundamental principle that every individual has a right "to share in scientific advancement and its benefits" (Global Alliance for Genomics and Health, 2014, p. 1). The human rights focus is an approach that aligns with global human rights frameworks also reflected in the institutions and instruments found across bodies such as the EU and nation states. While not a state instrument, the *Constitution* and the *Membership Agreement* serve dual purposes. The agreements serve as a contract which may be enforced when the terms of the agreement are breached, by revoking the organization's membership (Global Alliance for Genomics and Health, 2019). The agreement also establishes the tone and objective of GA4GH's mission to harmonize genomic data practices, such an agreement between members would serve to establish common ground.

Cross-Border Approach: Towards Collaborative Governance

GA4GH continuously engages with stakeholders to ensure the applicability and relevancy of the framework by conducting regular reviews of the framework to ensure alignment with developments in law, ethics, research and technology, (Global Alliance for Genomics and Health, 2014, p. 7). GA4GH employs a collaborative approach that involves input from organizations and bodies that utilize the GA4GH framework (Global Alliance for Genomics and Health, 2014, p. 6/7). Framework amendment recommendations put forward by members are circulated to allow for comment and input from stakeholders, potentially resulting in the inclusion of the recommendation in the Framework (Global Alliance for Genomics and Health, 2014, p. 7). Additional collaboration and feedback on the implementation of the framework occurs through consultations with patient advocacy groups, various committees, and biomedical bodies.

Analysis

The GA4GH, differs significantly from the EU and China case studies primarily because it is not a nation state or a collection of nation states under the umbrella of a supranational body. Indeed, GA4GH participants make up both public and private actors that exist inside and across national boundaries. Such a characteristic is a unique feature in that the Framework for sharing must be operational across various governance structures. The EU for example, has begun to address the challenges of data management by exploiting an existing structure that possesses regulatory instruments across various sectors (the European Union itself) creating practices and procedures that while at times different, have a common basis. Meanwhile, GA4GH attempts to bring together actors who may have few common data management practices and span vast geographical regions as well as technical capabilities. Additionally, challenges currently exist in most models for establishing agreed upon definitions and terminology around genetic data, such challenges are likely to be exacerbated on a global level.

Perhaps because GA4GH is stateless and is the product of global collaboration, it is best positioned to provide direction on the appropriate management of genetic data. Indeed, GA4GH may be immune from the accusations launched at the UNESCO Declarations for being Eurocentric and lacking biomedical expertise (Landman and Schüklenk, 2005). GA4GH has attracted biomedical experts, geneticists, ethicists, privacy and security experts as well as various other subject matter experts and global leaders to contribute to the Framework and its workstreams. The involvement of various international bodies is indicative of a global network approach not utilized by China or the EU who primarily focuses on the state or interstate driven activity. The GA4GH Framework has produced meaningful work to addresses consent, privacy, security, access and equitable distribution of research results in a tangible way. Indeed, the goal of achieving seamless data sharing is dependent on interoperability of technical systems, a current workstream supported by GA4GH.

GA4GH may encounter challenges with regards to enforceability as adherence to the framework is voluntary. Arguably soft laws such as the UNESCO Declarations are not considered legally enforceable, nevertheless, the principles of such instruments have been integrated into regional and national level hard laws. As an organization, GA4GH has not been in existence for the same length of time (2013) and adopted quite as broadly. Based on the research undertaken for this thesis, the Framework does not appear to outline processes for investigations or audit that may occur in the event of a privacy breach or failure to adhere to ethical practices. It appears that the Framework depends on the enforcement capabilities of national bodies to hold violating organizations to account. In the event that nations do not possess instruments that enforce principles outlined in GA4GH, violators may not be held accountable. Regulatory frameworks typically possess enforcement capabilities that play a role in punishment as well

as work to deter unwanted behavior. Finally, GA4GH lacks judicial capabilities or the ability to arbitrate disputes and set precedents for future use (Interview 5). This is in part due to the notion of state sovereignty and the fact that GA4GH has not had any official authority bestowed upon it. While GA4GH's global collaborative approach, resources and technical work has made great strides and as a stateless entity it is in a unique position to act as a neutral body, its lack of enforcement capabilities requires that it relies on the willingness of organizations to adopt principles and practices with few consequences for those that violate.

Application of Border Theory

GA4GH has established a functional border that enables sharing between organizations regardless of where they may be positioned geographically or in which country, they may conduct activities. Scholars as Ohmae (1995) may point to GA4GH as an example of the rise of non-state actors who are supplanting the state as a regulating power, thereby diminishing the role of the state and in turn weakening borders. However, it is made clear by GA4GH that there is no intention to displace states by challenging or circumventing national legislation and policy and requires its members to adhere to the appropriate channels for the collection use and disclosure of genetic data as set out by states.

Despite the development of a comprehensive principles-based framework, there are limitations for the ability of GA4GH to create the same functional borders as the EU since the organization is not a sovereign state and has no legal authority to impose its framework on other bodies. Nevertheless, the organization plays a valuable role in translating widely regarded privacy and sharing policies and championing the utility of genomics and facilitating interoperability. GA4GH as a global actor which engages with state and non-state actors around the world is perhaps best positioned to consolidate international data governance mechanisms such as the UNESCO Declarations, OECD Guidelines and Bermuda Principles under one framework. Consequently, in this case study, GA4GH plays a leadership role that can facilitate the development of functional borders between bodies.

4.5 Case Study Summary

All three case studies employ the use of global mechanisms (UNESCO Declarations, OECD guidelines, and Bermuda Principles), suggesting the existence of a recognized global framework for the governance of genetic data. However, the specific application of these principles and guidelines remains general in order to capture as many uses and contexts as possible. The application of more prescriptive practices and technologies for privacy and security would create a challenge for operationalization and result in outdated frameworks as uses and technology in the field of genomics evolve.

All three case studies utilize similar levers that manage genetic data, such as employing human rights-based guidelines, constitutions, and national legislation. Despite these similarities, the case studies have different approaches and practices for managing genetic data. There are two distinct border schemes employed in the case studies, limiting access through territoriality and enabling access through functional borders. China is an example of the state creating borders around genetic data that operates in parallel to its physical boundary lines. While GA4GH and the EU establish borders that enable cross-border sharing by relying on shared principles to set appropriate data management standards, thus creating functional borders. The functional border approach is likely to support international research and health care collaboration as it reduced barriers by "pre-approving" bodies. This may be likened to the Nexus card used by the Canadian Border Service Agency and US Customs and Border Protection to accelerate border-crossing by pre-clearing individuals (Canada Border Service Agency, 2019; see also Bradbury & Turbevill, 2008, p. 323). Meanwhile China's territorial approach may be an effective governance mechanism for protection and enforcement of the data, by tying the data to the state by requiring foreign researchers to partner with Chinese bodies. What this suggests, is if a state prioritizes the protection of genetic data and prefers to limit its sharing, a territorial approach may be the best method to achieve this. Conversely, if sharing data is the state priority, functional borders may enable this to take place in a secure and consistent manner.

With regards to developing a strategy for BC's genetic data governance, stakeholders need to agree on priorities. For example, is the provincial approach primarily about data protection and limiting access or enabling access and supporting collaboration? Setting priorities will help determine how the international declarations, guidelines and principles are operationalized in BC, much as they have for the EU and China.

TABLE 4 - RESEARCH QUESTIONS AND THE CASE STUDIES

Question 1	Question 2	Secondary Question 1	Secondary Question 2
What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?	What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?	What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving	Based on the findings, what are potential approaches for the BC context?

		health care while preserving human rights to privacy, autonomy and access to data?	
Case Studies Suggest	Case Studies Suggest	Case Studies Suggest	Case Studies Suggest
The state continues to play a leading role as a regulator. Borders may be employed to enable or limit sharing of genetic data based on priorities.	Territorial approach may be most appropriate for limiting access and protection as seen in China's case. Functional borders based on shared principles enable data sharing and collaboration.	There is a presence of an international genetic data governance framework in the form of declarations, guidelines, and principles which are grounded in a human rights-based approach.	BC needs to create clear and consistent priorities: a) data sharing and collaboration or b) protectionism and limited access to genetic data.

4.6 Interview Findings

Interviews provided a detailed snapshot of the current state of governance approaches across jurisdictions and insight into how governance mechanisms such as legislation are being operationalized in the field of genetic data. Professional opinion was provided on state and non-state involvement in regulation as well as public and stakeholder response to certain regulatory approaches. Drawbacks and challenges of certain approaches were highlighted as well as the benefits of each approach within jurisdictions. Common themes that arose during interviews included concepts regarding context such as jurisdictions' health care, legal system and communities. Trust and private sector involvement, data ownership, formalization of governance approaches, state involvement and use of legislation were discussed in all interviews.

CONTEXT

Each interviewee addressed the context of their jurisdictions and suggested factors unique to Canada. Interviews 4, 7 and 8 discussed the BC and Canadian context in detail outlining factors that may be unique to Canada or BC. Interviewees consistently expressed that the effectiveness of governance frameworks are dependent on the context in which they are applied. Context includes factors such as whether a society is collectivist or individualistic, capitalistic or socialist, has a privacy aware population, and whether there is a public health care system or a privatized one. Below are elements of context that were discussed in greater detail.

HEALTH CARE SYSTEM

A number of interviewees suggested that implementing an open data sharing framework may not be appropriate in a privatized health care system that is dependent on private insurance, such as the United States (Interview 1 & 5). A privatized system may incentivize corporations who provide services such as insurers to use genetic data to achieve favourable profit margins. Conversely, individuals in a universal health care system may feel more comfortable sharing their genetic data because they do not fear that their genetic data will be used against them by a privatized system (Interview 1). A universal health care system may incentivize data sharing as it has the potential to improve health care delivery which all patients will benefit from. What this suggests, is that shared resources in the form of health care systems, may contribute to more collectivist norms where the costs and benefits of sharing data are weighed differently than a society where individuals rely on a profit driven industry and must pay out of pocket to access services.

LEGAL STRUCTURE

Canada's legal system is bijural in nature which means that common law and civil law practices exist within the same two-tiered system. Canada also has a federal system that establishes a division of powers between provinces and the federal governments. The legislative jurisdiction of provinces includes dominion over areas such as internal constitutions, education, hospitals, and penalties for violations of provincial statutes like FOIPPA and PIPA (Beaudoin & Panneton, 2015). Some federal powers include trade, commerce, criminal law, Indigenous affairs and interprovincial works and undertakings (Beaudoin & Panneton, 2015), resulting in areas of potential overlap with regards to the cross-borders flows of genetic data. For example, providing health care to Indigenous populations has often resulted in a cross section of federal and provincial tensions when determining responsibility over the provision of services. A federalized environment creates challenges for harmonizing governance frameworks as it is dependent on consensus and the presence of complimentary regulating mechanisms. As a result, creating a

governance framework in BC that is harmonized across Canadian provinces and the Canadian government has proven to be challenging and may not be entirely possible without great collaborative effort.

COMMUNITY

I. FIRST NATIONS

The majority of interviewees did not consider their own jurisdictions' general population as unique with regard to the personal data they may possess. However, each interviewee acknowledged that there are groups of individuals or communities who are marginalized, vulnerable and historically have had their data misused in research or for the purpose of implementing xenophobic policies. Canada's large Indigenous population makes it unique compared to other nations. In the 2016 census, over 1.67 million Canadians identified as Indigenous, a population considered to be the youngest and fastest growing in Canada (Government of Canada, 2017a). Given the history of colonialism and the enduring legacy of residential schools, Canadian Indigenous data may require a unique approach to data governance.

A common sentiment was expressed that Indigenous communities need to be engaged in consultations given historical injustices and the challenging realities that many communities continue to face today (Interviews 4,7, & 8). Indeed, the federal and provincial governments' commitment to support the calls to action put forward by the *Truth and Reconciliation Commission of Canada: Calls to Action* includes the consultation of Indigenous communities to address the disparity in Indigenous health outcomes (2015, p. 2). An interviewee aptly stated that if reconciliation is a priority, a regulatory approach must give due consideration in the framing of Indigenous data governance. A potential approach is a separate framework for Indigenous data governance entirely in which communities control how their data is collected, used and shared. However, whether this approach is applied nationally, provincially or at a community level would require careful consideration given the unique history and culture of each community. For example, BC has more First Nations bands than any other province in Canada with the greatest range in culture and language compared to the language and cultural practices found across prairie bands (Indigenous and Northern Affairs Canada, 2010). As a result, the BC First Nation's context may be unique to that of any other province and require a nuanced approach (Interview 8).

On a national level there are strategies in place to address Indigenous data governance, a leading example is the creation of the OCAP® Principles (Ownership, Control, Access and Possession) created in 1998 by the *National Steering Committee of the First Nations and Inuit Regional Longitudinal Health Survey*. OCAP® principles are established standards that outline the appropriate collection, protection, use and sharing of First Nations' data and are considered the "*de facto* standard" for conducting research with

First Nations (FNIGC/CGIPN, 2015). A 2009 "DNA on Loan: Exploring Biobanking with Indigenous Values" forum explored the storage of First Nations' biological samples for the purposes of research with the goal of establishing national and international best practices and policy (Canadian Institutes of Health Research, 2019). These examples identify that in addition to global principles set out in the UNESCO Declarations and the OECD Guidelines, there are established national principles developed by Canadian First Nations groups that could shape regulatory practices. Literature and data contributed in interviews highlights the necessity for understanding the First Nations' context with regards to genetic data governance and the complexities it presents.

II. IMMIGRANTS

Approximately one in five Canadians is foreign born (Government of Canada, 2017b) which may have unique consequences for data governance. Interviewees suggested Canada's multicultural population contributes to diverse attitudes towards privacy as immigrants may bring experiences from their countries of origin. Foreign governments may impose greater degrees of control over citizens than those seen in liberal democratic societies resulting in a range of expectations to privacy than what may be the norm in Canada. Additionally, in many countries marginalized communities such as LGBTQ, ethnic or religious minorities are persecuted when such personal information is disclosed publicly. Understandably, individuals who then immigrate to Canada may be less willing to share personal information despite such prosecution being prohibited both legally and deemed socially unacceptable. Mistrust in institutions and government organizations may take generations to overcome.

III. GEOGRAPHY

Geographically, Canada has a large and unique landmass whose population is widely dispersed with concentrated urbanized pockets and sparsely populated regions (Interview 8). Interviewees acknowledged that the mosaic effect is pronounced in smaller communities where members are more likely to know each other and there is a greater likelihood that pieces of information that are anonymous in larger communities can be linked to easily reidentify individuals in smaller ones. While this is not necessarily unique to Canada, the dispersion of pockets from coast to coast are also not entirely common in other jurisdictions such as the EU (Interview 8). A framework that addresses the pronounced mosaic effect in rural communities will include requirements to consider population sizes to appropriately protect personal information.

In addition to the relationship between geography and populations is the impact of geography on technology. Interviewee 8 highlighted the high cost of technology particularly given the rate that data is produced, indeed, 90% of the world's data has been created over the last two years (Government of

Canada, 2019). Processing and storing such large volumes of data is costly and becomes more so when digital infrastructure must cover vast distances. There are additional costs associated with not only protecting high volumes of data but also the distances associated with a large geographical range. It is estimated that by 2021, cybercrime will cost Canada $6 trillion (Government of Canada, 2019). Interviewee 8 suggested that providing effective security may be particularly challenging in remote communities whose governments may not have the infrastructure or resources to use the latest cybersecurity technology as those employed by larger urban centres. While larger cities are more lucrative hacking targets given the amount of valuable data, smaller communities were not less worthy of privacy protection (Interview 8).

TRUST AND THE PRIVATE SECTOR

The notion of trust was referenced frequently, but its utility as a metric for determining a governance framework's success may be unreliable. Some interviewees stated that effective governance structures would increase levels of public trust, while others suggested levels of trust would not be influenced by governance structures. Multiple interviewees opined that the publics' attitude towards privacy is incongruent with the publics' actions. For example, an interviewee shared that citizens often resist sharing information with public bodies fearing privacy violation, but the same citizens were claimed to freely share their data with organizations widely known to violate privacy rights, for example Facebook. Some interviewees stated public bodies were trusted less with personal data while others believed they garnered more trust due to governments' responsibility to the public. However, most interviewees agreed that the private sector presents the greatest gap in data privacy regulation and should be a priority when establishing regulatory frameworks.

Currently, only BC, Alberta and Quebec have private sector privacy legislation that regulates how personal information is managed by businesses. Manitoba enacted the *Personal Information Protection and Identity Theft Prevention Act* (PIPITPA), however it is not currently in force (s.45). Health information legislations in the Yukon, Alberta, Ontario, New Brunswick, Newfoundland and Nova Scotia include private sector organizations along with public bodies. Despite the application of federal legislation PIPEDA, this leaves the territories, Saskatchewan, and Manitoba without regional private sector privacy legislation. Even provinces with health sector legislation that includes private bodies may be at risk for gaps in privacy protection depending on the use of the personal information and whether it is considered health information or whether private bodies are considered to provide health care. This may mean that corporations that collect personal information from consumer products such as fitness trackers, nutritional apps and direct to consumer genetic testing companies (Ancestry.ca and 23andMe), may not be

subject to health sector legislation in those provinces. Canada's patchwork of privacy legislation for the private sector may result in inconsistencies and gaps in protection. Given the primarily profit seeking nature of the private sector, ensuring data is collected, used and disclosed appropriately is of utmost importance to provide transparency to the public and facilitate trust, whether this has an impact on public trust or not.

DATA OWNERSHIP

The notion of data ownership arose frequently in interviews with most participants identifying a recent shift towards the promotion of data ownership in light of privacy breaches and misuse by corporations and governments. Generally, regulatory bodies recognized data ownership as an inherent right, while academics and policy makers suggested that owning one's own data may result in unintended negative consequences for research, innovation and even legal feasibility (Interview 1). Data ownership was also identified as being connected to the type of society individuals live in, for example capitalistic and individualistic versus socialist and collectivist. A strong sentiment towards data ownership was identified in capitalistic societies who prioritize the rights of the individual and have an economic focus (Interviews 1, 2 & 5).

In Canada's *McInerney v. MacDonald* (1992), it was decided that patients own their data, however physicians own the physical record that contains the data. As a result, patients may access and view their records and physicians are obligated to manage the records according to privacy legislation and college bylaws. The notion of data ownership in this regard may be problematic since the data which patients own is not tangible while the physical record containing owned by the physician is tangible.

FORMALIZATION

The formalization of data governance processes as seen in GDPR was referenced by various interviewees with a range in sentiment. Some believed formalization to be a negative outcome as it has added bureaucratic processes to agreed upon data sharing activities and led to redundancy that provide little value (Interview 5). Others found benefit in formalization of the data governance process as it established common language, clarified roles and responsibilities and facilitated multi-jurisdictional networking among regulatory bodies, as well as assisted in enforcement and investigations (Interview 7). Furthermore, proponents of formalization believed it contributes to increased public privacy awareness. Formalization or standardization of processes make clear requirements reducing confusion and inconsistency, however they may also remove the freedom to employ discretion based on the scenario, such as the level of risk and parties involved (Interview 5).

THE ROLE OF THE STATE

The degree of state involvement differed from one interviewee to the next depending on their location. For example, the interview addressing Chinese genetic data governance described a state heavy approach as compared to EU and Canadian interviews. Nevertheless, all interviews spent time discussing the current role of state involvement in genetic data regulation, suggesting that the state is a primary actor despite multi-national organizations and supranational bodies. Some interviewees asserted that the state has an obligation to play a leadership role in establishing an appropriate regulatory framework (Interview 3). However, it was suggested that state involvement after development and implementation of the governance framework should be restrained so as not to negatively impact research and scientific innovation (Interview 5). Other bodies like academic institutions, research communities, professional bodies such as the College of Physicians and Surgeons, oversight bodies and interest groups were all cited as having a role to play but were not deemed the primary developers of the governance framework.

From a national perspective, it is the Canadian Government's priority to more effectively utilize technology such as AI (e.g. diagnostic technologies) and big data to better serve Canadians (Interview 8). Emphasis was placed on ensuring that governments remain good stewards of personal data which they have been entrusted with. In order to achieve this, public bodies must be transparent with citizens on why their data is being collected, how it will be used, who it will be shared with and the benefit that will come from accessing personal information. Today, ministries and public organizations have more overlap in programs and services that require collaboration on shared files to address issues or deliver services (Interview 8). Interviewees stated that the collection of data by public bodies is essential in addressing current challenges such as the opioid crisis, chronic illnesses and mental health. Without access to raw data, public bodies will struggle to create evidence informed policies and risk wasting scarce resources on unproven strategies.

LEGISLATION AS THE PRIMARY REGULATORY MECHANISM

Interviews spent the majority of the session discussing the role of legislation as a mechanism for regulation. All interviewees identified legislation as the primary approach to governance, codes of ethics and review processes such as those found in research ethics boards were also cited. However, no interviewee suggested that research ethics boards have either been successfully utilized or are appropriately positioned due to a lack of capacity and privacy expertise to play a leading role in governance.

Despite legislation being a primary mechanism for regulation, interviewees outlined limitations that current legislation presents to utilizing data. In Canada, the *Privacy Act* (1985) governs the management of personal information by federal bodies, and primarily dictates the manner and form in which personal information is collected, used and disclosed. However, Interviewee 8 highlighted that the *Act* was created in 1985 when technology and the creation of data were vastly different and public organizations operated in a siloed manner. Given the interconnected nature of programs and services, silos of data are no longer an appropriate approach for data management. Consequently, Interviewee 8 suggested that the *Privacy Act* is unable to address the new big data environment and enable necessary data sharing so that it may meet the needs of Canadians. Suggestions arose in interviews that legislation should be broad and principle-based to avoid becoming obsolete and unnecessarily restrictive as technology changes.

GENERAL DATA LEGISLATION VERSUS SECTOR SPECIFIC LEGISLATION

With the recognition that legislation is a primary tool for regulation, there was division among interviewees whether a general data privacy legislation (omnibus legislation) or sector specific legislation approach was the most appropriate. General data protection legislation treats all personal data the same whether it is financial, medical or commercial in nature, while sector specific legislation brings into scope certain types of data or activities, for example health care sector specific legislation carves out all information that is health related. Interviewees who were proponents of omnibus legislation argued it provided more clarity and consistency with fewer loopholes for poor privacy practices (Interview 1). Omnibus legislation would also follow the data regardless of what category the personal data fell under, such as socioeconomic, commercial, health etc. Proponents of health sector specific legislation believe that there are unique circumstances for sharing and bodies involved in the provision of health care that require clear authorities under legislation to carry out their duties (Interview 3 & 4). A lack of sector specific legislation has been said to lead to confusion and inconsistent practice in sharing and protecting sensitive data such as health information. Others contended that public and private sector legislation remain separate as the purposes of corporations are different from government.

Within general or sector specific legislation, is the option to employ genetic exceptionalism. This approach again was met with a nearly even divide of critics and proponents. Some organizations contending all forms of personal data are equal, while others claimed it had unique characteristics that needed to be addressed separately. However, more arguments were put forward against genetic exceptionalism due to data linking with various forms of environmental and social data that would create confusion and exceptions.

4.7 Interview Summary

The data collected during interviews provided valuable insight into the complex genetic data environment. Interviews affirmed earlier findings in the case studies that identified the state as a key driver in developing and managing a governance framework with legislation being the main lever for regulation. The notion of context as a keystone for successful governance has signaled a need to better understand BC's context. For example, given BC's bijural system and public health care system which relies on the use of both public and private sector legislation, BC may be best suited to sector specific legislation (health information privacy legislation). Considering the need for enhanced interoperability and security, a functional border based on UNESCO and OECD principles would enable greater alignment with PIPEDA, GA4GH and GDPR reducing barriers to necessary sharing while providing appropriate privacy protection.

TABLE 5 - RESEARCH QUESTIONS AND INTERVIEWS

Question 1	Question 2	Secondary Question 1	Secondary Question 2
What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?	What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?	What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving health care while preserving human rights to privacy, autonomy and access to data?	Based on findings, what are potential approaches for the BC context?
Interviews Suggest	Interviews Suggests	Interviews Suggests	Interviews Suggests
Creating borders around genetic data is more complex due to the challenge of identifying what data is linked to	The state is a key driver in re-bordering genetic data for the purpose of regulation.	Legislation is the primary mechanism for governance.	BC has a public health care system, engages in public private partnerships and has a sizable and diverse First

genetic data or health data.	General data protection legislation can capture data linking to genetics follows the data through its lifecycle. BC may be best suited to sector specific legislation. Basing legislation on international principles outlined in UNESCO and OECD would enable greater alignment with PIPEDA, GA4GH and GDPR.	Context is critical for effective development of governance as some environments require a closed or open framework. Private sector presents the greatest risk to human rights principles. Utilization of sector specific legislation versus omnibus legislation is divided and may be based on the context of the jurisdiction.	Nations population whose data management needs may be unique from the rest of the population. BC's patchwork of legislation results in management and creates barriers to health care services. A federalized system is not conducive to the development of harmonized omnibus legislation in BC. A functional border is the product of principle-based protection and sharing and would reduce the data siloes.

4.7 Section Summary

All three cases demonstrate a consistent structure that employs human rights principles found in the UNESCO Declarations, information sharing supported by the Bermuda Principles, OECD Guidelines, constitutional charters, and national legislation. Each case study to varying degrees also is influenced by supranational structures. What these findings suggest is that a global approach exists for governing genetic data. This overarching framework is then shaped by contextual factors such as culture, political structures and state priorities. The EU and GA4GH prioritize collaboration and data sharing while China prioritizes national security, economic interests and privacy protection. Significantly, each case demonstrates a consistent reliance on the state to establish the framework and provide enforcement mechanisms. This challenges Ohmae (1995) and Castells's (1996) argument that the state has lost its

power. However, there are various bodies that contribute to the development of processes. For example, GA4GH consults and collaborates with numerous non-government bodies to develop policy, meanwhile China's process is primarily state led. Evident in all cases is a challenge in establishing consistent practices that may be operationalized across borders.

It is the unique context of each nation or organization that sets out priorities which then shape the governance framework and establish how principles are operationalized. For example, consent is an often-emphasized principle in various declarations and guidelines. It is then each governance framework that addresses how consent may be operationalized, whether it is obtained verbally or implied when individuals seek access to care. The operationalization of principles is driven by factors such as the type of health care system, involvement of private organizations and structure of the legal system among other factors.

Legislation is the primary mechanism for governance; however, each case study diverges in its legal approach. This is seen in the employment of either general privacy legislation (omnibus legislation) or sector specific legislation (health information legislation). Each of these approaches may call out genetic data specifically in provisions such as those found in GDPR, or it may be evident in standalone genetic legislation as seen in China. When examined with a border theory lens, legislation may both work to re-border and deborder. Re-bordering takes place when the object of a governance framework establishes parameters around associated activities with that object, in this case the object is genetic data. The act of states developing legislation around the collection, use and disclosure of genetic data is a re-bordering process. Limitations are placed on who may access the information, what may be done with it and where it may go or with whom it may be shared. At the same time, de-bordering occurs when legislation or policy stipulates when and with whom sharing may be enabled, thus creating a conduit between bodies. This de-bordering process may appear in many forms, GDPR for example uses an adequacy list while Canada uses contractual based agreements with OECD principles to determine whom information may be shared with.

Borders may be considered functional when nations and organizations engage in sharing activities by adhering to principle-based parameters that are carried out in parallel within the boundaries of each state. This can be seen with GA4GH and GDPR which facilitate sharing of genetic data based on common understandings and recognized legislation. There is an exception to this, by GDPR requiring a representative on EU soil, an aspect of governance is anchored within territorial boundaries. However, this merely highlights the enduring effect of state sovereignty and the challenges of enforcing extraterritorial legislation. The GA4G framework may also be limited to a greater degree by traditional

territorial borders as the organization defers to national legislation for regulation which may not enable principle-based sharing. Another example of territorial re-bordering may be seen with China, where under the new *Regulation*, foreign organizations conducting research using Chinese genetic data must not only adhere to Chinese law but are required to work with Chinese institutes (Article 21) and any resulting data must be shared with the partnering Chinese institution (Article 24). While the data may physically leave territorial boundaries, it is still connected to China along with any benefits that may be derived from its use in research. Castell's theory that spaces of places are being replaced by spaces of flows may see a reversal in China's case in that the flow of the information is released but is then recaptured by the state, who in this instance has retained much of its sovereignty. The unintended outcomes to research and innovation of such a territorial approach warrants additional research in order to understand the true costs associated with such a framework.

4.8 BC Context

What the research suggests, is that in order to achieve some degree of interoperability or compatibility with international bodies, BC may need to consider aligning with the UNESCO Declarations Principles of Human Rights, OECD Guidelines and the Bermuda Principles for sharing. Principle based legislation would not only remain adaptive to changes in technology and big data but would also support a secure functional border for data sharing between other states and international organizations. For the purpose of governing genetic data in BC, critical questions require answering such as what is BC's priority? If BC wishes to align its priorities with those of the federal government and commit to a digital strategy that supports the development of precision medicine, perhaps an omnibus piece of legislation will be able to bring into scope all the data associated with genomics research. The creation of sector specific legislation may pose challenges for cross-border sharing and interoperability, however within the Canadian context, most provinces already possess sector specific legislation and the feasibility of repealing FOIPPA and PIPA is unlikely.

Public engagement with BC citizens may reveal whether there is a general willingness to share data and what the expectations are for the collection, use and sharing of genetic information. Furthermore, engagements may identify citizens' views on data ownership, obligations to contribute to the health care system and whether fears of discrimination abound. BC's immigrant population and minority communities may provide insightful feedback and enhance privacy protection as well privacy education. With close to 200 First Nations bands and nearly 60 spoken dialects, BC's Indigenous population is one of the most diverse in Canada (Welcome BC, n.d.). The inclusion of First Nations in the development of a genetic data framework would work towards BC's commitment to truth and reconciliation and play a

critical role in responsible data stewardship. These contextual factors will determine how shared principles are realized in the BC framework.

5.0 Discussion and Analysis of Major Themes

The discussion and analysis in this section is based on the literature review findings, comparative case studies of the EU, China and GA4GH, and interviews with subject matter experts. Perhaps the most common theme found within the research, is the consideration of context. An understanding of the environment in which frameworks are deployed is integral to making the appropriate paradigm selection that supports information sharing while preserving the human right to privacy. Additionally, an understanding of context provided insight into the approaches employed by each case study.

The literature, the case studies (and interviews) highlight that re-bordering and de-bordering processes are occurring simultaneously with respect to the governance of genetic data, whether it is achieved through general privacy legislation or sector specific privacy legislation (and within this genetic exceptionalism). Each case study employs this process, however there is divergence in how de-bordering occurs, whether these are functional borders that are grounded in principle-based sharing between bodies or territorial in nature. In the following section, each theme will be discussed in further detail, the benefits and drawbacks of each, it's significance in each case study and what this may mean for BC.

5.1 Context

A consistent theme that arose in all three areas of data collection for this research (literature review, case studies and interviews), is the notion of context. In this situation, 'context' may be described as the background or setting in which frameworks are operationalized. Factors that contribute to context include concepts such as values and norms, for example collectivism, evident in many Eastern cultures and individualism, evident in Western cultures (Interview 2). These norms play a role in the publics' appetite for sharing their personal data (Interviews 1, 2 & 4). Arguably, societies that are collectivist will be inclined to share their personal data more freely if they believe it will contribute to the greater good. Conversely, individualistic societies place the rights of individuals before the rights of the group and thus may be less inclined to share their personal data (Interview 1 & 2).

Context may include political views, popular culture, and education levels. Interviewees have identified that perhaps varied levels of education in China may prevent individuals from understanding the risks of sharing their personal information, while nations with large highly educated populations may have a greater awareness of the privacy implications thus influencing risk tolerance and data sharing (Interview 2). Cultural differences in approaches to privacy may also impact the approaches to privacy and willingness to disclose personal information (Interviews 1, 2, 4, 6 & 8). Political appetite for enacting privacy legislation may be influenced by interest groups such as private corporations who acquire and sell

personal data. Conversely, public or international pressures exerted on governments, evident in China's enactment of genetic data legislation after the unsanctioned gene editing of two babies also plays a role in exerting pressure and driving regulatory change.

Geography or the physical location of the state and relationships with neighboring states may prioritize state privacy interests over individual interests (Interview 2 & 8). The composition of communities and whether they are highly dispersed rural communities or dense urban populations, impacts the ability to share information securely. For example, access to technologies challenge communications as well as the ability to employ sophisticated cybersecurity controls (Interview 8). Border related activities directed by security and immigration policy may provide insight to data privacy approaches as well. Perhaps the greater the securitization of borders, the less likely personal data will leave the state.

Interviewees suggested that administrative processes and state infrastructure such as the legal systems and ability to litigate, the health care model (public or private system), and role of private organizations such as insurance companies, contributes to public attitudes towards privacy and data sharing. Such factors heavily influence the efficacy of governance frameworks; failure to consider the nuances of each region could compromise citizen buy in, operationalization and ultimately the ability to protect privacy and support necessary data sharing.

However, the bird's eye view thanks to the UNESCO Declarations, suggests that there are a number of broadly shared values between nations and across cultures. Nevertheless, the variables that influence context shape the way such values are prioritized and realized into practice within each region. For example, while China recognizes the right to individuals' privacy and the need for consent, there is perhaps not the same individualistic approach to privacy employed by the United States where privacy is linked to data ownership (Interview 1). Much like DNA contains the code, the UNESCO Declarations create guiding principles for appropriate data management. However, it is the individual context of each region that expresses the way in which the principles are realized.

Despite the value in deferring to regional context, one of the greatest challenges to interoperability and consistency is the tailoring of frameworks which may lead to disparate privacy processes between regions resulting in incompatibility. Thus, a balance must be struck between respecting the priorities and realities of each region while preserving core principles and creating consistent practices. A component of this is agreed upon language and definitions that enable clear communication (Varga et al., 2012).

Border theory suggests that geography or proximity enhances sharing due to a greater likelihood of common values, practices and language referred to by Maillat as the "proximity effect" (Maillat, 1998).

As a result, there is a greater degree of certainty that data will be handled appropriately. For example, from the Canadian perspective, the EU's approach to data protection may be more readily understood than the regulations employed by China. Data sharing across vast distances increases uncertainty and may mean there will be greater differences in language and culture between data sharing parties. Arguably, the Canadian provinces are within the same nation and still face interoperability challenges.

5.2 Centralization and Enforcement

Each case study suggests that while borders are becoming more permeable due to the digitization of data, advances in technology and globalization, the state still plays a leading role in the regulation and flow of citizen data. However, international collaborations and sharing frameworks such as APEC, OECD and the UN, demonstrate the leadership and involvement of non-state actors. Furthermore, GA4GH and the EU are also examples of multibody frameworks.

However, international and global frameworks lack the enforcement capabilities conferred on the sovereign state. A current example of continued deference to the state is GDPR Article 89(2) carve out for certain data uses such as research which is left to state regulation. The processing of personal data for research, is not subject to restrictions placed on sensitive data or secondary use (Article 6(4); Recital 50). Personal data may be obtained without the consent of the individual and transferred to third countries if it is for the purposes of research on the condition that organizations employ appropriate safeguards. Another EU example of enduring state autonomy includes the UK and Poland's partial derogation from the EU Constitution outlined in the EU case study.

Article 27 of GDPR requires organizations to establish a representative in one of the EU Member States in which personal information is being processed for monitoring EU citizens or providing goods or services (Determann, 2018). The representative is a point of contact for supervisory authorities and EU citizens who may wish to inquire how their personal data is being processed. Public authorities and bodies are exempt from this requirement (Article 27(2)(b)). This has been highlighted as not only a way to ensure compliance with Regulation, but perhaps more importantly is a way to enable data protection authorities to contact and charge organizations operating outside of the EU (Determann, 2018). This acknowledges that state sovereignty poses challenges for enforcing extra-territorial regulations, thus requiring a representative of the organization to physically reside ***within the physical boundaries*** of the EU to enable legal recourse for non-compliance with GDPR. This suggests that GDPR is a bounded network of legal systems comprised of EU Members who possess functional borders in order to achieve transnational cooperation, and yet are centrally driven by mandating the protection of individual rights.

Despite the existence of sophisticated technology and global communities, requiring representatives to reside within the jurisdiction where data is being processed may be the most effective way to exert regulatory power over various actors. China also requires those handling Chinese genetic data to collaborate with local Chinese researchers. By requiring collaboration with a local researcher, China could ensure greater surveillance capabilities and increase its ability to successfully impose sanctions on foreigners who fail to comply with regulations.

GA4GH recognizes state regulating powers and as a result does not attempt to circumvent these requirements but rather enhance them. In other words, the state sets the parameters and bodies such as research ethics boards, privacy oversight bodies, data committees, and either scientific or medical communities play a role in fleshing out best practices based on context (technology, culture, demographics, risk and benefit). Conversely, downstream delegation of requirements can be seen in a highly formalized manner in China. There are drawbacks to an overly centralized framework driven by the state. A state-centred approach is often criticized for creating barriers to the delivery of services and research (Interview 5). The state may contribute to the formalization of privacy processes adding additional layers to data sharing requirements that are disproportionate to the risk that sharing certain data presents, resulting in the inhibition of research, innovation and valuable collaboration (Interview 5). Some individuals have suggested that GDPR while broadly written and flexible in spirit is being applied in a prescriptive manner (Interview 5). Additionally, there may be unintended consequences to this formalization process. Indeed, there are contentions that a new industry of privacy specialists has emerged seeking to profit off the heightened privacy requirements adding further layers to the privacy process such as the requirements for more lawyers and data protection officers (Interview 6).

However, without clear direction that is communicated from a central authority, there is a duplication of efforts, resulting in inconsistent practices and potential gaps in protections. In Canada, a clear centralized framework comprised of general privacy legislation that enables data sharing between provinces would support the delivery of health care, particularly in the case of limited resources such as diagnostic tools and specialists. A framework that supports consistent application within the state will find greater consistency when engaging in cross-border sharing with foreign bodies.

In the absence of regulatory frameworks, private organizations that are not elected by citizens begin to regulate based on corporate interest rather than the interests of individuals, Canadians in Canada and Chinese in China. Such an example may be seen with organizations such as Facebook, where regulation in this sector has found little success (Curry & McMahon, 2019). Reigning in self-governance and altering business models to behave in a privacy compliant manner is a greater challenge than building a

robust framework from the outset. Government should provide leadership and set clear expectations for the appropriate collection, use and disclosure of personal information for its citizens, including genetic data. China, EU or GA4GH do not enable industry or private corporations to dictate what is appropriate data sharing. Private bodies such as direct to consumer genetic testing companies like 23andMe or Ancestry.ca and pharmaceutical companies have been consistently identified by interviewees as the greatest area of risk to individuals' personal information. Public bodies and public agencies are typically governed by additional legislation and policy that creates parameters around the collection, use and disclosure of personal data.

The state, while central to providing direction and enforcement capabilities, is not the only actor in regulation. Included in this regulatory framework are academic institutions, research ethics boards, and privacy oversight bodies. These various bodies create best practices that meet the contextual needs of the region, respond to public queries, conduct investigations as well as address sector specific needs. This should include stakeholders such as Indigenous populations whose personal health data has been misused in the past (Interview 4). The development of the Ownership Control Access and Possession Principles (OCAP) principles as well as the Truth and Reconciliation Commission of Canada provides direction towards a First Nations data governance framework that will help meet the unique needs of Indigenous communities and build trust between First Nations and governments. There are unintended consequences to creating special categories of data or group membership and would require extensive engagement with First Nations to establish an appropriate approach to that would not have consequences for health care delivery.

The scientific community plays a role in establishing norms and appropriate practices creating global standards for research, adherence to these is rewarded with continual funding and collaboration. Feedback from interviews has suggested that addressing research data the same way as personal data which is used to make decisions about individuals, may not be an appropriate approach (Interview 5). Research data typically already requires the consent of individuals and undergoes research ethic board review. Additionally, research data has been argued to not have the same impact on the individual because it is not being used to make decisions about the individual thereby potentially denying them access to services (Interview 5). Nevertheless, results from the research may later be used to make decisions about individuals, for example research has found that Ashkenazi women are at a higher risk for breast cancer, data that may be utilized by insurance companies to exclude coverage (Peterson, et al., 2002). In light of this possibility, research ethics boards have a valuable role to play as a body that addresses the nuances of research (Interview 5).

Based on interview, research ethics boards (REBs) were identified as bottlenecks for research data sharing. REBs have been found to have low utility due to their lack of expertise in privacy and security and may over or under protect data as a result (Interview 5). A reliance on REBs in Canada to consistently make decisions about data sharing and privacy may not be the best use of REBs, however their involvement is critical as data exists on a spectrum of risk which is weighed against the benefit of conducting such research and the potential risks to individuals, an assessment that cannot be addressed through state legislation alone (Interview 5).

5.3 General Privacy Legislation vs Sector Specific

Canada's current federal legislation, PIPEDA is insufficient at addressing the risks to genetic data as it fails to address public organizations (with the exception of federal works and undertakings as per s.4(1)(b)). Furthermore, the *Privacy Act* is considered to be outdated and designed for siloing data (Interview 8). Legislation such as GDPR, applies to anyone handling personal information regardless of whether they are in the public or private sector, thus reducing the confusion and in turn any gaps.

Disparate provincial health sector legislation across the country further challenges interoperability. For example, health information legislation has been enacted in all provinces but BC and Nunavut. Differing consent models, breach reporting requirements, and data residency requirements discourage sharing of data. Interviewees opined that regulation needs to follow the movement of the data, particularly in the case of patient care and for conducting valuable research (Interview 1). Patients often access services such as diagnostic technology or specialists in different provinces and require their information to follow them or leave the province when required. Additionally, multi-data sets are utilized in genomic research which involves linking various information which may be categorized as socioeconomic data instead of health data (Interview 1). This variance creates challenges for what legislation the data falls under (general privacy legislation such as FOIPPA or sector specific legislation), thus creating uncertainty and inconsistency (Interview 1).

Finally, capturing all those bodies who may collect personal health information as custodians or their affiliates under health information legislation creates challenges for regulating the private bodies who do not traditionally provide health care services but nevertheless possess patient level data (e.g. personal devices that track fitness or nutrition). Genetic data is being held by private companies such as Ancestry.ca which are not delivering health services. As a result, broad overarching legislation that captures all personal information whether it is collected, used or disclosed by public or private bodies may address the increasingly varied data sets that are being utilized in health care delivery and research as

well as the growing data industry which seeks to obtain personal data and conduct analytics for individual use – an industry in particular need of regulation.

National legislation plays a leading role in governance and is perhaps best in the form of general data protection versus sector specific legislation which may fail to capture bodies that will begin to collect more and more personal information. This is in part due to the internet of things (IoT) as well as the challenge of including all personal information utilized in various data sets to conduct meaningful genomic research.

While China's legislation is not sector specific, it is specific to genetic data. Such a targeted approach may allow for more clarity, however addressing genetic data so specifically may result in the regulatory framework becoming outdated as advances in research and technology change our understanding and use of genetic data alters. Given the recent adoption of China's new *Regulations*, it is yet to be seen what impact its provisions will have on cross-border research. Despite GDPR's approach being a general privacy legislation, it does address genetic data as sensitive data which has specific requirements for consent. Perhaps a future challenge for GDPR may be the scoping of genetic data when such data is linked with other information or is the result of analytics. Genetic exceptionalism may not provide any additional benefits of privacy or protection in this regard. However, genetic exceptionalism may create important messaging to custodians of data that genetic information warrants careful privacy and security considerations.

5.4 Summary

While various themes emerged such as data ownership, the concept of trust and patient engagement, the key themes that may play a critical role in the effective development of robust genetic data sharing frameworks requires the involvement of the state to sponsor and develop the framework and delegate the principles downstream. The ability to enforce compliance and dole out impactful sanctions in the event of non-compliance is also further enhanced by establishing an enduring connection with foreign representatives.

Re-bordering around genetic data appears to be a natural outcome of regulating through legislation. A key consideration is whether there are de-bordering provisions within the legislation that enable sharing through functional borders. Currently, FOIPPA's data residency requirement has a territorial aspect, which has often frustrated sharing of data and collaboration between bodies. Given the reliance on public private partnerships and international research, BC may be unable to achieve Canada's objective to utilize data to improve public services. While omnibus legislation such as GDPR could be the most streamlined

and comprehensive approach, the political complexities of Canada's federated system and the existing patchwork of legislation in BC makes it an unlikely champion. A sector specific approach with no data residency requirement may be the most appropriate fit at this time and would address the current needs of the health care system as well as medical research. The drawbacks to this include the challenge of scoping out genetic data in a way that does not create for narrow application of protections or create barriers to sharing data between jurisdictions such as other Canadian provinces.

However, developing legislation that is principle based by looking to the UNESCO Declarations and the OECD Guidelines supports broad and consistent practices that align on a federal level and internationally. Bringing into consideration a key contextual characteristic of BC's Indigenous community, the employment of OCAP and Biobanking Data Governance principles will be a step in a direction that supports truth and reconciliation. While a separate framework for Indigenous genetic data governance create additional layers of re-bordering, historical abuse of this data warrants special protection and governance. Canadian public and private bodies may be included as partners in the de-bordering of that information under special terms and conditions decided by the Indigenous community.

In essence, an effective governance framework will protect genetic data by re-bordering and subsequently enable valuable sharing of the data by de-bordering through provisions in legislation. Perhaps equally as important is that the borders created are functional where they enable interoperability between parties instead of limiting movement of the data to traditional territorial boundary lines, particularly in the dawn of the new digital age.

TABLE 6 – RESEARCH QUESTIONS AND MAJOR THEMES

Question 1	Question 2	Secondary Question 1	Secondary Question 2
What can border theory learn from the governance of genetic data, specifically functional or territorial approaches?	What can border theory reveal about cross-border sharing that will enable bodies to develop governance frameworks that support appropriate sharing?	What are the key mechanisms of an effective framework for cross-border sharing of information that enables international collaboration for the purpose of improving health care while preserving human rights	Based on findings, what are potential approaches for the BC context?

		to privacy, autonomy and access to data?	
Answer 1	Answer 2	Secondary Answer1	Secondary Answer 2
Territorial boundaries may not be an appropriate fit with genetic data given digitization, biobanking, and data linking. The creation of functional borders using principle-based governance mechanisms such as legislation may support rapid digital sharing while still ensuring privacy protections.	Re-bordering and de-bordering through legislation may be an effective way to ensure privacy and facilitate appropriate sharing that has enforcement mechanisms.	State driven legislation which is principles-based may be the most robust and responsive to rapid technological innovation and create interoperability across different cultures and contexts.	UNESCO Declarations, Bermuda principles, OECD Guidelines and First Nation's OCAP principles provide a foundational framework for governing BC's genetic data. BC's legal and political reality may not be conducive to general legislation approach. Employing sector specific legislation risks omitting "non-health" data and private companies, and non-health care uses.

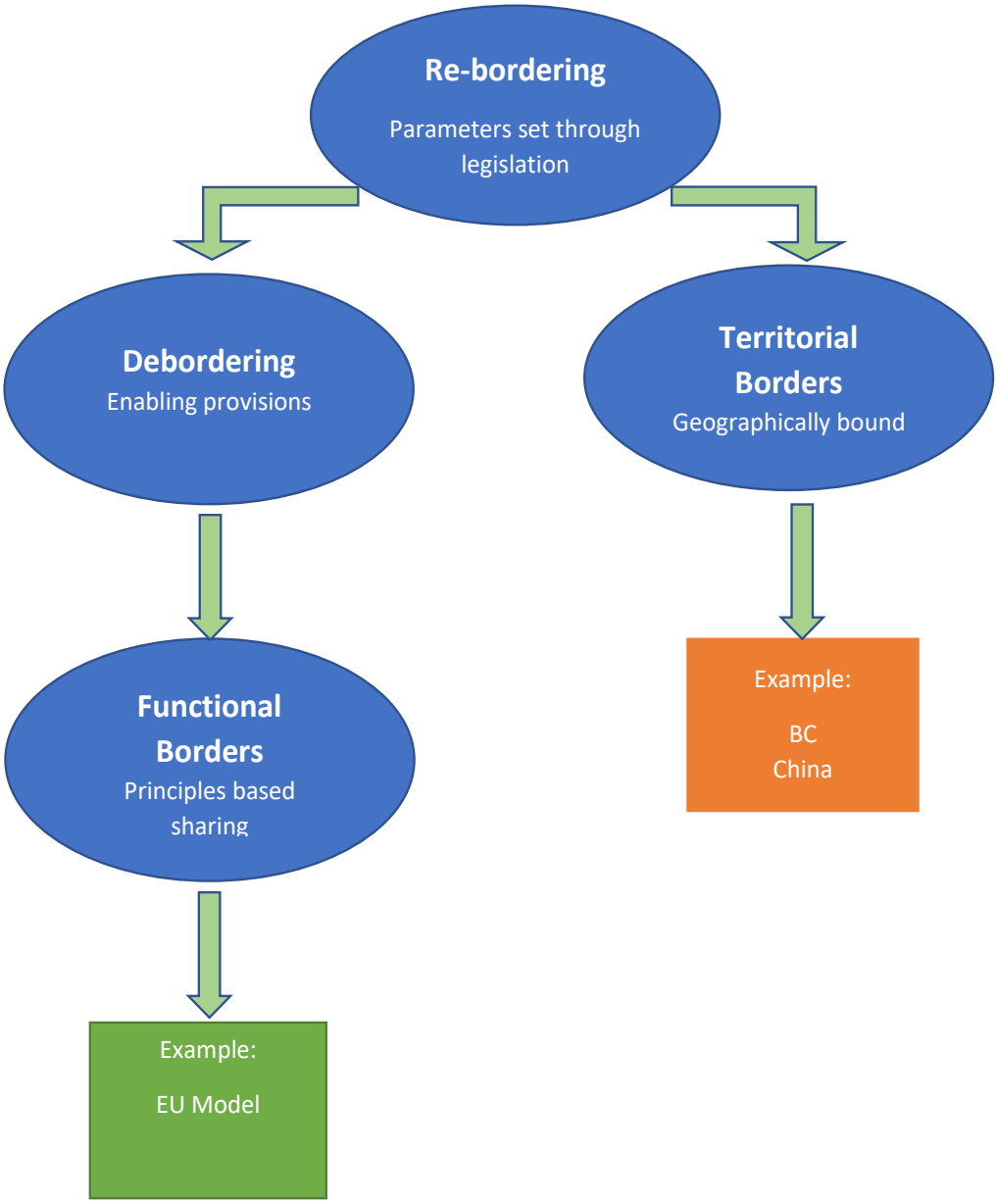

FIGURE 2 - USE OF LEGISLATION TO CREATE BORDERS FOR THE PURPOSE OF GOVERNANCE

6.0 Conclusion

Canada exhibits a dual system whereby the rights of individuals are recognized and protected; however, values of collectivism are evident in the preservation of a universal health care system. This suggests that Canada exists on a spectrum between China's socialist values and the United States' individualistic values. There is a need for broad general data protection that will follow the data and bring within scope the varied data sets required for genomics and its related activities. Such an approach would include capturing all the new custodians of personal health information and holding them accountable for the appropriate care and control of the data. The regulatory framework must recognize that genetic data exists on a spectrum of risk that requires context and consideration for a rational and yet thoughtful approach to weighing the costs and benefits of data sharing. By engaging local bodies to provide context, best practices may be developed to ensure the greatest benefit and the least risk to patients and research participants.

Due to the *Canadian Constitution* and provincial jurisdiction, it is unlikely that a federal level omnibus legislation could be successfully enacted. Instead, BC would benefit from closer collaboration with the federal government on the work that is being done with regard to any PIPEDA amendments in order to better align provincial legislation; enabling BC to maintain GDPR adequacy. Combining PIPA and FOIPPA to create a general privacy legislation that addresses the public and private sector would create consistency and capture the various bodies that hold genetic data. However, the probability of combining two separate pieces of legislation is unlikely to occur in the near future. Therefore, in order to address the current governance gap, health sector specific legislation that employs the UNESCO Declarations (human rights framework) would help BC align with jurisdictions such as the EU and China. Additional guidance may be sought from GA4GH to support interoperability and identifying common language and definitions used in frameworks around the world. Finally, continual engagement with Indigenous communities to ensure the incorporation of OCAP principles into the governance framework is critical to the BC context and is a step towards developing trust and enabling benefit sharing from genetic research.

The examination of genetic data governance in the EU, China and GA4GH has provided some clues about the changing role of boundary lines. The digital world and communication technology has created its own "spaces of flows" and with it, membership and governance needs. Such technology has enhanced the state's capacity to deliver goods and services but has also challenged its ability fully control these new "spaces of flows". In today's environment, where sharing of data is critical for the efficient delivery of citizen services and privacy protection is increasingly critical, state borders must remain flexible and strong. Functional borders which may be achieved through legislation and agreements are often driven by

the state. Regardless of the involvement of non-state actors, the state remains central to the regulation of cross-border activities and plays a pivotal role in the re-bordering and de-bordering processes. Finally, there is a place for the simultaneous use of functional and territorial borders. Purely functional borders such as those witnessed in the GA4GH lack enforcement capabilities, since the organization is not bounded in any physical territory. Therefore, functional borders may find greater enforcement capabilities if they are grounded in some aspect of territoriality as witnessed in GDPR or China. Nevertheless, there are drawbacks to a strong territorial approach in that it may create barriers to sharing and provide little legitimate protection.

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Appendix 1

INTERVIEW QUESTIONS

More specific interview questions will be developed for each individual project. Themes explored in the interviews will vary by the thematic focus of each study. Below are some sample questions for the thematic areas that we anticipate we will be exploring through interview research.

1) Governance: Policy actors will be asked to discuss issues along the following themes:

    a. Governance mechanisms: Are border governance mechanisms and changes to governance mechanisms being driven by local needs and community demands or are they primarily driven from above? By national actors? Provincial actors? Supra-national actors?

    b. International agreements: How have new/old international agreements shaped the governance of cross-border sharing of data? Do they have more or less impact on private or state actors?

Example: To what degree do frameworks such as the UN Declarations and Bermuda Principles continue to influence the cross-border flow of genetic data within between organizations and states?

    c. How has judicial interpretation of privacy legislation impacted the regulation of cross-border data sharing (i.e. outcomes of GDPR)?

    d. What are the challenges in implementing regulatory genomic data sharing frameworks consistently across regions?

    e. Is there any concern within public bodies that new regulations may deter international research collaboration?

    f. Is it possible to adequately meet the public's expectations to privacy in one framework?

    g. Is a consent model critical to ensuring privacy in the regulation of genomic data, or may this be achieved in an authority-based model? How may this successfully be operationalized?

    h. Is there generally a strong reliance on nation states to enforce frameworks (considering state sovereignty)? What other non-legal mechanisms may bodies leverage to achieve compliance?

    i. What is the greatest barrier to sharing data across borders, e.g the absence or presence of legislation/regulation?

2) Flows: Policy actors, employers, and private organizations will be invited to discuss issues along the following themes:

a. Are there overlapping jurisdictional regulatory regimes that shape, impede, or enhance, movement across borders?

b. What is the greatest operational challenge when engaging in cross-border data sharing within the context of public private partnerships?

c. Does public trust differ when personal information is shared with a private organization versus a public organization? Does this change when personal information crosses borders?

d. How may principles of privacy, security and consent be transferred across borders from one cultural context to the next?

e. How have local stakeholders been engaged to develop privacy, security and consent models?

f. How is data ownership being addressed, and is this changing the way it is collected, used and disclosed currently or in other fields?

3) Security: Policy actors, and security experts, will be invited to discuss issues along the following themes:

a. How are issues around flows (ensuring quick and efficient movement across borders) balanced with security concerns?

b. How have new technologies and potential new technologies enhanced the security of genomic data in transit and rest?

c. What is the current approach to establishing consistent security practices such as anonymization despite global/regional differences in technological capabilities?

d. How does genetic exceptionalism impact privacy, security and information-sharing on a local and global scale?