Genetic Renaissance:

A Legal, Philosophical, and Ethical Examination of Consent Using Autonomy & Privacy in Genetic Testing

by

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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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Abstract

Genetic testing has gained traction in the media with the recent Pentagon ban and continuing increases in public consumption of at-home tests. Public discourse surrounding this technology prompts further exploration of the multifaceted parameters that govern its use. This thesis takes on the task of analyzing and dissecting these comprehensive features, with a specific focus on the legal, philosophical, and ethical aspects of the matrix of genetic testing. It aims to understand the application of these layers to the different contexts of genetic testing: the clinical and research contexts, as well as the direct-to-consumer context. By examining the process of genetic testing, from obtaining informed consent and collecting samples to the interpretation and communication of results, this project aims to understand all the dimensions involved. The most prevalent dimensions are autonomy, privacy, and ownership, and it is this trifecta which is most impactful on informed consent.

The examination will begin by providing an overview of the technical science behind genetic testing, to better understand the uses of this biotechnology in each of the contexts (i.e. clinical, research, and direct-to-consumer). Understanding this will allow for a smooth transition into an extensive outline of the legal, philosophical and ethical concepts that are tied to informed consent. This thesis focuses on laws and policies that are applicable in the United States of America and Canada, although there are many international regulations that vary in severity and depth. These legal frameworks essentially delineate how persons should be treated across contexts, including specific regulations surrounding how informed consent must be obtained, how samples must be stored or retained, and how personal data (e.g. genetic testing results) can be used and protected.

Following from this legal backdrop, a literary and historical evaluation of informed consent is outlined to establish just how foundational it is to bioethics. And essential to this are the philosophical principles of autonomy, privacy, and ownership. Although most of the thesis will focus on established frameworks, it will raise questions about the fundamental issues that plague these concepts, including the lack of consideration of collectives in consent and ownership, and the inconsistent protocols involved in direct-to-consumer testing that allow for major trespasses on personal rights by corporations that are not required to operate as healthcare institutions. In exposing these weaknesses, this thesis does not necessarily seek to provide concrete solutions for such large problems, but rather to suggest possible criteria for solutions going forward. The main point this thesis seeks to show is that despite the huge strides in biotechnology, there is still substantial space for improvement in

bioethics, with specific focus on the development of policies and legislations that can capture the nature of consent across social and testing contexts. This kind of work towards ameliorating the essential legal, philosophical, and ethical aspects is essential for ensuring the protection and empowerment of individual and collective rights, especially in emerging fields such as genetic testing, where the current frameworks are inadequately suited for comprehensive coverage.

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Okay, last off, my Spotify library, because I couldn't have done it without you.

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Chapter 1:

The Pentagon Problem: An Introduction into Genetic Testing

In 2019, the Pentagon issued an organization-wide statement warning Department of Defence employees and military personnel against using direct-to-consumer genetic testing kits ("Direct-to-Consumer Tests," 2019; Murphy & Zaveri, 2019). These include the at-home and mail-in deoxyribonucleic acid (DNA) tests offered on online sources such as Ancestry.com and 23andme ("Ancestry.com," 2023; "23andMe.com," 2023). This came as a result of increased security concerns, where the Pentagon specifically cited "privacy and surveillance" as the main apprehensions against endorsing the alleged safe access of these widely available commercial tests (Elliot, 2019). Commercial DNA tests can also be referred to as recreational or non-medical tests. Despite their promoted uses, the government branch noted that any usage has the possibility of causing "unintended security consequences and increased risk" for breaches (Elliot, 2019). Further reasons for this recommendation include the unreliability of the results of these tests, and the potential to negatively impact service members' career trajectories in some ways (e.g. as a result of any breaches, lineage or health concerns, etc.) (Murphy & Zaveri, 2019).

The warning from the Pentagon comes in the wake of the skyrocketing popularity of these direct-to-consumer genetic tests among the general public. However, despite being written for internal purposes, the Pentagon's message spread outside of the military branch caused various responses. Upon wider release of the internal memoranda circulated within the Department of Defence, the genetic testing companies released their own statements rejecting some of the listed concerns, in order to assuage customers in light of fears that may impact sales (Murphy & Zaveri, 2019). This prompted a clarification that the Pentagon "does not advise against genetic testing altogether" but rather, recommends that military personnel (specifically) seek out licensed professional for any genetic or health testing (Murphy & Zaveri, 2019; U.S. National Library of

Medicine, n.d.). The main concerns of the government branch appear to lie specifically with the commercial genetic tests that are marketed directly to consumers, which continue to target the general public.

While the Pentagon and other government bodies, such as the government of France, continue to advise against or completely ban personnel from using direct-to-consumer testing, approximately 30 million people worldwide have taken a recreational DNA test (Advisory Board, n.d.; Furlong, 2020). Even in light of this "surging public interest in ancestry and health", the Pentagon maintains its position of strongly advising military personnel to only use legal and approved means of testing for health and genetics (Regalado, 2019). This is not the first time that the Pentagon has issued advisories against publicly endorsed trends and popular culture, sometimes even going to the point of completely banning them. Most recently includes the recent ban of drag shows on US military bases in response to the criticism faced by/of the LGBTQ+ community, or the ban of the popular video sharing app, Tik Tok for all military personnel for privacy and security reasons (Holpuch, 2023; Wolff, 2020).

Despite the Pentagon's strict aversion to these readily available consumer tests, they continue to be heavily marketed to the wider, non-governmental population. In order to affirm their popularity in the zeitgeist, pop culture icons such as Olympic athletes have been used in client-facing press materials, including the homepages of the genetic testing companies' websites (Sokolove, 2018). Marketing strategies for consumers generally promote the tests as means to "discover you" by thoroughly uncovering all health and ancestry information at the most detailed level, however they neglect to mention any of the potential harms to the individual, their autonomy, or the harms to those around them (Sokolove, 2018).

This kind of outcry against genetic testing has been seen before in instances like the case of Henrietta Lacks. Instead of institutional hesitation to adopt genetic testing, this response is a public one in light of the protocols and protections in place for individuals seeking this kind of procedure. Although HeLa cells are foundational to many lifesaving treatments and biotechnological advancements, the sentiment following the revelation that Lacks was not aware that her cells would be taken or used for any research nor was she or her descendants compensated for the great discoveries made using the genetic sample. It raises specific questions regarding individual *and* collective rights in bioethics, specifically ownership and consent rights. Chapter 6 will further discuss this case and consider its various implications.

To truly understand the broader sentiments surrounding these tests, it is imperative to briefly outline what they are and how they work. The process of using direct-to-consumer genetic testing allows interested parties to bypass the standard obstacles presented in traditional healthcare settings such as time constraints and affiliated costs. Instead, direct-to-consumer tests are requested and essentially performed by the consumers themselves, when they are interested in finding out more beyond the standard inquiries into genetic history – including ancestry and health, as well as "personality, athletic ability, and child talent" (Oh, 2019, 1; Horton *et al.*, 2019, 1; Savard *et al.*, 2020, 63-64). After obtaining a self-collected sample, usually either "saliva or mouth cells", consumers provide the overseeing company with the genetic material that can then be isolated and tested (Oh, 2019, 1; Ogale *et al.*, 2019, 2). These "client-centric" models of genetic testing usually analyze the samples for a comprehensive "profile report of various phenotypes" and genotypes based on the genetic composition, varying based on the requests of the consumer and the operational nature of the company (Oh, 2019, 1).

There are several different contexts wherein a genetic test would be required. The recreational context encompasses the most popular source of debate and even controversy (Koch, 2018). They are also the tests that the Pentagon appears to be the most concerned with, as they are generally the only tests available in a direct-to-consumer format. Other contexts include the clinical and research contexts, where the goals of the former include conducting "genetic screening" and "genetic diagnostic tests" for patients, and the latter include furthering scientific findings regarding "unknown genes" with the data collected from participants (USNLM, n.d.). Another context that incorporates the collecting of genetic material is DNA profiling for forensic investigations (Bukyya *et al.*, 2021). This final context does not always include considerations of consent and individual autonomy.

It is important to note that, despite the inherently scientific component of the companies offering such services, they remain commercial enterprises that seek to make a profit and maintain a robust clientele.[1] Much of these products entered the public consciousness through mass marketing campaigns that aimed to portray it as the future of cutting-edge science, especially in the midst of an increased public health interest in genomic research (Horton *et al.*, 2019, 1; Genome British Columbia, 2023). The general strategy of advertising that endorsed these readily available tests was to pitch them as a means for patients to take the reins in actively "managing their own health", affording them a sense of empowerment and agency in a process that once seemed so complicated and inaccessible to the average person (Horton *et al.*, 2019, 2). With the presentations of "personalised medicine", the reception of such products manages to maintain a glamorized portrayal of a "highly

[1] It is worth noting that, within the current healthcare structure of the United States of America, there is an attitude of consumerism that renders the patient a consumer. This is especially the case considering the construct of health plans and the commercialized nature of medication in an advertising-forward world (Gross & Laugesen, 2018; Weil, 2019, 343).

accurate" recipe of each person's composition in a bottle (Horton *et al.*, 2019, 1). Generally, laws make it difficult for companies to engage in purposefully "deceptive", "false or misleading advertising claims", as they are regulated by several governing bodies on different levels (Hudson *et al.*, 2007, 636). They also impose standard requirements for all laboratories, including those under corporate umbrellas, to ensure that tests are conducted properly and interpreted correctly (Hudson *et al.*, 2007, 635-636; Orth, 2021, 210-211). This might make it difficult to see the perils/pitfalls of genetic testing, even in light of the Pentagon's warnings.

The claim that these tests have the capacity to bolster individual autonomy seems to be central to the overall mission of direct-to-consumer tests. By putting the onus of decision-making in the hands of consumers, they are provided with the resources to make an informed decision about their health (Samuel *et al.*, 2017, 1). Though this may seem like a great way to empower patients in taking the helm of their own treatment, the nature of these (generally) for-profit companies makes it so that a completely transparent process that aligns with the guidelines of medical testing is not entirely possible (Laestadius, 2016; Koch, 2018). Since their conception, these tests have been shrouded with concerns regarding the "analytic and clinical validity, clinical utility…emotional harms…and inappropriate health-care decisions" (Laestadius *et al.*, 2016, 513; Laestadius, 2016). This sentiment might make it so that any empowerment experienced by the consumer is diluted in favor of maintaining obscure corporate interests (Roberts, 2022).

At the crux of these concerns are questions of autonomy and consent, underlying the implications of "privacy, confidentiality, and secondary use policies" regarding collected data samples (Laestadius, 2016). Even amidst the abundance of rich research that continues to flourish in this burgeoning area of bioethics, there remains some uncertainty with regards to the broader impacts

of autonomy and consent on legislation and policy relating to data genetic testing, as well as scientific developments resulting from the collected data.

One of the pillars of bioethics is informed consent, or the practice of ensuring that patients have "comprehensive information, enabling them to make independent choices" (Scott *et al.*, 2003, 44). This process includes the disclosure of "verbal and written information" that fully debriefs the patient on the entire scope of the test, including the purpose and process, "institutional affiliations", as well as what will become of the collected data once the trial or research is completed (Sand *et al.*, 2010, 4). Informed consent implies and requires autonomy which, simply, is the individual right to "self-rule or self-government" (Scott *et al.*, 2003, 43). This autonomy is bolstered in medical and research settings when patients are given a comprehensive demonstration of what their options and treatments are. Since commercial genetic tests are distinct from those tests that are conducted within the research, clinical and forensic tests, they are necessarily governed by different implications for philosophical principles such as consent and autonomy, and different laws and policy regulations.

This thesis will aim to unravel the intricacies of genetic testing, with a specific focus on the contrasts between the direct-to-consumer context and the research and clinical contexts. From the start of the process with obtaining informed consent to the handling and interpretation of data samples, it will seek to outline just what people are giving up and gaining across each context. Due to their central importance to all considerations of direct-to-consumer testing, this project will use informed consent and autonomy as a lens through which to examine the other, darker side DNA sample testing. It will these two concepts in its exploration of the process of collecting, storing and retaining genetic data. Chapter 2 will provide a cursory understanding of the science underlying genetic testing in general, and the ways in which the samples are used in each specific context. In Chapter 3, an extended overview of the laws and regulations governing genetic testing in Canada and

the United States is provided to outline how individuals and their data can be used and protected. Following from this, Chapter 4 will cover the history and literature on informed consent before Chapter 5 explores the philosophical principles that underlie genetic testing, such as autonomy, privacy and ownership for both individuals and the relevant collectives. Despite focusing on the established frameworks surrounding genetic testing, Chapter 6 will aim to uncover the potential downsides of these current paradigms, and the weaknesses of the legal and ethical regulations which govern it.

This thesis is mainly explorative in nature, so rather than proposing any firm solutions to the large bioethical problems at hand, it will aim to discuss and evaluate the issues while *suggesting* potential solutions. In examining the legal, philosophical, and ethical web that underlies consent in genetic testing, it will highlight the pivotal role that autonomy, privacy, and ownership play in ensuring that decision-making is informed and voluntary. While it acknowledges that bioethics and the regulations governing such technologies have come a long way, this thesis will demonstrate that there is still much room for amelioration and collaboration to ensure that policy and legislation can adequately grasp the nature of consent. This is essential for the protection and empowerment of rights, and for developing laws that are consistent across contexts. As it stands, the framework of informed consent is an inadequate measure of protection for individuals and for their communities, regardless of context, but especially in the novel direct-to-consumer genetic testing arena.

Chapter 2:
Sequencing Science

With the continuous scientific advances in molecular biology and medical technology, genetic testing becomes more widespread and established as a tool for understanding human health, detecting disease and abnormality, and personalizing medical interventions. To properly appreciate the depths of its benefits, however, it is important to provide a clear understanding of what genetic testing really is, and *why* it is used to the extent that it has been. The aim of this chapter of the project is to elucidate the delicate science of genetic testing that binds the rationale behind its integration into the commercial, clinical, research and forensic contexts.

Kate E. Lynch (2023) begins to answer the daunting question of "what" exactly genetic testing is by establishing that our understanding of genetic testing varies depending on our understanding of the term "genetic" (Adolphs *et al.*, 2003, 59; Lynch, 2023; Sequeiros *et al.*, 2012, 114). Per their analysis, there are differing grasps of genetics concepts which would change the definition, such as those about the source of the genetic sample obtained. In one technological leaning definition, genetic testing would be any kind of procedure that relies on analyzing the genetic sample, whether it be from somatic cells or the germline (de Paor & Lowndes, 2015, 18).[2] Another definition would consider tests of the same nature that aim to detect "potentially heritable genetic changes" that *might* occur in a fetus, or that may develop in the future (Harper, 1997, 749; Genetic Alliance, 2008, 73). A third, more rigorous definition of genetic would confine it to the material obtained from the germline *only*, thus including tests that do not account for hypothetical changes or mutations that may

[2] Germline cells are specialized mammalian cells that are involved in reproduction, and are responsible for passing genetic information from parents to the offspring, including any mutations. Somatic cells are all other cells that are not involved in reproduction, so they compose all organs, tissues, etc. Any mutations to somatic cells occur after conception and are not hereditary.

occur post-conception. It is not necessary to parse the meaning of genetic testing in this way, as the required procedures may inextricably require genetic material that would apply in all of the aforementioned contexts, since the core of genetic testing is to detect variations in the DNA.

Genetic testing procedures are designed to do more than just seek out "specific inherited changes" in individuals (National Cancer Institute, 2019). The information gained from genetic testing can be used to "confirm or rule out a diagnosis" in symptomatic individuals, to understand family history for ancestry or genetic conditions, or to "locate possible genetic conditions in newborn babies" for treatment cases (Genetic Alliance, 2008, 73; Burke, 2002, 1867, 1872). This align with Harper's definitions of genetic testing, wherein these procedures can cover vastly different genetic variants to uncover the underlying profile of an individual (Cleveland Clinic, 2022). In order to do so, individuals provide their "blood, skin, hair, or other body tissues" as well as "amniotic fluid" for analysis by certain specialized laboratories, per the nature of the test and the suggestions of the genetic counsellor (where prevalent) (Genetic Alliance, 2008, 73; Cleveland Clinic, 2022). These laboratories tend to focus on either cytogenetic, biochemical or molecular methodologies, depending on the aim of the tests (Genetic Alliance, 2008, 73, 78).

Just as there are a variety of contexts wherein genetic testing is needed and different laboratories that can be tasked with analysis, there are various kinds of tests. Some of the most common types of genetic testing include: diagnostic and screening tests, "newborn screening", "carrier testing", "prenatal diagnostic testing", "predictive or predispositional genetic testing", and "forensic testing" (Genetic Alliance, 2008, 74; Burke, 2002, 1868). Diagnostic tests are often the most reliable way to confirm symptoms corresponding to genetic diseases in individuals (Burke, 2002, 1867). A diagnosis can also be indicative of a familial affliction, where other members of the same family can be genetically impacted by the same mutation. Screening tests are done with the

purpose of identifying individuals or populations that may be at risk for certain specific genetic disorders, even if they may be asymptomatic (NHGRI, 2023). These individuals or groups may be especially susceptible to risk due to familial history, ethnic groups or other factors (Saini *et al.*, 2011, 111). Although genetic testing can be used to improve predictive diagnosing and preventative treatment, a diagnostic test does not guarantee treatment options (Burke, 2002, 1868, 1872). Screening aims to identify these potential genetic disorders in individuals to implement treatment plans and interventions where possible, and minimize further genetic mutation in future generations. This points to genetic testing being more than just an individual issue – all of the relevant sociopolitical, legal and ethical issues that impact those seeking such tests can extend to those who are tied to them in the most minute way.

The most common kind of genetic testing involves prenatal assessments to help parents and those looking to have children decide what course of action best suits them given a comprehensive genetic profile. Tests such as newborn screening, which occur postnatally, carrier testing, where parents are tested to see if they carry alleles for receive traits that might be passed on to their offspring, and prenatal diagnostic tests have become standard procedure for new parents (Genetic Alliance, 2008, 73-74).[3] However, these are not the only uses for genetic testing. Tests are also used in clinical and research settings, as well as for the purposes of furthering forensic investigations. For individuals interested in learning more about their genetic history outside of these contexts, direct-to-consumer genetic tests have also become widely available and popular.

In clinical settings, genetic tests are completed with the purpose of diagnosing diseases in symptomatic individuals with predisposition to risk. Tests are selected for their ability to meet the

[3] An allele is a variation of any one of two or more genetic sequences at a given location on a chromosome. There are dominant and recessive alleles, which determine the phenotype of the organism.

aims of the clinical pursuit, while meeting the standards of validity and utility that require tests to be able to "accurately and reliably" predict clinical diseases, and have some positive impact on "patient management decisions" (Franceschini *et al.*, 2018, 3; Hayeems *et al.*, 2020, 97). Clinical testing usually encompasses the aforementioned prenatal testing scenarios, as well as the direction of intervention and treatment, with the support and guidance of genetic counsellors and physicians who are bound to certain regulations and laws of practice (NIGMS, 2022). These healthcare providers are tasked with assessing patients based on their medical history, potential symptoms and risks, as well as providing them with comprehensive information about the process and potential risks and outcomes to obtain their fully informed consent. Then, a DNA sample can be collected, usually "saliva, cells from a cheek swab or a blood sample" (Martins *et al.*, 2022, 1331). The tests can be targeted genome sequences that analyze a single gene, or they can be panel tests that asses for "changes in many genes in one test" or "large-scale genetic or genomic testing" that analyze all aspects of the DNA (CDC, 2022). Once results of the analysis are obtained, geneticists and genetic counsellors are tasked with providing correct and concise interpretations of the results to ensure that patients can be guided in the course of their treatment and interventions (Martins *et al.*, 2022, 1334).

Research settings, on the other hand, are tasked with breaking ground on new discoveries of mutations and genes through means such a gene sequencing, which allows for the detection of "nearly all DNA variation in a genome" (Costain *et al.*, 2021, 1626; Armitage, 2022). Where there are "more than 1,100 genetic tests available clinically", research settings provide "several hundred more" tests (Hudson *et al.*, 2007, 635). This setting also allows researchers to study the distribution of genetic variation across populations, rather than just one individual at a time, to understand such phenomena as "the correlation between genotype and phenotype" and promote the development of treatments and drugs (Gal *et al.*, 2006, 2). While research is bound by regulations and laws of its own, they are not

entirely the same as those that are relevant to clinical genetic testing, especially as individuals change from patients to participants across the contexts. The laws governing the research setting apply to every step of the process, from participant recruitment, debriefing and obtaining informed consent. Participants are recruited based on several traits pertaining to the study at hand, including their membership to specific groups (e.g. ethnic), their family history, or any symptoms they may exhibit. Similarly to clinical contexts, DNA samples are collected from participants and analyzed in a laboratory setting. Aside from analyzing the genomic sequencing, research contexts can also complete statistical analyses to ensure the validity and significance of the obtained results (Lobo, 2008; Clarke *et al.*, 2011, 126). Depending on the nature of the study, results can be kept confidential to the researchers and the participant, or they can be shared anonymously for wider third-party use in further research.

The advancements in genetic testing have also "revolutionized the science of crime detection" and allowed for the resolution of many open cases due to its "probative value" as a result of the "criminalities and medico-legal identification" aspects (Bukyya *et al.*, 2021, 135; Panneerchelvam & Norazmi, 2003, 20). Aside from its uses for the purposes of identification, crime scene analysis, resolving cold cases (e.g. missing persons, kidnappings, etc.), it can also aid in resolving issues of paternity (Centre for Genetics Education, 2021). While improving on criminal proceedings, it can also aid in the pursuit of a true justice for a system that intends to overturn wrongful convictions and minimize future erroneous convictions (LaPorte, 2017; Gould *et al.*, 2012). To ensure that genetic information is being handled properly during investigations, there is a strict chain of custody that must accompany evidence without which the "legitimacy" and "integrity" of the sample can be called into question (Badiye *et al.*, 2023, 2). Although this implies, rightfully so, that forensic genetic testing can contribute to "miscarriages of justice" that lead to wrong verdicts, it is

worth noting that these issues exist within the criminal justice system which is fraught with persistent systemic issues and requires deep reform for proper justice to be carried out (Elster, 2017; Mandhane, 2017; Bezzina *et al.*, 2021). As such, the regulations binding forensic genetic research intersect with criminal legal legislations, such as governmental statutes and codes. Furthermore, the ethical considerations in this context differ greatly due to the weight of criminal proceedings, and the prioritization of the legal process over individual concerns such as autonomy and consent (De Groot *et al.*, 2021).

Unlike previous contexts, forensics do not always obtain targeted DNA information from relevant parties. Crime scenes often contain "traces of biological material from an unknown person" that is implicated in the crime, and these materials are collected and analyzed for "information about physical traits" that can be used to find suspects (Morling, 2004, 11). With the aid of a warrant, a sample can be obtained from a suspect under requirement of law, thus obligating them to comply (RCMP, 2004). Obtained DNA samples are analyzed using short-tandem repeats, the "industry standard for forensic DNA typing" of analyzing "repetitive DNA sequences in microsatellite regions" (Keerti & Ninave, 2022, 1; Morling, 2004, 10). Analyzed samples are compared against existing databases (e.g. Combined DNA Index System; National DNA Data Bank (NDDB)) in order to obtain the statistical probability of a match that would determine the outcome of the case (RCMP, 2021; FBI, 2016; Morling, 2004, 10). While forensic testing offers many avenues for analysis, it will not be a focal point for this thesis as the issues relevant to the other contexts of genetic testing vary.

Even more interesting is the commodification of genetic testing, which has become easily accessible for individuals who emphasize the "value of information" that is found in their genetic code (Grosse & Khoury, 2006, 449). The direct-to-consumer tests are purchasable from companies via the internet and allow individual consumers to complete the test on their own by collecting the

sample and sending it back to the company for analysis (Office of the Privacy Commissioner of Canada, 2017; USNLM, 2022). These tests are different from other kinds of genetic testing in that they do not necessarily require the involvement of a healthcare provider or even an insurance company to oversee and authorize the proceedings, or provide counselling (USNLM, 2022). As such, the onus of responsibility lies entirely on the consumer and how they are able to understand the instructions and interpret the results. This appears to be very appealing for consumers, who tend to appreciate the sense of autonomy that these tests give them over their own health in administration and over their raw data (Oh, 2019, 1-2; USNLM, 2022).

With these "recreational" tests, consumers are able to test for diseases, but they are more commonly used for ancestral information or "biometric/life-related concerns" to understand "phenotypes or genetic predisposition" for prevention rather than diagnosis (Oh, 2019, 1; Martins *et al.*, 2022, 1333). Despite their mass popularity, laws and regulations concerning direct-to-consumer testing are not as advanced as those governing clinical and research tests (De Groot *et al.*, 2021, 788). The tests themselves are often considered to be inaccurate and unreliable, if not difficult to interpret without the aid of a professional healthcare provider (Martins *et al.*, 2022, 1343). In addition to this, the ethical concerns are much more precarious due to the delicate nature of the informed consent in direct-to-consumer genetic testing, as well as issues with privacy and data sharing that do not measure up to other kinds of testing. These issues will be thoroughly discussed and evaluated in Chapter 6.

Despite the mention of all of the contexts wherein genetic testing is relevant, this project will continue to focus on the research, clinical and recreational/commercial settings.

Chapter 3:
Genetic Code of Conduct

Aside from the technical science behind emerging technologies of genetic testing, the ethical, legal, and regulatory dimensions surrounding its use are one of the most important aspects to consider. The purpose of this chapter of the project is to delve deeper into the intricate laws and policies that govern genetic testing across the world, focusing on North American/those placed in Canada and the United States of America. By doing so, the methodology of how governments have acknowledged the importance of this relatively novel technology, all the while implementing safeguards for fundamental individual rights, will be assessed. The focus will be on those individual rights such as privacy and autonomy and how they are protected in the face of rapid advancements. This chapter will continue the overall trajectory of this project by considering the complex questions that are raised at the intersection of science, technology, ethics, and societal norms.

By focusing on both federal laws that apply nationally and provincial or state laws that are specific to certain jurisdictions, a comprehensive foundation of the legal frameworks that guide the use, broadcasting, and protection of genetic data collected across different contexts will be provided. The comparison of the American and Canadian jurisprudence and policy will be an enlightening exercise in drawing out the similarities and differences of relatively contrasting legal systems. To emphasize these characteristics, several international examples will be used to emphasize the different approaches that governments are taking towards ushering in the "genomic era" (Guttmacher & Collins, 2003, 996). These considerations are especially critical in light of the expansive potential that genetic data can unlock, versus the preservation of fundamental human rights that might be infringed to reach these new heights.

Moreover, by analyzing similar legislative bodies such as the *Genetic Information Nondiscrimination Act* (GINA) in the United States of America and Canada's *Genetic Non-Discrimination Act*, the approaches to ensuring the duties and responsibilities of healthcare providers and researchers, laboratories analyzing samples, and companies providing access to genetic tests are outlined. These duties are just as important as the rights proffered towards patients, participants and their families as they work towards continuing to ensure these rights. Furthermore, they continue to outline the multifaceted approach to understanding genetic technology and implementing measures for positive scientific advancement and social protection.

3.1 An Ethical Overview

Although the ethics and philosophy concerning genetic testing will be examined in further detail later on in this project, it is beneficial to outline briefly the relevant concepts prior to engaging with the relevant legislative statutes and policies. Following the events of World War II, it became clearer than ever that certain rights must be aggressively protected to ensure that all humans have access to them, regardless of geography or political affiliation (Gumbis *et al.*, 2008, 77). Although the ratification of the Universal Declaration of Human Rights, which formed the "foundation of international human rights", did lead to significant positive changes for many around the globe, it did not entirely eradicate crimes against humanity (Gumbis *et al.*, 2008, 77; 3). In one form or another, several rights can often to be trespassed or nearly overstepped by the very same bodies that are meant to protect them.

3.1.1 Autonomy

One of the most fundamental, contemporary human rights that is also susceptible to violation is that of personal autonomy. Autonomy is a state of *self*-governance and *self*-determination that is of even greater concern in the face of expanding technologies such as genetic testing. Simply put, to be

autonomous is to be recognized as a rational moral agent with free and independent thoughts, feelings, choices and actions. This freedom relies on one not being unduly influenced by outside sources in any way, so that their decisions and actions are fully self-guided and authentic, or agential choices that they can take responsibility for and ownership of even after time has passed. Autonomy accounts for one's capacity to deliberate and make judgements based on the contextual, sensory, and historical information they have, before making any kind of decision to act. As such, autonomy involves an affective, cognitive and physical capacities, although no one aspect is entirely removed from the others in ensuring autonomy and free will.

As an intrinsic value, autonomy should be heralded as valuable in its own right, even though it can lead to happiness and developed well-being. However, one's freedom to lead a prosperous private life without external influence does not negate the fact that certain external factors can have an important impact on living a life that is truly autonomous (Stoljar, 2017, 27). This is because autonomy is relational in nature, impacted by a "range of social conditions" that can bolster or impair autonomy across contexts (Stoljar, 2020, 347). Even so, to be truly autonomous is to be "governed in one's actions...by values, principles or reflections" that are authentically one's own (Christman, 2013, 691). This extends further to the legal definition of autonomy, which means "self-rule" and is essential to the concept of consent (Saunders, 2011, 94; Suksi, 1998, 97). The legal definition corresponds, in certain senses, to the philosophical overview proffered by the likes of Natalies Stoljar and John Christman. It will also be instrumental to the legislations and policies considered throughout this chapter.

3.1.2 Privacy

Stemming from autonomy is privacy, a fundamental value and ethical consideration associated with personal boundaries and the limitations of societal and governmental intrusion on the

"self-regarding, personal, or intimate" (Allen, 2019, 31). Put simply, privacy is the universally valued "right to be let alone" or free from external "interference or intrusion" of any kind (IAPP, n.d.; Panther Protocol, 2022). In a narrower sense, privacy can be defined in terms of *informational* privacy or the *legal* conception of privacy rights. Based on the former sense, privacy rights are defined by W. A. Parent (1983) as "the condition of not having undocumented personal knowledge about one possessed by others" (Panther Protocol, 2022; Parent, 1983, 269). In this sense, privacy is seen as "control" per Alan Westin, specifically a control over information about oneself, who can be given selective access to it, and the right to protect it against undue invasion (Westin, 1967, 485). As well, in an advancingly technological society, privacy is of greater concern as surveillance and governmental interference threaten to not only extrapolate information by any means necessary (i.e. regardless of consent) but potentially use it to exploit and/or manipulate citizens. This allows for privacy to also be interpreted as a "withdrawal of a person from the general society" to a degree that allows them to balance their desire for anonymity and autonomy with their desire to participate in society (Westin, 1967, 27).

In the latter, legal sense, privacy refers to the extended rights that protect the freedom to exercise a private life. This encompasses freedom from undue surveillance and interference, as well as the freedom to limit access to information (Mokrosinska, 2018, 124; Schafer, 2011, 6-8). It also refers to the "independence in making certain kinds of important decisions" that pertain to one's life, thus upholding its inextricable connection to autonomy and dignity (Parent, 1983, 315). There is some intersection between the legal definition and the philosophical definition of privacy where Judge Thomas Cooley referred to it as the "right to be let alone", but the legal right to privacy extends heavily to other aspects of private life (Moore, 2008, 412). A definition that offers a compromise between the philosophical and legal is proffered by Judith Wagner DeCew, who cites that privacy

pertains to “whatever types of information and activities are not, according to a reasonable person in normal circumstances, the legitimate concern of others” (Moore, 2008, 412). By this, DeCew incites the legal standard of the reasonable person as a measure of what ought to be restricted from public concern, including both personal information and how one chooses to live their life (i.e. surveillance). Like autonomy, this project will further explore the legal and philosophical implications of privacy to better understand their application with regards to genetic testing in Chapter 5.

3.1.3 The (Brief) Meeting Point

Where both autonomy and privacy have roots in philosophical and legal tradition, they are also intrinsically tied to one another in that privacy has a strong role in upholding individual autonomy. By ensuring an individual’s control over their personal information and to whom they disclose it to, individuals can be empowered to make independent choices in their best interest without external coercion and in accordance with the constitutionally protected rights. As these two concepts continue to be the foundations of individual rights, they are notably present in regulations governing modern technologies such as genetic testing. The various legislative pieces and policies created by governments around the world aim to address a host of ethical and legal inquiries with respects to autonomy and privacy. By outlining and analyzing the key legislative documents involving genetic testing, a clearer understanding of importance of balancing scientific progress, while safeguarding individual rights of privacy and autonomy (and consent, which plays an important role in this context).

3.2 Canadian Federal and Provincial Laws

3.2.1 Canadian Human Rights Act

Passed in 1977, the *Canadian Human Rights Act* is legislation created with the express purpose of ensuring that everyone has access to equal opportunity (*Canadian Human Rights Act*,

1985). This means that individuals are empowered to live life as they wish and receive accommodations as they require for an equitable good life. Most importantly, the Act protects people from discrimination on the basis of "race, national or ethnic origin, colour, religion, age, sex, sexual orientation, gender identity or expression, marital status, family status, genetic characteristics, disability or conviction for which a pardon has been granted" (*Canadian Human Rights Act*, 1985).

The provisions of the Act apply to various federal institutions such as banks and telecommunications companies, First Nations governments, as well as individuals operating within federal jurisdiction including employees (*Canadian Human Rights Act*, 1985). This also means that discrimination and harassment are prohibited in areas like employment, provision of commercial goods, and tenancy to continue ensuring that individuals have access to equal opportunity in all aspects of life (*Canadian Human Rights Act*, 1985).

Two human rights bodies emerged from the Act: the Canadian Human Rights Commission, and the Canadian Human Rights Tribunal. The Commission is independent from the government and tasked with receiving and investigating any complaints that emerge regarding discrimination or harassment in any of the aforementioned protected areas (CHRC, 2023). If any of the complaints are not settled by the Commission, they are referred to the Tribunal, a body that is akin to a court of law but operates less formally, for adjudication (CHRT, 2023).

Since 2017, the Act has been ensuring that individuals are protected from genetic discrimination at all levels, including employment under federal jurisdiction (CHRC, 2020). This means that individuals cannot be discriminated against on the basis of their genetic characteristics or information, or the results of any genetic testing; they are also protected from being forced to complete a genetic test. Furthermore, if a person's genetic makeup requires that they receive some

kind of accommodation, the Act ensures that they are able to receive all the accommodations and protections they need without exploiting or exposing them to undue harm and discrimination.

3.2.2 Genetic Non-Discrimination Act (2017)

In 2015, Bill S-201 was introduced to the Canadian Parliament aimed at ensuring specific protections from discrimination. It went on to become the *Genetic Non-Discrimination Act* (GNDA), a legislative piece that worked to address the concerns regarding potential misuses of genetic information and protection from genetic discrimination (*Genetic Non-Discrimination Act*, 2017; Walker, 2016). In the same vein as the *Canadian Human Rights Act*, the GNDA also protects individuals from discrimination in employment through amendments made the Canada Labour Code (CLC), or from being discriminated in other federal sectors (Walker, 2016). As genetic testing becomes more mainstream, the GNDA was instituted to protect individuals from any potential negative consequences that might arise after they receive the results of their genetic tests that may compromise their employment or ability to obtain adequate insurance (Walker, 2016; *Genetic Non-Discrimination Act*, 2017). For example, an individual seeking employment could have also undergone genetic testing for any reason. If, throughout the hiring process, the results of their testing reveal that they may have a genetic predisposition to a certain condition, the employer may choose to forgo further considering them due to concerns about healthcare and replacement costs or absences leadings to inefficiency (de Paor, 2015, 162). This is an example of an instance that would trigger GNDA protections for the implicated individuals.

Aside from protecting individuals from discrimination and ensuring their privacy, the GNDA also promotes genetic research and testing. By emphasizing these rights, the Act can promote participation in research and testing, thus promoting scientific advancements (Bombard & Heim-Myers, 2018, 579). Not only is this participation necessary for the advancement of research and

scientific discovery, it is critical for developing accurate personalized healthcare in the medical sector (Bombard & Heim-Myers, 2018, 579; Cowan *et al.*, 2022, 645). Without the efforts of such bills, public confidence would not be bolstered with regards to the protection of their civic rights in an ever-evolving technological landscape, but also towards the potential fallouts of scientific advancements (e.g. misuses of their private, genetic information). By passing legislations such as the GNDA, governments affirm their positions towards their citizens, but also as pioneers in the field.

Although the bill did face certain missteps before federal acceptance, and it was struck down by the Quebec Superior Court in 2018 for potential issues regarding its constitutionality, it remains an important step towards safeguarding individual rights in a technological world.

3.2.3 Canadian Institute of Health Research Act (2000)

Established in 2000, the *Canadian Institutes of Health Research Act* (CIHR Act) is federal legislation that established the Canadian Institutes of Health Research (CIHR). The Act was created to empower the CIHR, which is a federal agency that is tasked with promoting and supporting scientific and health research across the country (CIHR, 2022). It outlines the specific mission, role and functioning, as well as the governing hierarchical structure of the CIHR that align with its objective of improving the health of Canadians, and improving the health services, products, and overall system (*Canadian Institutes of Health Research Act*, 2000).

The Act is able to achieve its mission through federal funding that is allocated to innovative health research projects and programs for cross-disciplinary researchers in health (*Canadian Institutes of Health Research Act*, 2000; CIHR, 2022). All of the initiatives that are supported by the CIHR Act are required to "meet the highest international scientific standards of excellence and ethics" to ensure that a discussion of ethical issues and the principles underlying them in health research is promoted (*Canadian Institutes of Health Research Act*, 2000). By requiring that all funding and support be

reported to the Minister of Health, the Act also ensures that there is full "transparency and accountability" for the financial investments (*Canadian Institutes of Health Research Act*, 2000).

In providing the legal foundation for the CIHR to support the advancement of health research in Canada, the Act also supports the advancement of genetic testing. The Institute of Genetics (IG) is the specific body of the CIHR that oversees research on "human and model genomes and all aspects of genetics," including genetic testing, by providing regulations and funding for related programs (CIHR, 2023). Funding is often the most integral aspect of a research project, regardless of discipline, as it ensures adequate infrastructure for a "successful execution of the research project" (Neema & Chandrashekar, 2021, 134). Without adequate funding, ample research that enables the exploration and understanding of the human genome would not be available. This would limit the number of tests and medical advancements that are available for Canadians, including recreational and diagnostic tests.

The CIHR Act also mandates that the CIHR apply its knowledge to the "development and implementation of innovative policy and practice" that impacts research (*Canadian Institutes of Health Research Act*, 2000). This is reflected in the role that the CIHR plays in shaping health related policies that extend to genetic testing. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS II), for example, is a policy statement that is issued by the CIHR in collaboration with other federal research agencies (Panel on Research Ethics, 2023). Together, these agencies represent the three main federal research agencies – the CIHR, the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy statement outlines the requirements for all research involving human subjects, including genetic sampling, data collection, and most importantly,

informed consent. The TCPS II and its measures of informed consent are discussed in greater detail in Chapter 4.

3.2.4 Health Canada

Health Canada is a governmental department that is tasked with overseeing the regulation of healthcare services that aid in the maintenance and improvement of health, including medical devices and products, as well as diagnostic tests (Government of Canada, 2023). For genetic testing, the department ensures the safety, accuracy per effectiveness standards, and ethics of all research and procedures prior to their public marketing and use (Health Canada, 2012). Devices that are used for diagnosing or predicting genetic disorders are governed by Health Canada's *Medical Devices Regulations*, which is part of the *Food and Drugs Act of 1985*. To ensure that all genetic testing devices meet the threshold standards, Health Canada requires that manufacturers obtain a Medical Device License that allows them to operate in Canada (*Food and Drugs Act*, 1985). This is especially the case for in vitro sample testing, where Health Canada issued specific regulations for *In Vitro* Diagnostic Devices (IVDD) to ensure that these devices meet the safety and performance standards (Health Canada, 2016; *Food and Drugs Act*, 1985).[4] The department also has regulations for genetic testing pertaining to assisted human reproduction, outlined in the *Assisted Human Reproduction Act* (2004). These include regulations for preimplantation genetic testing (PGT) for embryos that are created using in vitro fertilization (IVF), to provide the standards of use to screen embryos prior to implantation.

[4] *In vitro* testing refers to controlled laboratory tests and analyses of biological samples taken from the body and examined outside of the organism. Genetic *in vitro* tests have the capacity to detect diseases and conditions which makes them especially relevant for preimplantation and prenatal genetic testing.

Just as the CIHR does, Health Canada provides ethical considerations and research guidelines for all types of research, including genetic testing. Through the Health Canada and Public Health Agency of Canada (PHAC) Research Ethics Board (REB), the department can ensure that all research is conducted in a manner that is conducive of scientific conduct, as well as "protects and respects" participants (Health Canada, 2023). REBs are critical to any research project as they provide approval for the methodology, practice, and ethics, thus unauthorized projects cannot be recognized. They also ensure that research meets the mandates it is constricted to by the funding grants provided by the government in accordance with the guidelines mentioned in the TCPS II (Health Canada, 2023).

3.2.5 Personal Information Protection and Electronic Documents Act (2000)

In 2000, Canada enacted the *Personal Information Protection and Electronic Documents Act* (PIPEDA) for "private-sector organizations" that handle personal information over the course of their commercial activities. The Act came as a response to the increased use of electronic communication where there was a strong need for adequate laws that "govern the collection, use and disclosure of personal information" to ensure that individual privacy (as well as other fundamental rights) are protected (*Personal Information Protection and Electronic Documents Act*, 2000). This law was created as a mirror to the European General Data Protection Regulation, thus allowing for the regulation of information between Canada and Europe to continue the protection of civilian rights internationally (Delphix, n.d.).

Aside from protecting individual rights, PIPEDA also serves to enable the needs of organizations that require collected data in a way that does not violate persons. In this way, it is able to create sanctions against the corporate misuse of personal information. This include genetic data that is collected by medical organizations or companies that conduct genetic testing (e.g. 23andMe.com) outside of the realms of federal jurisdiction.

3.2.6 Canadian College of Medical Geneticists

Aside from regulations overseeing research, including that pertaining to genetic testing, there are also regulations that present mandates on research, healthcare providers and practitioners in Canada. The Canadian College of Medical Geneticists (CCMG) is a "national voluntary specialty organization" that represents physicians and clinical professionals working in genetics and genomics (CCMG, n.d.). The organization issues specific practice guidelines for different areas in genomics, including those regarding the retention of cytogenetic or molecular specimens, cytogenetic analyses, and so forth (CCMG, n.d.). These regulations cover the entirety of the genetic testing process, from the requirement to obtain valid informed consent; pre-test genetic counselling (where relevant); the proper means of testing; disclosure and interpretation of test results; and the proper use and maintenance of testing technologies (CCMG, n.d.). The CCMG also outlines specific position statements that highlight the organizations stance on important prevalent topics like patient autonomy, informed consent and the implications of genetic testing (CCMG, n.d.; Allingham-Hawkins *et al.*, 2009).

A similar organization is the Canadian Medical Association, a voluntary group of physicians and medical learners that is tasked with advocacy for national health matters (CMA, n.d.). The organization is tasked with advancing the "needs and interests" of Canadian physicians for optimized patient care, "generate and disseminate actionable data, research and insights", as well as driving "reform in a complex health system" (CMA, n.d.). One of its key outputs is the CMA Code of Ethics and Professionalism, a piece that outlines the ethical "commitments and responsibilities of the medical profession (CMA, 2018). Although not specific to genetic testing, the Code emphasizes key qualities that pertain to physicians and researchers working with human patients, including "respect for persons" and a "commitment to justice" (CMA, 2018, 2). This aligns with the importance of

informed consent, and respecting and empowering patient autonomy, which are essential for genetic testing.

Another organization that operates similarly is the Canadian Association of Genetic Counsellors (CAGC), which is specific to genetic counsellors who are extremely important to the process of genetic testing. The goal of the CAGC is to promote "high standards of practice" while "facilitating and supporting professional growth and increasing public awareness of the genetic counselling profession" (CAGC, 2006). The Code of Ethics issued in 2006 by the CAGC aims to emphasize just that, with specific measures for conduct and practice. It specifies the professional responsibilities and ethical considerations of genetic counsellors, including respect for individuals and their families, emphasizing "dignity and compassion", and encouraging "diversity, pluralism" as well as equal access in treatment and research (CAGC, 2006, 1-2). This also includes providing accurate information that can be understood by patients for the purposes of obtaining informed consent, and supporting subsequent patient decision-making (CAGC, 2006, 1).

3.2.7 The Constitution Act (1982)

The 1982 *Constitution Act* provided updates to the Canadian Constitution that insured its full independence while guaranteeing fundamental rights to its constituents. Although it does not explicitly cite genetic testing, the 1982 updates to the Act include the *Charter of Rights and Freedoms* which list certain provisions that are relevant to genetic testing and its different contexts. While the *Charter* does guarantee a multitude of rights and freedoms for Canadian citizen, it is crucial to recognize that no rights are absolute.

Section 2 of the *Charter* guarantees the right freedom of thought, belief, religion, peaceful assembly, association and expression. This provision protects individuals from discrimination on the basis of any of their personal affiliations, including the "right of press and other media" to conduct

their free speech. In the realm of genetic testing, this right could be considered as protection for individuals from discrimination on the basis of genetic testing results that may instruct their expression, opinions or beliefs.

Section 7 of the *Charter*, specifying the right to life, liberty, and security, ensures that all citizens have the right to exist free from interreference, such that any interference must conform to the "principle of fundamental justice," including due process. This includes an individual's right to make informed decisions about their life and health, and the right to have their genetic data protected from undue disclosure.

Section 8 protects against "unreasonable search or seizure" to emphasize a minimum "reasonable expectation of privacy" that all citizens have. This provision is underscored by the values of "dignity, integrity and autonomy," and it seeks to prevent unjustified searches and seizures or properties, information, or any such personal matters. The notion of privacy is of the utmost importance to the context of genetic testing, so a provision such as s. 8 would ensure that genetic data cannot be collected or used without proper consent or justification.

Section 15 of the *Charter* states that all are equal under and before the law, with assurance that all have access to "equal protection and benefit of law." Based on this, all individuals have the right to equal protection and freedom from discrimination based on protected classes, such as race or disability, as well as genetic characteristics. Any discrimination on the basis of the latter, including test results, that might result in negative consequences in employment or insurance would be a violation of these *Charter* rights.

3.3 American Federal and State Laws

3.3.1 Genetic Information Nondiscrimination Act (2008)

The *Genetic Information Nondiscrimination Act* (GINA) is a federal statute instituted with the aim of prohibiting any "discrimination on the basis of genetic information" by employers and health insurers (GINA, 2008). These prohibitions extend to all employment-related decisions such as hiring and firing, or in the process of seeking insurance, including to deny coverage or set premium rates. At its core, GINA is concerned with the potential misuses of genetic information, which includes privacy infringements and trespass of individual rights. It also promotes novel research and technologies for the advancement of science and medical therapies that benefit genetic research (GINA, 2008). By establishing legal protections for individual rights, it also promotes participation in research and honest disclosure to healthcare providers for comprehensive patient care.

In many ways, GINA is very similar to GNDA, including its commitment to keeping genetic information confidential and private, like other medical information (GINA, 2008). However, GINA continues to focus on protecting individuals in employment and health insurance, whereas GNDA protects individuals in a wider scope. Section 206 of GINA ensures that personal data is private and secure by preventing employers and insurers from requesting this information (GINA, 2008). In the case of any violations of GINA's mandates, individuals can seek legal recourse against the discrimination by filing a complaint with the Equal Employment Opportunity Commission (EEOC) or with the Department of Health and Human Services (DHHS), depending on the infraction (GINA, 2008; EEOC, n.d.; U.S. Department of Health and Human Services, 2023).

3.3.2 Health Insurance Portability and Accountability Act (1996)

The *Health Insurance Portability and Accountability Act* of 1996 (HIPAA) is a federal law that instituted "national standards" for the protection of sensitive and private patient data from undue

disclosure. Its Privacy Rule and Security Rule was introduced in response to issues relating to health insurance, privacy, as well as security of electronic data. The former is responsible for the protection of "protected health information" with specific prescriptions for how individuals are able to "understand and control" the manner in which their information can be used (HIPAA, 1996). The latter is responsible for protecting a "subset of information covered by the Privacy Rule," namely the "identifiable health information" that exists electronically, dubbed "electronic protected health information" (HIPAA, 1996). These two HIPAA rules are critical for how health-related information, including genetic data, is protected, handled, and transmitted.

Based on the standards set in the HIPAA Privacy Rule, all covered entities are required to provide consent and "authorization or permission" before their information can be disclosed for any reasons beyond "treatment, payment, and health care operations" (U.S. Department of Health and Human Services, 2022). However, patients do have the right to access their own healthcare information and data from their healthcare providers. In addition to protecting patient confidentiality, HIPAA allows for the use and disclosure of protected health information for research purposes by a covered entity without patient permission under certain conditions. These conditions include permission from an Institutional Review Board or a Privacy Board, and explicit notice from the researcher that the information is "necessary for the research" (U.S. Department of Health and Human Services, 2022). These protections also serve to enforce individual rights while promoting research interests and public confidence to participate in research.

HIPAA and its associated rules do not explicitly list any laws against genetic discrimination. However, its emphasis on privacy and protection against inappropriate disclosure of genetic information can contribute to reducing discrimination on the basis of genetic data, including the

results of genetic testing, while protecting those who seek or participate in such research and clinical treatments.

3.3.3 Food and Drug Administration

Genetic testing and laboratory-developed tests are overseen by a set of guidelines and regulations written by the Food and Drug Administration (FDA). These standards are aimed at ensuring the safety, accuracy, validity and reliability of genetic tests, laboratory analyses and all related products (Immunology and Microbiology Devices, 1982). Furthermore, they aim to "ensure patient safety" and health by maintaining the safety, quality, and effectiveness of genetic tests before they can be marketed and publicly used (FDA, 2019). The purpose of the FDA's oversight is to minimize or prevent misleading test results that could impact treatment and health of patients through classifications and constant quality control. Even after tests are released and used in clinical treatment and research, the FDA continues its mission by regular post-market surveillance (FDA, 2019). By ensuring patient rights, including safety and health, the FDA Regulations also prompts the development of genetic tests and encourages "genomic research within clinical studies," including promoting patient participation in this research (FDA, 2018, 1, 3).

The FDA is specifically responsible for overseeing direct-to-consumer genetic tests before they are sold to consumers by the various companies that create them. This responsibility is unique in that such a regulatory body does not exist in other countries such as Canada, where DTC genetic tests are not federally regulated or controlled (FDA, 2019). The specific attention paid to these commercially available is a critical step towards ensuring patient safety, autonomy and privacy in an emerging and often unregulated market. There are also other specific genetic tests that the FDA is responsible for regulating, including companion diagnostics, which can be a medical device, product or test (including genetic) that can provide essential information for the "safe and effective use of a

corresponding drug or biological product" (FDA, 2023a). These tests are also responsible for ensuring that patients can receive the most accurate treatment possible in the course of their clinical diagnosis through genetics. In order to best direct consumers, stakeholders and healthcare providers on the various aspects of genetic testing regulations issued by the FDA, there are different guidance documents that offer specific information (FDA, 2023b).

3.3.4 Clinical Laboratory Improvement Amendments

Another set of regulations that oversees the quality and accuracy of laboratory-generated tests, including genetic tests is the *Clinical Laboratory Improvement Amendments* (CLIA). The CLIA includes within it "federal standards" that apply to all American "facilities or site that test human specimens for health assessment or to diagnose, prevent, or treat disease" (CDC, 2023). All regulations issued by CLIA are administered by the Centers for Medicare and Medicaid Services (CMS), except for those involving research. As such, all clinical laboratories are required to be properly and fully certified to receive any funding through Medicare or Medicaid, CLIA itself "has no direct Medicare or Medicaid program responsibilities" (CMS, 2023). In addition to laboratory certification, CLIA is also responsible for issuing personnel certification, including ensuring that they have the required education, training and experience required for proper testing (CDC, 2022b). Through proper certification and monitoring, CLIA can ensure that all test results are accurate, and based on "competent and reliable scientific evidence," regardless of which laboratory was responsible for testing and analysis (CDC, 2022b).

By enforcing such stringent requirements on clinical laboratories, CLIA is able to ensure that patient safety and individual rights such as privacy and autonomy are protected through proper laboratory conduct and testing regulations. Although research laboratories are not subject to CLIA measures, the organization does encourage these labs to maintain a similar level of quality standards

to ensure that all testing, including genetic testing, is equitable across laboratories. This also bolsters public confidence in genetic testing and encourages participation in research and clinical testing with the knowledge that privacy and autonomy are secured through federal efforts.

3.3.5 National Institutes of Health

The National Institutes of Health (NIH) is a central biomedical and health-related research agency that is part of the United States Department of Health and Human Services (NIH, n.d.). It is an agency charged with advancing scientific knowledge regarding "the nature and behavior of living systems" and ensuring that this knowledge is successfully applied to "enhance health, lengthen life, and reduce illness and disability" (NIH, 2017). The organization provides a platform for the Genetic Testing Registry (GTR), a freely accessible comprehensive online tool for information on genetic tests and the laboratories that offer them (USNLM, n.d.). This information includes the "test's purpose, methodology, validity, evidence of the test's usefulness, and laboratory contacts and credentials" (USNLM, n.d.). The database, created by the National Center for Biotechnology Information (NCBI), offers up-to-date information in a clear and transparent medium that can be used by the general public, as well as healthcare professionals and researchers (USNLM, n.d.).

With the evidence-based information provided in the database, individuals and healthcare providers can make comprehensive decisions about medical treatment and intervention about the clinical validity and utility of genetic tests. It can also be used as an educational tool with a vast amount of resources for patient education (USNLM, n.d.). It is also a useful educational for researchers compiling information about research studies and data interpretation. As such, the NIH's GTR is a tool that contributes to education on genetic testing, which is essential for ensuring healthcare providers are able to complete information to obtain proper informed consent from patients.

3.3.6 Constitution of the United States (1787)

The *Constitution of the United States* was written in 1787 and ratified in 1788, making it a well-established written charter of government. It is a document which ensures its citizens rights and duties, while also outlining those of the government towards the constituents. Like most documents of its time, it does not address modern technologies such as genetic testing, however some of its principles and rights are relevant and applicable to genetic testing. While the *Constitution* does guarantee many rights and freedoms for American citizen, it is crucial to recognize that no rights are absolute.

The First Amendment of the *Constitution* ensures the "freedom of speech, the press, assembly, and the right to petition the Government" for all (U.S. Const. amend. I). It is the most known amendment to the 1787 *Constitution*, and requires that Congress not make any laws that limit or prohibit anything to do with individual or collective speech or expression. Although it is not directly related to genetic testing, it has implications for individual's freedom to access, share, or even discuss their genetic data without fear of repercussions such as censorship.

The Fourth Amendment protects against "unreasonable searches and seizures" of people, their property, and data (U.S. Const. amend. IV). The only way to justifiably override this protective right is through issue of a Warrant as evident justification of this gross trespass of individuals. This can translate to the need to protect the privacy of genetic data and disallowing any disclosure without consent and permission from the involved individuals. Although there are certain very specific contexts where genetic information can be accessed without the need for consent, it is important to note that these are not taken lightly due to the sensitive nature of the subject matter.

The following amendment emphasizes the right to due process, which encompasses "the promise of legality and fair procedure" (U.S. Const. amend. V; Legal Information Institute, 2022). It

also protects individuals from self-incrimination who might intentionally or unintentionally provide information that might even suggest their involvement in criminal acts (Legal Information Institute, n.d.). This amendment is especially the case when genetic data may be required as evidence in legal proceedings, if it may be a possibility that accessing their genetic information would somehow incriminate them. Despite this, some court rulings have noted that, like other rights, the Fifth Amendment is not absolute and does have limitations in certain scenarios.

Another right listed in the Ninth Amendment provides that the misinterpretation or failure to explicitly mention certain rights in the Constitution does not mean that they are not protected or that they can be denied (U.S. Const. amend. IX). An interpretation of this amendment could include the right to privacy and control of one's genetic data from unauthorized access and undue disclosure. This is because the novelty of genetic testing could be considered under the umbrella of "unenumerated rights" that this amendment protects, including the right to be safe from discrimination on the basis of genetic information and the right to receive adequate information about procedures relating to genetic testing to ensure informed decision-making (U.S. Const. amend. IX).

Chapter 4:
The Thing About Consent

4.1 Foreword to Consent

Bioethics is defined as the area of study concerned with the ethical, social, and legal issues that populate over the course of medical and scientific research. Within this kind of research is a requirement to maintain "patient autonomy and basic human rights" throughout the various bioethical procedures (Satyanarayana Rao, 2008, 34). The intersection of these principles forms consent, a concept that essentially forms the foundation of contemporary bioethics and ethical clinical practice (Gordon, 2012, 289; Samuels *et al.*, 2017, 1). In the context of biomedical research and treatment, consent was established as a protective measure for patients "against the self-interest of the medical practitioner or organization" overseeing the procedures (Dwyer, 2003, 328).

Consent is a topic that is often invoked in ethical considerations across various disciplines aside from bioethics, such as feminist epistemology and legal jurisprudence. It often represents a focal point of discussions regarding respect and boundaries (SACE, n.d.). A basic definition of consent would establish it as an agreement between two or more parties to comply with the standards set forth in the contract, including engaging in some sort of activity (Ministry of Advanced Education and Skills Training, 2023). This consent can be given explicitly through "affirmative, voluntary words or actions" with a universally conveyable meaning (Indiana University, n.d.). More popularly used in sociopolitical disciplines concerned with sexual activity and education, this definition forms the basis for various nuanced conversations of accord. However, it is just a simple definition that forms the basis for the more complex definitions and arguments required in bioethical contexts.

4.2 The Legal, Philosophical, and Bioethical Parameters

An extension of consent is informed consent, most often used in bioethical discourse and healthcare contexts (Kapp, 2008, 196). Informed consent represents the foundation of the tangled web of ethical principles established in the "Bible of bioethics", titled *Principles of Biomedical Ethics* and penned by Tom Beauchamp and James Childress (Dwyer, 2003, 328). In general, informed consent can be recognized as a "systematic approach to patient education and medical decision-making", from both a legal and medical standpoint (Epstein, 2006, 344). Earlier iterations of informed consent established it as a "the physician's disclosure of information rather than on the patient's understanding of that information", adopting a physician-centric model of defining this concept (Childress & Childress, 2020, 423). More contemporary conceptions continue to rely on the same requirement for debriefing patients or research participants prior to procedures. However, they ground their definitions of informed consent on obtaining valid consent from a "reasonable person" that has been adequately debriefed by "prudent physicians" in more ways than just hard to understand forms and impersonal prescriptions (Childress & Childress, 2020, 423-424; Faden & Beauchamp, 1986, 5). So informed consent is instead contingent on the "subject's *understanding and consent*", in a patient-centric model (Beauchamp & Childress, 1994, 142). Even with such measures, the definitions remained vague, obtuse and imprecise (Faden & Beauchamp, 1986, 223).

In general, the "legal, philosophical, regulatory, medical, and psychological literatures" have recognized informed consent based on the elements that compose it (Faden & Beauchamp, 1986, 274). These elements include: disclosure, comprehension, voluntariness, competence, and consent (Faden & Beauchamp, 1986, 274; Beauchamp & Faden, 2004, 1682). Their importance varies per circumstance, but the consensus appears to require the presence of at least *some* of these elements for a valid, informed consent (Faden & Beauchamp, 1986, 275). Most of the previous understandings of consent over-emphasized disclosure as an essential component of informed consent, at the physician's

or researcher's discretion. Despite their apparent importance, these elements, on their own, cannot give rise to a definition as they lack the "more comprehensive treatment" required to reach a meaning (Beauchamp & Faden, 2004, 1279-1280).

Following the recognition that most historical discussions and conceptions of informed consent did not clearly highlight the required criteria and conditions for such an important obligation to be met, researchers set out to illustrate just what these conditions were (Faden & Beauchamp, 1986, 208). At the crux of this vagueness is a recognition that informed consent is based on the "self-determination and well-being" of the patient (Childress & Childress, 2020, 425). In their most critical volume, Beauchamp and Childress' describe four principles that ought to guide bioethics, identified as being "autonomy, beneficence, non-maleficence, and justice" (Dwyer, 2003, 328; Page, 2012, 3). Put simply, the principles of non-maleficence and beneficence refer to the duty of "avoiding harm" and that of "providing benefits", respectively, justice refers to that duty of ensuring the "fair distribution of goods and burdens" among all, while the respect of autonomy – or respect for persons, per The Belmont Report – refers to the promotion of self-directed decision-making in individuals (Gillon, 1985, 1806; Kopelman, 2006, 123; Varkey, 2020, 22). These are explicitly grounded principles that stem from generally outlined functions of informed consent, including the "promotion of individual autonomy", "protection of patients and subjects", the "avoidance of fraud and duress," the "promotion of rational decisions," to name a few (Childress & Childress, 2020, 424).

Of the four principles, autonomy has often been defined as the "ultimate moral foundation" of informed consent, such that it takes precedence over the remaining conditions outlined by Beauchamp and Childress (Pugh, 2020, 137). Its importance is further highlighted by the propensity of other critical principles to be recognized within the four main ones offered by Beauchamp and Childress. These include those of "confidentiality and truth-telling", which stem from the principle of autonomy,

maintaining its status and importance overall (Page, 2012, 3). Truth-telling refers to a "full disclosure" of *true* information regarding the patient's medical case (Varkey, 2020, 20). It almost aligns with the Kantian duty to never lie, due to the dire consequences that may arise in instances where physicians lie or withhold pertinent information that they think the patient cannot or should not know (Zolkefli, 2018, 135). These consequences include a severe hindering of their capacity to make an informed decision about their treatment and lives, and by extension impeding their autonomy. The notion of truth-telling also conforms to the principle of non-maleficence, since lying or withholding constitutes some level of harm to the patient – although in rather paternalistic settings, such as medical contexts, this was not always the tradition (Zolkefli, 2018, 135). Confidentiality is a form of non-disclosure, such that it obligates the physician to keep private certain information pertinent to the patient from third-parties, with very few explicit exceptions (Varkey, 2020, 20; Roberts & Dyer, 2003, 445). Although, *prima facie*, there appears to be a certain tension between the two duties of confidentiality and truth-telling, they are essential for ensuring the autonomy of individual patients throughout the course of treatment (Roberts & Dyer, 2003, 445).

The importance of autonomy further stems from the self-centered nature of its concern, such that it aligns with the goals of contemporary bioethics in centering patients in their own treatment. By its very nature, autonomy refers to a state of self-governance, wherein individuals are able to "think, decide and act freely and independently" without external influences (Gillon, 1985, 1806). This ability to self-determine one's life trajectory is essential and ought to be perceived as present in all competent adults. In a patient-centric model, the duty to respect and uphold autonomy can be understood as putting the onus of properly disclosing *all* information that is essential for exercising self-determination on the physician (Varkey, 2020, 19). However, even after recognizing the essential nature of autonomy to informed consent, it does not correspond to a comprehensive definition.

A definition of informed consent that continues in this tradition of centering autonomy is proffered by Ruth Faden and Tom Beauchamp in *A History and Theory of Informed Consent*. Their interpretation of informed consent represents it as "an autonomous authorization" by the patient, making it a specific kind of autonomous choice that one endeavours to make under certain conditions (Faden & Beauchamp, 1986, 277; Pugh, 2020, 155). This definition is the widely adopted in the medical and ethics contexts. The parameters of this interpretation require more than just agreeance or compliance, or what Jon Waltz and T.W. Scheuneman would label "*awareness* and *assent*" (Faden & Beauchamp, 1986, 278). Rather, patients must have certain capacities that enable them to "causally" provide the consent, including "intentionality", "understanding" and without the undue influence of coercive forces (Pugh, 2020, 154; Beauchamp & Childress, 1994, 143).

Such capacities include competence, or the "capacity to act autonomously", which is generally recognized as an overarching requirement for autonomy and informed consent (Varkey, 2020, 19). Being able to detect competence in patients is one of the basic "core ethical behavioral skills" that physicians ought to have to be able to practice properly (Varkey, 2020, 18). In order to be able to be considered competent, a patient must exhibit a vested interest their own treatment, and in being free from coercive forces that may impede their "bodily integrity" (Faden & Beauchamp, 1986, 42). They must also have the ability to "state a preference or choice," comprehend the circumstances of their situation and any possible consequences, as well as the ability to "reason through a consequential life decision" (Varkey, 2020, 20). In this way, they are able to make decisions, and authorize the decisions by assuming responsibility and giving another the authority to implement the corresponding action (Faden & Beauchamp, 1986, 280). Without meeting these ascribed criteria, a patient can be labelled as incompetent, thus making them unable to provide informed consent.

Faden and Beauchamp also provide another interpretation of informed consent; this interpretation relies on an analysis of informed consent based on the available laws and policies within the sociopolitical infrastructure (Faden & Beauchamp, 1986, 274, 277). Based on this, informed consent is neither exclusively an autonomous act (as per the previous iteration) nor are they authorizations (Faden & Beauchamp, 1986, 277). This "effective consent" is specifically "policy-oriented", linked to "legally and institutionally valid consents and refusals", thus distinguishing it from the previous interpretation because it can be procured through institutionally mandated procedures with accompanying rules and protocols (Faden & Beauchamp, 1986, 280-281; Epstein, 2006, 342). This means that to obtain informed consent is to comply with the contextual procedural prerequisites, including those of genetic testing. In order for it to be *effective*, the obtained consent must conform to designated rules outlined in legislations and policies, as well as those requiring "disclosure, comprehension, the minimization of potentially controlling influences, and competence" (Faden & Beauchamp, 1986, 282).

The difference between the two interpretations offered by Faden and Beauchamp, or the *senses*, as they describe them, is that automatically holding informed consent to be autonomous authorization may not always conform to the requirements needed for it to be considered effective. Similarly, it may be the case that the rules and regulations that govern effective consent do not always require – or even allow for – autonomous authorization in accordance with the first interpretation of informed consent. The institutional or legislative criteria for autonomy may differ based on organizational or geographical location, and they may be different depending on the context. This means that upholding autonomous authorization to be a blanket requirement would make it difficult to obtain informed consent in certain settings where it would also require effective consideration. In other words, autonomous authorization can accompany effective consent, but it does not necessarily

guarantee valid effective consent. This is also the case in contexts where genetic testing is required, such that the purposes and procedures of testing can vary greatly leading to a change in the nature of informed consent.

Not only is informed consent an ethical duty, but it is also deeply intertwined with the legal duties to which people – especially those of authority – must conform. The legal definition of informed consent provides a different side of the history and nuance of its importance. It similarly holds that informed consent is an "agreement to an interaction or action" that is solidified after full knowledge of "relevant facts" of the circumstances and future or alternative possibilities (Legal Information Institute, 2020). These facts must be substantial enough to ensure that the reasonable person can autonomously make a proper and empowered decision about their treatment. Depending on the nature of the treatment, the consent can be either implied or expressed – the former is provided through "words or behavior," as interpreted based on the circumstances (Klein Lawyers, 2022). In fact, informed consent as a concept emerged over a century ago in a legal judicial decision on a case regarding the right to self-determination and autonomy, *Schloendorff v. Society of New York Hospital* (1914) during which a patient had surgery performed on her against her express wishes in a paternalistic violation of her rights (Green & MacKenzie, 2007, 115). The patient, Mary Schloendorff, had initially only agreed to an examination of her case by her doctor, however ether was administered and a surgery took place against her will. This case established that self-determination and autonomy were of the utmost importance for patient care, and that cognitive capacity be a pillar of the legal understanding of consent such that "every human being of adult years and sound mind" have the express, constitutionally protected right to determine what happens to their self and body (*Schloendorff v. New York Hospital*, 1914). Cognitive capacity is of the utmost importance as a legal standard for informed consent as it discloses a requirement for assessing

individuals' ability to understand the relevant information presented to them and to decide based on it (Leo, 1999, 133). Furthermore, the ability to communicate this consent – whether verbally or through established non-verbal expressions – is also etched into the legal requirements of consent, thus cementing competence as a standard (Sugawara *et al.*, 2019, 3; Gerver, 2020, 39). The legal decision also established the exceptions to this kind of assault crime, including unconsciousness and emergencies, however Scholendorff's case did not conform to these exceptions.

One of the very first appearances of "informed consent" as a term came in a legal judicial decision regarding medical malpractice, *Salgo v. Leland Stanford University* (1957). The plaintiff, Martin Salgo, underwent a surgical procedure that left him paralyzed after doctors failed to properly informed him of the risks and benefits associated with this life-altering treatment. The physician was found to be negligent in their actions, and liable for withholding pertinent information and failing to obtain informed consent. Based on the parameters of the "prudent practitioner," an extension of the rational person, the judicial decision established certain duties that bind physicians (*Salgo v. Leland Stanford Etc. Bd. Trustees*, 1957). They are outlined by the "duty to disclose" such that physicians must provide important information beyond the "administrative burden" to reveal the nature of the procedure, and the "duty to call a specialist" when they themselves are unable to provide adequate information or explanation to patients (*Salgo v. Leland Stanford Etc. Bd. Trustees*, 1957; Katz & Fox, 2004, 20).

In Canada, similar landmark cases emerged that established a precedent for patient-centered models for the proper "dissemination of information" and the procurement of informed consent (Klein Lawyers, 2022). The 1980 landmark Supreme Court case, *Hopp v. Lepp*, found that consent does not bar physicians from being liable for negligence unless they were able to demonstrate that their patients provided valid, informed consent. Specifically, informed consent was framed as the

being present in parallel with a fulfilled duty of disclosure or duty to inform – without conforming to this duty, consent cannot be informed. Another case, *Kenny v. Lockwood*, demonstrated the importance of correctly and accurately describing the treatment, procedure and implications to patients prior to proceedings to ensure that there is not breach of duty or harm to the patient (*Hopp v. Lepp*, 1980; Rozovsky, 1973). Physicians are especially required to inform patients about the "probable risks," as well as the "material and immaterial risks" (*Hopp v. Lepp*, 1980, 209). Both of these landmark cases established that there can be a breach of duty regardless of the competency of the procedures or treatments themselves, as this is not an issue that is entirely predicated on the technical abilities of the physician or healthcare provider, but rather on the protection and empowerment of patients (*Hopp v. Lepp*, 1980, 205).

While this case began the development of an official doctrine of informed consent in Canada, *Reibl v. Hughes* (1980) officially established itself as the golden standard for physician duties. The case involves plaintiff John Reibl, who was receiving care for an occlusion that impaired blood flow through a major artery (*Reibl v. Hughes*, 1980). Although the surgery itself was successful, Reibl suffered a stroke that left him paralyzed on one side of his body. This led to his position that the operating physician was both negligent and guilty of battery, as Reibl believes that the consent he provided was incomplete and not informed. Previous interpretations of informed consent established it as a duty of disclosure on the part of the physician – however, the more patient-centered models apply the standard of the reasonable person. To evaluate the failure to disclose adequate information, the provided information must be measured against what a reasonable patient would do in the same circumstances (*Reibl v. Hughes*, 1980, 882). As such, the duty to disclose is breached if the physician fails to give the patient sufficient information that would allow the reasonable person in a similar

position to make a properly informed choice. This also applies to the bounds of where liability can be established for physicians.

To properly understand the amalgamation of legal, philosophical and bioethical requirements for obtaining valid informed consent, the Office of the Privacy Commissioner of Canada provides a list of guidelines (Office of the Privacy Commissioner of Canada, 2018).

4.3 Relevant Contexts

According to the United States National Institutes of Health, genetic testing comprises "an analysis of human chromosomes, genes, or proteins" for the purposes of detecting "heritable disease for clinical purposes" – this definition categorically limits the instances where genetic testing occurs (Franceschini *et al.*, 2018, 569). However, in general, there are several different contexts wherein the collection of genetic DNA samples would be warranted or required. Some of these contexts require that a patient or individual be approached by an external party, such as certain research scenarios or for the purposes of forensic investigations. Other contexts require a patient or individual to approach researchers, medical practitioners, or companies engaging in genetic analysis, including for the purposes of treatment or recreational genetic testing. As such, these genetic tests can be conducted for the purposes of screenings, diagnostics and prognoses for treatments, prenatal testing, testing for potential inherited markers in newborns and adults, as well as participating in research studies (USNLM, 2021; Mayo Clinic Laboratories, 2020).

To ensure that there is a consistent and salient foundation for informed consent forms, there are certain "necessary and critical" ideas that make up a "standardized core set of consent elements" that ought to be included within it (Ormond *et al.*, 2021, 8; Longstaff *et al.*, 2022, 1500). Of these concepts, there are the aforementioned disclosures regarding the purpose and process of the test, and options regarding secondary use and findings (NHGRI, 2022). In additions to this, there is the

indication that "genetic testing is always voluntary," as well as the specification of whom the results will be reported to, and whether there are any limitations from the testing (Ormond *et al.*, 2021, 8; ARUP Laboratories, 2018; Weill Cornell Medical College, 2014). Many of these concepts emerge from pre-existing literature and policies that recommend certain procedures, however it is not necessarily the case that there actually is a standard practice for genomic testing across contexts or institutions (Longstaff *et al.*, 2022, 1501).

In Canada, there currently do not exist any "government-approved guidelines" for genomic testing (OCED, n.d.). However, the Canadian College of Medical Geneticists (CCMG) and the Canadian Association of Genetic Counsellors (CAGC) offer policy statements and guidelines on appropriate conduct (OCED, n.d.; Allingham-Hawkins *et al.*, 2009). Further guidelines are outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS II), a joint policy statement issued by Canada's three federal research agencies – Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (UBC Office of Research Ethics, n.d.). Research involving humans in the United States is subject to federal regulations under the Department of Health and Human Services' (HHS) Common Rule, and the Food and Drug Administration's (FDA) policy for the Protection of Human Subjects (Gutman, 2016, 10). Despite the call for a standardized set of elements relating to informed consent, there are still differences across contexts.

4.3.1 The Clinical Context

In clinical settings, genetic tests are requested by the overseeing physician or by the patient within a medical context for a specific reason, including to find out more information to decide on treatments (CDC, 2022; USNLM, 2021). These scenarios include "genetic consultation or routine

primary care," as well as "pre-natal screening, screening for genetic carriers of a genetic disorder for reproductive purpose," and potential disorders emerging from family histories (Franceschini *et al.*, 2018, 570; Pagon *et al.*, 2021, 344). Such tests are performed in laboratories that must conform to certain mandates, such as the federal prescriptions of the CLIA in the United States, or the "voluntary standard" introduced by the Standards Council of Canada in response to the inadequate measures set by Health Canada (Pagon *et al.*, 2021, 344; Holloway *et al.*, 2019, 1067-1068). These laboratories can also charge a fee for conducting the tests, regardless of the purpose as it occurs in the clinical setting (Pagon *et al.*, 2021, 344). Due to the novelty of this kind of technology, it is critical that physicians and medical practitioners ensure that they have all the pertinent information regarding the appropriate uses, the relevant processes, and long-term impacts of these tests, including their "validity, safety, and efficacy" (Holloway *et al.*, 2019, 1067).

When patients request genetic tests, it is usually recommended that they seek genetic counsel with a professional medical practitioner. This is even in cases when the test may be recommended by the physician or may be essential for the procession of the treatment process, as "participation in genetic testing is completely voluntary" (Mayo Clinic Laboratories, n.d.). In Canada, this is enforced through the *Genetic Non-Discrimination Act* (GNDA) (2017) which prohibits any party from "requiring an individual to undergo a genetic test or disclose the results of a genetic test" for any reason, except for clinical treatment or research, which have their own requirements. The American counterpart to this piece of legislative code is GINA, or the *Genetic Information Nondiscrimination Act* (2008), which seeks to protect citizens against discrimination on the basis of genetic information disclosure in healthcare, including insurance, and employment (NHGRI, 2022). This is because the main harm that patients and participants might experience from genomic testing is informational,

such that their data may be used in ways and for purposes to which they did not consent, or were unable to consent to due to a lack of adequate debriefing prior to the procedures (Wolf *et al.*, 2019, 8).

As the technology of genetic testing becomes rapidly intertwined with primary care in clinical settings, it is critical to ensure that the nature of informed consent is evolving quickly enough to keep up with these changes. In this context, clinicians are often bound by the laws and regulations that impose the kind of consent they ought to obtain from their patients and the manner in which they should proceed to obtain it (Spector-Bagdady *et al.*, 2018, 82). Their overarching goal remains to aid patients in making "better-informed decisions for themselves and their families" (Spector-Bagdady *et al.*, 2018, 82). Based on this, and with reference to Faden and Beauchamp's framework, the kind of informed consent that clinical settings require is a mixture of autonomous authorisation and effective consent (Beauchamp & Faden, 2004, 1279; Epstein, 2006). This is to the extent that effective consent "presupposes" autonomous authorization in the sense that any individual who is deemed able to receive and respond to pertinent information regarding their treatment in accordance with the rules and regulations is necessarily understood to be autonomous (Epstein, 2006, 342). While some have argued against this position, citing that legal definitions of autonomy that are adopted in clinical settings may not always be emblematic of true autonomy, this project will not attempt to argue for either position.

Informed consent rules in these contexts can often be seen being "paired" with government mandates, including legislations and policies (Spector-Bagdady *et al.*, 2018, 82). It is especially pertinent considering the "fundamental advances in genetic technologies", wherein there are many concerns that lie beyond the scope of standard measures of informed consent (Spector-Bagdady *et al.*, 2018, 82). This includes protection against the non-consensual disclosure of genetic information and secondary uses of the collected data, which can lead to explicit or proxy discriminations across

various settings (Yesley, 2009, 31; Martani *et al.*, 2019, 3). Even though it is acknowledged that the use of data collected in clinical settings for learning and research purposes is imperative to medical advancements, there are no exceptions to these laws, aside from several explicitly stated ones (Martani *et al.*, 2019, 2).

In the United States, patient information – including genetic data – is protected such that no uses, whether "primary or secondary" can be done without the explicit authorization of the patients or subjects, according to the 1996 *Health Insurance Portability and Accountability Act* (HIPPA) (Martani *et al.*, 2019, 3). Despite this proclamation, HIPAA Privacy Rule allows for 12 stated "'public purpose' exceptions" to this rule, wherein disclosure to patients that their information will be shared – and by extension, their consent will be violated – is not necessary (Clayton *et al.*, 2019, 20-21). Furthermore, disclosure rules do not apply to the same extent with regards to treatment – there is no "minimum necessary provision" which limits the amount of information that can be shared, if this information is being shared for the purpose of treatment (Clayton *et al.*, 2019, 12). In Canada, the Tri-Council Policy Statement (2022) provides that data can be used for "secondary analyses", provided that no identifiable information on the patient is included (CIHR *et al.*, 2023). There are, however, circumstances where the Statement allows for secondary uses of data, such as instances where patients do provide their consent, or where physicians have managed to satisfy the requirements of research ethics boards (REBs), regardless of patient consent (CIHR *et al.*, 2023; Martani *et al.*, 2019, 3).

4.3.2 The Research Context

The research context, which finds itself inextricably tied to the clinical aspect, is the primary driver of advancing genomic knowledge. The main undertaking of tests conducted for the purposes of genetic research is to discover and understand new genes, develop tests for clinical use, and aid the

treatment of genetic conditions (USNLM, 2021; Vieira, 2014). Genetic materials used in research processes are obtained in a variety of ways, including clinical testing where patients may be required or encouraged to complete tests by their healthcare practitioners, and subjects who join or are sought after for specific research projects (CIHR *et al.*, 2023, 12.0). Participants' genetic "data and/or biological materials" can be taken directly from them when they consent to the use of their information for projects (CIHR *et al.*, 2023, 12.0). As well, individuals can also become participants in research by donating "organs, tissue or their entire body" posthumously (CIHR *et al.*, 2023, 12.0). In order for researchers to be able to use genetic information, participants must have been properly and adequately debriefed about the purposes and procedures of the study, the long-term impacts and what their genetic information will be used for.

According to the National Human Genome Research Institute, the importance of the genomic research extends beyond scientific findings and has serious "implications for identity and privacy". This means that the requirements for informed consent are not only enforced by the parameters of the research study that the researchers should carefully include, but also by "laws, biobanks and data repositories" or REBs (NHGRI, 2022). The Institute recognizes that there ought to be a level of collaboration or "dynamic interaction" between the parties implicated in the process of informed consent, including the participant themselves, REBs, the researchers, as well as legislative bodies (NHGRI, 2022).

For the same reasons that informed consent in clinical contexts is considered to be effective, it is also considered to be as such in research contexts. In this context, informed consent serves two main purposes – "to educate individuals about the risks and potential benefits of their possible participation in research" and "to establish the voluntary willingness of the individual to participate" (Gutman, 2016, 3). While there ought to be assurance that the participants are able to give voluntary

ongoing consent that can be revoked at any times following a thorough disclosure, researchers must also conform to certain institutional frameworks (Health Canada, 2022; Rego, 2020, 2; Hamvas *et al.*, 2004, 554). As such, the informed consent in this context is motivated by the "demands in the legal and healthcare systems" that align with promoting the autonomy interests of participants (Beauchamp & Faden, 2004, 1278). This makes it a semi-seamless mixture of autonomous authorisation and effective consent (Beauchamp & Faden, 2004; Epstein, 2006). Autonomy, as a constitutionally protected measure across the world, including the United States and Canada, continues to be the pillar by which such policies and legislations are drafted, thus guiding the development of informed consent across clinical and research contexts (Justia, 2022; *Canadian Charter of Rights and Freedoms*, 1982).

Based on the TCPS II (2022) specifications in Canada, REB review and approval is always necessary for proceeding with any kind of research involving genetic testing (CIHR *et al.*, 2023, 12.3). However, they do not always need participant consent for all cases. When conducting research that "relies exclusively on the secondary use of non-identifiable" materials, consent is not required (CIHR *et al.*, 2023, 12.3B). This is to say that as patient information is kept confidential and they are not identifiable, their data can be used regardless of the source of collection or presence of consent. The TCPS II also governs genomic research involving families, as well as communities and groups. To ensure that REBs are operating in accordance with the regulations set forth by the TCPS II and in the interests of participants, the Canadian Association of Research Ethics Boards (CAREB) (Health Canada, 2022). The purpose of this is to maintain the integrity of research involving human subjects, and ensuring that REBs are compliant with the rules and regulations that bind informed consent. In the United States, informed consent in research was codified in law in the *Code of Federal Regulations* (Bazzano *et al.*, 2021, 81; Health Canada, 2022). Contained in this law is the Common

Rule, which explicitly states that informed consent requires "key information" that is presented in a "concise and focused" format for ease of comprehension (Bazzano *et al.*, 2021, 83).

4.3.3 The Direct-to-Consumer Context

Returning to direct-to-consumer genetic tests, the issue of consent becomes more delicate. DTC genomic testing is largely unregulated, especially in Canada (Cernat *et al.*, 2022, 154; CMA, 2017). While the FDA regulates some DTC tests, by either limiting their capacity for testing for certain conditions or imposing strict operating regulations, there exists no such legislative body in Canada that governs these tests (Cernat *et al.*, 2022, 154-155). While there are recommendations, such as those offered by the TCPS II and other relevant genetic research organizations in Canada (including provincial doctor boards, such as the policy statement released by the Doctors of BC), they do not make any explicit mandates (Doctors of BC, 2015). However, there are some standards that the distributing companies ought to endeavor to meet.

Even though DTC tests are "administered" by the patient themselves, there are still requirements for consent by the companies that are responsible for selling the tests and subsequently analyzing the results (in collaboration with specialized laboratories). Generally, DTC genomic testing occurs when individuals themselves elect to have specific tests done, however, "genetic counselling is recommended" through independent services or through the DTC companies (Hamvas *et al.*, 2004; Smetana *et al.*, 2020, 563, 568; Friend *et al.*, 2018, 7). The recommendation that patients undergo proper genetic counselling by a certified health practicioner is made to ensure that patients are able to receive "adequate information in an understandable way about the benefits and risks and function and type of test" (Martins *et al.*, 2022, 1341). However, since patients often opt-out of such counselling before and after DTC genomic testing, valid "informed consent is unlikely to occur" (Martins *et al.*, 2022, 1341).

Although the goal is to ensure that DTC genetic companies found their operations on the basis of "science and ethics," it is crucial to recall that they are "commercial entities" with different goals and approaches than healthcare practices (Committee on Energy and Commerce, 2010, 107; Martins *et al.*, 2022, 1341). In this way, they likely regard the process of obtaining informed consent as being akin to entering a "contractual agreement with the consumer" rather than an obligation based in any "duty of care" or "code of ethics" to which they must be held (Martins *et al.*, 2022, 1341).

By framing the informed consent as a contract, the context transaction is switched from healthcare to business, rendering the concerns, issues and protocols of the latter at the forefront of consideration. Instead of viewing the consumers as persons who are interested in learning more about their bodies and health, they are seen as just shopping for any other product and made to be a means to a profit for large companies. It also changes the responsibilities that companies many feel they have in the process of obtaining informed consent. The voluntariness that is typically prescribed to consumers in a market continues to apply here, since the onus of becoming informed and understanding the terms of the agreement is on the individual seeking the product (i.e. the consumer of the genetic test), not on the company itself. And, in further contrast to other contexts, while DTC companies are required to provide information on their genetic testing products, they are not required to provide any measures to ensure consumers can access and understand this information prior to consenting. Furthermore, since these companies are *approached* by individuals seeking DTC genetic testing, it can be easy for them to assume that people have given their "implied consent" (Office of the Privacy Commissioner of Canada, 2017). Even with the implication of consent provided by consumers seemingly willingly signing up for these services, companies are encouraged to seek out explicit, informed consent. The model of consent that such companies rely appears to continue in the

mixed model of autonomous authorization and effective consent, however it is different in that it lacks the substantive "informed" nature of the consent.

Instead, these DTC genomic testing companies focus on the core elements of "strong privacy protection" and informed consent despite the former being most concrete due to the nature of their operations (Committee on Energy and Commerce, 2010, 107). They consider it important to emphasize the "privacy risks" that consumers might encounter throughout the process, often encouraging them to seek out the information themselves (Office of the Privacy Commissioner of Canada, 2017). Their purpose may be to offer consumers with a service – of uncovering their genetic history and information – it is actually to "provide growing opportunities to use extensive genetic data and family medical history for research purposes" (Koch, 2018). Despite the keen interest in privacy concerns and maintaining consent as a pillar in their corporate operations, several DTC companies have been accused of encouraging customers to "secretly test" their family members and friends – this is a direct and clear violation and contradiction (Committee on Energy and Commerce, 2010, 33). Thus, the "analytical and clinical validity," "clinical utility," reliability of these tests, as well as the results, their interpretations and laboratory affiliation/credibility are questionable *at best* (Hock *et al.*, 2011, 326, 332; Horton *et al.*, 2019, 2; Chahinian, 2019).

Direct-to-consumer genetic testing is usually referred to as recreational genetic testing because the results are very rarely "conclusive" enough to be considered diagnostic in any capacity (Oh, 2019, 2). Consumers are responsible for providing "genetic and self-reported information" to DTC companies which is used to compile their comprehensive genetic profiles (Committee on Energy and Commerce, 2010, 121). However, due to the variation in assessments, the lack of regulation that leads to a wavering "clinical validity and reliability," it is difficult to ascertain the truth of any results that arise (CMA, 2017). Even if they were to be conclusive, they could only be properly

interpreted as such by a physician or genetic counsellor. However, it is very strongly recommended by healthcare providers and genetic counsellors that DTC genetic tests *not* be used to guide or inform any health decisions regarding diagnosis and treatment, especially without the consultation of a healthcare practitioner.

Despite the warnings and hesitation of medical professionals to embrace results from DTC genetic testing, many patients are steadily using the results to "self-diagnose and self-treat" themselves and their family members without a clear understanding of the repercussions (Lovett *et al.*, 2012, 146). Due to its widespread popularity, this might be causing a spread in frivolous, unnecessary overtreatment and intervention for, sometimes, nonexistent ailments (Lovett *et al.*, 2012, 142). Furthermore, the inappropriately interpreted results and lack of testing or follow-ups after these tests can lead to misdiagnoses or ignoring critical conditions (Lovett *et al.*, 2012, 142; Roberts & Ostergren, 2013, 184). Since consumers willingly elect to participate in DTC genomic testing, there are no policy or legislative movements forcing companies to enforce genetic counselling for informed consent prior to the tests, or after the fact to ensure proper analysis and interpretation (Roberts *et al.*, 2011, 329).

Chapter 5:
Privacy Paradox and Philosophical Paradigms

With every new genetic test that is developed for public use, there are a plethora of statues, laws and policies that become relevant. These are legislative bodies that govern the development, use, and distribution of biomedical devices and products, including genetic tests. Although they are critical and represent an important barrier of protection from the potential encroachments of rapid, unprecedented technological and scientific advancements, they cannot simply be understood as the undisputed black-letter laws. The legal standards set forth for conduct in the face of such overwhelming innovation is but one aspect of the larger picture in addition to the laws and policies governing genetic testing, there is also a requirement of carefully considering and discerning the ethical principles underpinning these laws.

The aim of this chapter is to further delve into these ethical principles and how they underscore the regulations, while emphasizing the inherent connection between the specific laws and ethics. Specifically, this chapter will continue the task of unraveling the delicate balance between promoting scientific advancement, maintaining and empowering individual rights, and protecting societal interests. With this understanding, the invisible string between autonomy, privacy, and ownership, and legal measures can be superimposed on DNA sample testing. Previously, this project began a cursory explanation of autonomy and privacy to preface an overview of Canadian and American laws and policies governing genetic testing. This chapter will continue deeper into these explanations by incorporating relevant philosophical outlooks and demonstrating their application to genetic testing, and the intersection between laws and ethics in this context.

5.1 Autonomy Unplugged

Autonomy is a fundamental principle of personal agency, and a founding ethical and legal standard to which all have the right to (Jewkes, 2014, 147). This is to say that autonomy is not something that one bestows unto another or gives to them, rather it is an "inalienable right to self-determination" that is inherent to all people (United Nations, 2012). Regardless of anything, such a right cannot be stripped. By introducing autonomy in this way, its importance can be emphasized as it continues to underscore all ethics and laws relating to personal governance and decision-making.

Basically understood, autonomy refers to the ability to be "self-legislating or self-regulating", thus able to determine how to live one's own life (Kuflik, 1984, 272). It is the "sense of volition" or control that one perceives in *and* attributes to themselves by labelling it a "locus of causality" for their decisions and subsequent actions (Martela & Riekki, 2018, 2). This means that an individual not only has the ability to choose for themselves, but to *think* for themselves as well (Friedman, 1986, 20). By thinking for themselves, they are able to base decisions on their lived experiences, which culminate in traits that surround/relate to "sanity, reason, guilt, responsibility, desire, sexuality" (Christman, 2009, 51). Each of these represents the combination of one's history and self over time, which are informed by their relational context including relationships and interactions (Christman, 2009, 20; Mackenzie, 2008).

According to traditional conceptions of autonomy in bioethics, there is a "tendency to distort the relationship between individuals and the world" where individuals are often considered separately from their contexts (Azétsop & Rennie, 2010, 3). This perspective is a limiting one that, at once, "exaggerates" the effect that individual agency and internal contexts have while underestimating that which the external context has on the ability to exercise autonomy (Azétsop & Rennie, 2010, 3). The traditional view of autonomy also decidedly views autonomy as a binary, in that individuals either

definitely have it or not, regardless of the context or situation. This is also a narrow perception of the manner in which people exercise their agency in various domains, as it can inadvertently restrict them in certain contexts where their agency simply would have manifested differently. While it may be understood why this position is taken, because healthcare contexts can often lead to impairments in normative judgement and self-authority, it is not the case that autonomy should be dismissed as entirely absent in these contexts (Mackenzie, 2008, 512).

Instead, individuals should be seen as being an amalgamation of their internal *and* external dimensions, which allows for more flexibility in the considerations of their ability to self-govern – even in healthcare contexts (Anker, 2020, 528). It is especially important to account for both due to their codependency and cohesive impacts on one another, where agents often "internalize external reasons" that impact decision-making, and thus agency, while simultaneously contributing to their external context (Anker, 2020, 531). To internalize reasons is to incorporate them into one's own existing frameworks, and accept them without feeling coercion or influence to use them in future judgements. By internalizing such external concepts, one is adopting and endorsing them into their rational and moral identity, and is able to justify this addition to their existing self to ensure agency through the changes. Even so, autonomy is not simply a switch that is clicked, but rather it "comes in degrees and is domain specific" – so it necessarily looks different under different circumstances for different people (Stoljar, 2020, 346; Mackenzie, 2008, 523; Stoljar, 2000, 95).

For an individual to be able to rely effectively on their own volition, it is essential that their decision-making processes and rational deliberation abilities be free from coercion, including that which impacts their "immediate situation" and any situations thereafter (Friedman, 1986, 20). The volition, or the "series of complex, open decisions between alternative actions", coincides with the cognitive capacity to make rational deliberations, and both represent the "internal condition" of

autonomy (Haggard, 2008, 944; Anker, 2020, 528). This internal aspect is the conscious power that drives outward action in a way that is representative of the agent's "true self", or the "basis of autonomous choice", motivated by "embodied capacities, commitments, bodily traits, values, and desires" that encapsulate the individual (Friedman, 1986, 22; Christman, 2009, 7). By adhering to this matrix of the internal self, decisions are rooted in the will of the individual rather an inherently external source. In contrast, the external factors represent anything that is outside of the individual, including but not limited to culture, social context, interpersonal relationships, education, and so forth.

The source of such "volitionally necessary aspects of identity" also makes it easier for individuals to authentically embrace what they are attaching to themselves (Oshana, 2005, 81). To emphasize this authentic integration of decisions and the reasons behind them, John Christman provides the "nonalienation condition" of autonomy (Christman, 2005, 279). This condition is created to counter the alienation that agents experience when they cannot identify with a view or trait that has been assigned to them, causing negative experiences that lead to some rejection of this trait (Christman, 2009, 143-144). So, the nonalienation condition requires that an agent identifies with the value or opinion that meets this trait without feeling the need to repudiate it after reasonably deliberating on it, per the procedural requirements of genuine reflection. As such, by meeting Christman's nonalienation condition, agent choices are considered to be autonomous when they can authentically identify with their holdings after adequate deliberation. Such a condition for autonomy also understands that "perfect independence" from external influences is not required as it is not possible; rather, that explicit coercive forces not be the directing force for decision making (Harris, 2016, 79). This recognizes the delicate balance between owning that individual's motives be formed

"independently of their socially constructed authority" (Benson, 2005, 108; Stoljar, 2000, 106; Benson, 2014, 128).

Just as people are recognized as being multi-faceted with "multi-levels of mentalistic phenomena" that influence contexts, so is autonomy (Friedman, 1986, 19). Not only does autonomy lie on a sliding scale that varies from one context to the next, its definition is also susceptible to changes across settings. Despite these differences, autonomy remains an inalienable and inherent right that all people possess, protected by law and authority (Misselbrook, 2013, 211). Even more than this is the notion that autonomy is, essentially, foundational to all laws and policies in a liberal democracy – even a pluralistic one founded on a variety of values (Levey, 2012).

Aside from the legal presence of the principle of autonomy, it is also a deeply entrenched ethical doctrine (Coggon & Miola, 2011, 523). In his *Categorical Imperative*, Immanuel Kant essentializes Human Dignity by specifying that people ought only to be treated as ends in themselves, never as means to an end (Hill, 1994, 9). This is because people are beings with rational capacities that can allow for decision-making and goal-oriented actions, such as the choice to agree to partake in genetic testing, and this "rational nature" is, for Kant, intrinsically valuable just by virtue of being rational (Kant, 2012; Cummiskey, 1996, 62). Following from this, humans, as rational beings, ought to be respected as intrinsically valuable and treated as such – even by one another. According to this view, people have a *duty* towards one another to respect dignity and uphold autonomy. Part of this is ensuring that individual autonomy is empowered, since any means of coercion and deception would be paradigm violation of Kant's Categorical Imperative and induvial autonomy (Dean, 2006, 51, 200). A clear case of this kind of violation in this context would be the failure to provide adequate debriefing and information prior to a genetic testing procedure. This would lead to a shaky consent, at best, and a violation of the requirement to ensure that people are able to make choices and take

actions based on "personal values and beliefs" (Dean, 2006, 200). Without clear instruction and information, people are unable to assess a situation adequately or form their values and beliefs accordingly, thus leading to a gross violation of personal autonomy.

The ethical importance of autonomy can also be linked to its personal importance. As previously mentioned, the volitional capacity is deeply intertwined with personal values and beliefs, that does admittedly require some level of cognitive capacity or competence (Seitz & Angel, 2020, 1; Beauchamp, 2010, 46). In addition to this cognitive aspect, there must be a kind of "perceptive and affective information processing" that takes place to corresponds to the formation of beliefs, opinions, views, and attitudes about the world (Seitz & Angel, 2020, 1-2). Although this project does not aim to argue that cognitive capacities are the *only* important aspect of volition and autonomy, it does not seek to deny their significance. There is a sense in which humans are recognized as being self-governing *because* they are autonomous, according to philosophers such as Kant (Schneewind, 2012, 6). This is due greatly to their cognitive capacities, as they are able to rationalize and conceive of duties and legislations for themselves that they must ensure they can follow (Ameriks, 2012, 93). Kant's view is slightly stringent and not entirely applicable in the case of genetic testing, they emphasize the value of humanity that is at the heart of all policies and legislations that concern autonomous decision-making processes to do with medical and healthcare.

More clearly, this personal sense in which autonomy is important recognizes it as a "basic psychological need" that is a strong predictor for well-being and flourishment (Deci & Ryan, 2008, 183). This is because autonomy is necessary for self-determination, functioning and decision-making across situations, regardless of whether it is diminished or maximized. It is "essential for optimal functioning" across contexts, cultures and situations, and so its personal, legal and moral significance is further enshrined (Deci & Ryan, 2008, 183). By accessing this essential need, personal identity is

bolstered and affirmed through the ability to exercise autonomy to direct decision-making and actions, such as partaking in genetic testing and similar procedures (Veltman & Piper, 2014, 4; Oshana, 2005, 78).

The basis of genetic testing has been discussed at length throughout this project, and it is clear that autonomy continues to play a central role. As the science and legislation in this novel area of research and clinical medicine continues to expand, so does the malleability of the philosophical understanding of agency. With the capacity to gain such in-depth access to one's genetic blueprint, there are many opportunities for making serious and impactful medical decisions – however, as this project has explored, these decisions start long *before* any meaningful disclosures of information. Even before stepping into a physician's office or a research laboratory, people have become privy, through internet access, to information on technologies like genetic testing which inform their decision-making. However, it is up to those overseeing the procedures to make sure that interested parties have a comprehensive and detailed overview of all related information, including the positive and negative aspects of undergoing any kind of procedure, including a DNA sample test.

Part and parcel of this detailed debriefing process is ensuring that informed consent is obtained prior to any procedures. Without consent, there can be no autonomy. This strong relationship has been exponentially expounded upon throughout the entirety of this project, and continues to form the basis for discussions going forward. By providing a fully informed consent, individuals – whether as patients in a clinical sense, participants in a research sense, or consumers using DTC tests – are committing to making a "certain kind of autonomous decision" to authorize a procedure upon themselves (Pugh, 2020, 160). This is a decision that is only empowered by having unhindered access to information that is accurate and comprehensible, while also referring to their personal histories, desires, and preferences. In this way, a person can be truly empowered to take ownership of their

decisions and subsequent actions (Benson, 2005, 101). Furthermore, with a full arsenal of information, they are able to internalize their decisions and provide ample justifications for their choices, thus ensuring that they do not become alienated from them even after the passage of time. This is especially serious in the case of genetic data, which might be the most personal information that one can disclose about themselves.

When information is revealed through DNA sample testing, people are able to learn more about themselves, including delicate data about their genetic makeup, further details on their "identity traits", thus implicating the way they make choices and what options they settle on with regards to treatment (Oshana, 2005, 78). These are all decisions that can only be autonomously made with ample information, consent, and respect for privacy without external coercion. The element of privacy is just as central to genetic testing, and follows suit from autonomy, where individuals cannot have autonomy without privacy and vice versa (Wilson, 2007, 353). Although privacy is an essential good, it is not "intrinsically good" in the same way that autonomy is, which is why is it is an "indispensable" requirement for the development of autonomous people that follows from autonomy (Kupfer, 1987, 81). In this way, its protection is instrumental to the creates the space for the flourishing of the ultimate (intrinsic) end, which is agency and autonomy.

5.2 Lock & Key: Privacy Continued

Privacy is both connected to and distinct from autonomy. It is a concept with a "long development" yet it continues to elude those who seek to define it, remaining in "disarray" and shrouded in vagueness (Lukács, 2016, 256; Solove, 2008, 1). Rather than focus on the vagueness of privacy, this project will attempt to capture the multifaceted nature of such a complex concept that is fundamental to autonomy and control over information in various senses, including legal and philosophical. This concept becomes even more important as the technological age continues to

advance, with things like digital technologies and genetic testing becoming more popular and accessible (Becker, 2019).

In Chapter 3 of this project, privacy was understood to generally be the desire and right of individuals to "choose freely how much of themselves to expose to others" – whether that be of their physical person, life, or personal information (Office of the Privacy Commissioner of Canada, 2016; Kupfer, 1987, 81; Office of Ethics, n.d.). This definition encompasses within it both the philosophical sense of privacy relating to control offered by Westin, specifically on informational control, as well as the legal sense of freedom to exercise private life. Privacy remains fundamental across the legal, philosophical and ethical spheres because it allows individuals to direct their lives, "irrespective of social and political pressures" (Mokrosinska, 2018, 118). While this may present a tension between individual privacy and society as a whole, it is better presented as an emphasis on individual privacy towards the betterment of society and the systems governing it (Mokrosinska, 2018, 118, 120). This is because, within a liberal democracy, privacy is a "necessary condition" for most values and rights, primarily that of autonomous development (Kupfer, 1987, 81). In a sense, privacy is a partial "form of self-possession" that protects from unwarranted and undesired external possession of the self (McCreary, 2008).

Unlike autonomy, it may be difficult to see privacy as being intrinsically valuable (Kupfer, 1987, 81). Aside from the development of the autonomous self, privacy is an instrumental conduit towards the development of "autonomy privacy", and according to Charles Fried, a fundamental value of intimate interpersonal relationships (Office of Ethics, n.d.; Fried, 1968). The main function of privacy can be understood as a protection from invasive interference into one's life, activities, preferences (Cohen, 2012, 115). Briefly, in the context of interpersonal relationships, whether in-person or online, people often self-disclose when getting to know others. Throughout self-disclosure,

individuals are allowing themselves to be vulnerable by revealing information about themselves (Crowley, 2019). Since it can often be difficult to disclose what is deeply personal, there is a "need to sensitively assess privacy from the given information" in light of potential benefits and losses in social contexts (Thon & Jucks, 2014, 4-5). This outlines the deep connection between self-disclosure and privacy, thus emphasizing the integral nature of privacy across various settings. It also aims to further distinguishes it from autonomy, whose main function is simply being free from interference.

Privacy, then, is clearly implicated in protecting individual interests, including their rights and liberties (Rachels, 1975, 323, 331; Solove, 2008, 21). Some have even gone to the extent of claiming that cases – legal or otherwise – involving privacy concerns are actually about "liberty and autonomy" (Solove, 2008, 31). This is because privacy is considered to be, categorically, a "precondition" for autonomy and the development of the autonomous self (Gumbis *et al.*, 2008, 80). As previously mentioned, the autonomous self requires privacy to ensure that it can exercise its rights and freedoms without having to allow unfiltered access to its personal endeavours or having a specific conception of the good life imposed on it. Specifically, "decisional privacy" is presupposed to autonomy, where this kind of privacy underlies unwarranted and unwanted external interference with decisions and subsequent actions (Lanzing, 2019, 559). As such, privacy is essential for safeguarding autonomy and self-determination and, by extension, liberal democracy. Furthermore, with an established understanding of both privacy and autonomy, the "autonomous self is definitionally capable of both choice and consent" (Cohen, 2012, 112). Due to this deeply entrenched connection between privacy and autonomy, many things such as personality development, decision-making, and informed consent continue to be impacted. The principle of respecting autonomy is a "negative obligation", meaning that it is a duty to refrain from impeding individual self-governance in ways that control or constrain (Christman, 2005, 107; 20). Within this principle, there are two concepts that can

be derived from within it: that of "to respect", and that regarding "autonomous choice" (Ebbesen *et al.*, 2015, 3). These concepts are clearly outlined in privacy practices across contexts, including genetic testing.

The relationship between privacy and autonomy is reflected in informed consent. Just as informed consent is a "prerequisite" for any clinical treatment or intervention, privacy is a precondition for autonomy (Valimaki *et al.*, 2000, 8). Privacy also seems to presuppose informed consent, in that the requirement to protect all personal information and maintain confidentiality is a necessity for both valid informed consent as well as for autonomous decision-making. By upholding conditions of privacy – whether informational, legal, decisional, or otherwise – Máté Dániel Szabó's definition of privacy, which is one's right to decide about themselves, can be promoted (Lukács, 2016, 259; Office of Ethics, n.d.). In doing so, the basic foundational tenets of informed consent that were outlined by Beauchamp and Childress, as well as the legal rights of and duties towards patients are adhered to.

This continues to be critically important in the context of genetic testing (Valimaki *et al.*, 2000, 9). Not only is privacy implicated at the start of the process, where individuals provide their sensitive information to physicians, researchers, or companies, it continues to be just as relevant after DNA samples are collected, analyzed, and retained. In a sense, all of one's information can be condensed into the sliver of genetic sample that is handled for analysis, and retention for the purposes of storage. As such, everything relating to this sample can leave individuals vulnerable, especially in light of the development of national and international genetic databases that are often referred to in forensic cases and research initiatives (Godard *et al.*, 2003, 100). The arising concerns surrounding data protection and confidentiality ensure that matters of privacy and informational control remain at

the forefront of consideration at every step of the way, since the kind of consent may differ at each point based on the condition of use (Godard *et al.*, 2003, 89).

Since the appreciation of privacy as fundamental to most basic interests and rights is evident in both the outlined concerns as well as the frameworks that uphold it, it may not be entirely farfetched to claim that there must be some kind of "special privacy protection for personal genetic information" (Tavani, 2004, 19). While this project will not attempt to outline a specific framework for this kind of privacy protection, it will maintain that the current legislations and policies are a good start to ensuring constitutional protections in the new genomic era (NHGRI, 2021; Office of the Privacy Commissioner of Canada, 2017). Their aim appears to be maintaining individual control over access to private information, including genetic data, which is essential for upholding rights including autonomy.

Although there have been concerns that these "reasonable" laws are inadequate at striking a proper balance between scientific innovation and personal rights, the consensus remains that striving for an advanced society cannot come at the cost of such rights (Tavani, 2004, 19; Christiani *et al.*, 2001). So much so that many experts have advocated for the application of human rights laws when regulating technologies such as genetic testing (CBC Radio, 2019). This would be essential for ensuring that the individual to whom the sample belongs is protected throughout the entirety of the genetic testing process, while allowing for innovations to take place.

5.3 Who's Got It? More on Ownership

The kind of control associated with privacy can also be seen as a sort of ownership (Solove, 2008, 26). Generally, ownership is explained in terms of economics and concerned with physical structures like property. Philosophers including John Locke, John Stuart Mill, and Karl Marx have provided competing theories that outline just how essential property is for affirming autonomy.

Locke argues that earth and all of its resources belong to the humans who inhabit it, instituting ownership (identified as the right to property) as the natural right to "acquire" from the earth (Locke, 1689; Oxenberg, 2010). This kind of ownership is used by individuals to sustain themselves by having and owning, but also having a sense of autonomy and agency over themselves (Locke, 1689; Hill & Nidumolu, 2021, 11). From this, follows Locke's concept of "self-ownership", which is defined as the independently natural right to themselves and the fruits of their labour; as such, everything within the person, everything the person creates, and everything they acquire falls under the umbrella of their property (Olsthoorn, 2020, 242; Neill, 1989, 226). Within the context of liberal democracies, this self-ownership can be expressed in terms of "the possession of 'certain unalienable Rights'" and a "realm of personal sovereignty", further emphasizing the importance of autonomy of the self (Seagrave, 2011, 711). Without this self-ownership, basic individual rights such as decision-making and privacy would be at risk of trespass, or may not even be recognized at the levels they currently are (Thrasher, 2019, 126).

Another theory that emphasizes this sense of control that individuals have over themselves is proffered by Robert Nozick, in what he describes as the entitlement theory. On this view, Nozick provides a view of distributive justice for the fair distribution of goods in a society, such that individuals have a right to their property without interference from governments or other parties (Davis, 1977, 220). Essentially, this theory of justice is composed of three main parts: individuals can acquire property in a fair, non-coercive manner and remain entitled to that property; individuals can also transfer said property to another as long as all parties in the transaction are in accordance with the terms of the transfer; and, should there have been some past violation of the two aforementioned conditions, this error must be rectified according to an appropriate theory of justice (Adie & Effenji, 2018, 80). In some sense, property can also be understood to be the person themselves, including

what is described as their "natural assets" (Rice, 2001, 242). As such, this sort of ownership that Nozick describes pertains to persons and themselves, so individuals have property rights over their own selves (Okin, 1987, 79; Kukathas, 2001, 8806).

Ownership is, in a sense, "an act of will" where persons recognize themselves to be the exclusive authority of themselves so that any decisions that will impact them must be made by them (LeFevre, 1966, 26). Since individuals have this kind of ownership over themselves, then any "product" of themselves – such as genetic materials – would be subject to the same notions of distributive justice listed by Nozick's entitlement theory. In accordance with his understanding of autonomy as being a fundamental moral value and the exigence of fairness and justice, then the decisions and choices of uncoerced individuals must be respected and empowered over the course of transactions (Lowe, 2020, 689; Rice, 2001, 241-242). This is especially important when the property in question is part and parcel of the person themselves, so a key compositional ingredient into everything that they are. In a way, this demonstrates how ownership presupposes autonomy – when people recognize the natural right to self-ownership and what that entails, they are able to understand what requires protection and how this protection can be ensured.

When applying these views of ownership to genetic testing, it is established that individuals own themselves, and that their bodies, minds and anything that they create from these natural resources are part of their property (Carter, 2019, 98).[5] As such, people are able to enter into uncoerced, unforceful "transactions" involving their DNA with the recognition that there are laws and policies that protect their interests in these dealings. The contracts that individuals enter to prior to these transactions – namely, informed consent contracts – ensure that they are fully debriefed of all

[5] A case that explores these complicated ties is *Peerenboom v. Marvel Entm't, LLC* (2017), where the plaintiff alleged that his and his wife's DNA was being collected secretly. This case stirred the conversation regarding personal ownership over genetic materials and established a legal precedent for judicial concern (Staley, 2017).

relevant information before, during and after the process of collecting genetic materials (Kadam, 2017; Resnik, 2009, 2). Genetic material, according to these contracts and the governing laws, must be consensually and willingly given away or shared. Any forceful taking of such private property warrants legal repercussions and reparations, in accordance with the entitlement theory established by Nozick. All of these elements serve to empower their autonomy, while protecting their privacy and ownership rights. These rights extend even beyond the tests themselves, to once samples are analyzed and retained – regardless of the testing context – as well as the implications for future innovation and discovery.

5.4 Conclusion

Overall, this chapter was mainly concerned with the ethical background of the philosophical concepts that ground genetic testing. While informed consent is the foundation of bioethics, there are principles that underlie that require attention to understand the transient nature of consent in this emerging context. Specifically, this chapter went over autonomy, privacy and ownership, providing definitions for these concepts and outlining how they intersect and interact with one another to create the landscape of informed consent in genetic testing.

Briefly, autonomy was defined as the ability of rational agents to make rational deliberations and decisions based on the cognitive, affective, physical, and historical information they possess. Essentially, autonomy is required for rational agents to engage in decision-making. While we appreciate autonomy for its own sake, regardless of its instrumental benefits, there are values that are just as important and just as necessary for the autonomous self, such as privacy.

In a technological age where access and information are essential aspects of participating in a data-driven society, privacy is a major concern. Privacy, while hard to define, is in the most relevant sense the state of being free from unwanted intrusion, surveillance, or interference – whether this be

with regards to one's decisions, self, or physical person. It also involves keeping one's personal matters private and safe, thus allowing individuals to conduct themselves without needing to disclose their private information. Privacy is an essential condition for bolstering autonomy, as an autonomy life is difficult to live if one is being intruded upon or if personal matters are made unwillingly public. This is required for genetic testing, which deals with very intimate and private details.

Ownership is also implicated by privacy. When it comes to biological material, there is an ongoing debate regarding who owns this private property and who can exercise rights over it. While it is agreed that individuals own their genetic sample, what happens with the results of testing depends on the context, which Chapter 6 will attempt to clarify. Working in tandem, privacy and ownership are essential for upholding autonomy and agency in individuals, who are then able to provide informed consent across the various testing contexts.

Chapter 6:
But Wait! An Enquiry into the Dark Side of Genetic Testing

6.1 Henrietta Lacks and The Other Side

A very infamous series of events that altered the direction of modern science and medicine, as well as policy approaches to biomedical advancements happened with the untimely death of Henrietta Lacks. In 1951, Lacks, a Black woman and mother of five living in Baltimore, was seeking treatment for cervical cancer (Nuwer, 2013; Deutsch, 2017). While she was being treated for her cancer, cells and tissue samples were removed from her tumor and sent to a laboratory "without her knowledge or permission" – which was a common occurrence at the time (Beskow, 2016, 397). Her cancer cells, dubbed HeLa cells, were discovered to have been able to reproduce and survive indeterminately in culture (Deutsch, 2017; Beskow, 2016, 397). Although this cell line became the basis for many biomedical findings that have been essential for modern medicine, and the HeLa cells remain viable and used even today, the means by which this science came to be should not be disregarded (Beskow, 2016, 397). Neither Henrietta Lacks herself nor her family were consulted or informed of any kind of usage of her biomaterial, and her descendants have yet to benefit from any of the "extremely lucrative" discoveries that the HeLa cells have given rise to – including the COVID-19 vaccine (Beskow, 2016, 397; Thaldar, 2023, 2).

Thus far, this project has focused almost entirely on outlining the mechanics of current legislations and policies of genetic testing, and discussing the relevant philosophical topics such as consent and privacy. This angle has allowed for an exploration into the current established dynamics involving healthcare practitioners and patients, and direct-to-consumer companies and their consumers. While these measures show a positive trend towards establishing procedures that can protect individuals seeking treatment or to learn more about their genetic information, as well as

ensuring that medical and research practices are completed safely and properly, genetic testing is not without its perils. The purpose of this chapter is to delve into the darker side of this continuously growing industry to demonstrate what exactly the hazards are for participating individuals across contexts.

The privacy and autonomy implications in the case of Henrietta Lacks extend beyond simply her own violated consent and trust in the medical context. Due to the various findings that her cell culture has given rise to, as well as the very public nature of her widely used genome, her descendants have a rather detailed, publicly available genomic profile even generations later (Nuwer, 2013). Not only does this expose her family members to information that they did not consent to receive, it also negatively impacts them through the stigma of genetic information. While there are currently certain safeguards against discrimination on the basis of genetic information, such as the *GNDA* in Canada or the GINA in the United States, these regulations may not always extend to all prevalent infrastructure – such as life insurance – or protect against social stigma. As such, Lacks' descendants are hugely disadvantaged by a continuing disregard for her consent, privacy or right to care, while reaping none of the financial benefits.

Henrietta Lacks' story is a sharp magnifying glass onto the issues within bioethics, and continues to present compelling reasons to remedy these fatal shortcomings. Even now, after many policy alterations and government-enforced regulations across the world, under certain legal standards, the doctors who harvested and used Lacks' cells for research would not have faced any consequences had there been no identifying information; specifically, the "HeLa" label that directly links the cell culture to Lacks (Thaldar, 2023, 4). While it is essential to ensure scientific progress where necessary, so much so that it is a fundamental human right that all people can benefit from these advancements, it is important to ensure that this progress does not come at the cost of human

rights (International Science Council, n.d.; Mann *et al.*, 2018). The pattern of lending preference to this progress in what can only be described as a flawed utilitarian calculus is a pattern of systemic issues that plague most publicly accessed institutions. The case of Henrietta Lacks is characterized as one of the most important cases in patient rights, privacy, and ethical considerations in healthcare and research, paving the way to the larger discussion this chapter will attempt to participate in.

It continues to be true that genetic testing is an extremely powerful and ever-advancing tool in the fields including medical treatment, research, and forensic investigation (USNLM, 2021). As much of this project has discussed, genetic testing has the unique ability to offer information about personal ancestry and makeup, even using this information to "predict" one's future. However, while the general sentiment is that genetic tests conducted within the clinical or research contexts are generally more secure and protected than direct-to-consumer tests, the case of Henrietta Lacks demonstrates that no tests are without certain risks (Ravenscraft, 2019). This great advancement does not come without a plethora of potential problems, including concerns about the very things that are meant to be fundamentally protected within legislative codes. Some of the main sources of concern with genetic testing are the infringement of privacy rights, and the breach of informed consent contracts.

6.2 Addressing the Issues

Like most invasive procedures in medicine and research, genetic testing requires informed consent. Many of the earlier chapters of this project have delved deeply into the history, legality and ethics of informed consent in order to establish its historical importance.[6] Despite its vitality, informed consent is not immune to the problems that usually plague the healthcare industry and

[6] Another significant case study on the importance of consent is the U.S. Public Health Service's Syphilis Study at Tuskegee (Heintzelman, 2003).

research contexts. One of these issues is the challenge surrounding communicating the pertinent information required to ensure that people are completely informed prior to engaging in procedures. A main requirement of valid informed consent is to ensure that individuals have a sincere "comprehension of adequate information", assuming they meet the underlying conditions of reasoning and cognitive capacities (Rego *et al.*, 2020, 2). Although the clinicians and researchers have a duty of care to ensure that they are conveying the information to their patients, there may often be a disconnect in communication considering the acute level of scientific literacy required. While a patient would suffer the consequences of not being fully informed, the onus is on the healthcare provider or researcher to ensure that they have a sufficient grasp of the details – including benefits and possible negative outcomes – before completing a procedure.

The important role of communication continues past the procedure and into the results phase of genetic testing, where the analyzed genomes are interpreted to aid in treatment, or informing patients of their genetic profile. However, genetics are complicated in the sense that they cannot be isolated from one another or from the external environment (Lobo, 2008; Waters *et al.*, 2014). Attempting to communicate this nuanced relationship is necessary in the debriefing stage prior to obtaining informed consent, but it is just as important to ensure that it is understood throughout the interpretation stage. While it can certainly render the informed consent fragile, if not invalid in some cases, it also has long-term implications for how patients approach treatment decisions and plan their lives going forward.

Similarly to other kinds of tests, genetic tests can also result in tests that are either invalid or inaccurate, or even "uninformative, indeterminate, inconclusive, or ambiguous" (USNLM, 2021). Aside from the positive or negative results, genetic tests can yield false positive or false negative results. The former, false positives, occur when results indicate a risk for a certain condition in an

individual that is actually unaffected (e.g. they do not have the indicated genetic condition or related mutation) (USNLM, 2021). On the other hand, false negatives refer to any results which indicate the absence of any kind of genetic condition in an individual who is actually affected (e.g. the person does have the related condition or mutation) (USNLM, 2021). This demonstrates how inaccurate genetic tests can be, which is a major weakness that can lead to a variety of issues. It is also a reminder that "testing is targeted", so patient expectations ought to be managed in the process of debriefing in order to ensure that results are not misinterpreted (Joy, 2017). While it is hard to strive for complete accuracy with any kind of testing, the stakes with genetic testing are entirely too high to rely on large gaps in statistical accuracy and correctness (Evans, 2019). The inaccuracy can lead to things such as missing genetic markers for diseases, which can require further testing and may lead to incorrect assessment and treatment, or a false sense of security (USNLM, 2021). Although this risk of inaccuracy is especially high in direct-to-consumer testing, it is present in other kinds of genetic testing such as pre-natal testing (Kliff & Bhatia, 2022).

In addition to the physical impacts of genetic testing, people can experience a heavy psychological impact. Regardless of the result, it is possible that the tests themselves can generate experiences such as "anxiety, distress, and depression" depending on their knowledge and perception of the tests (Oliveri *et al.*, 2018, 2). This is an important reason for why genetic counselling and complete debriefing are essential prior to the procedures. Even during the counselling processes with medical professional, people can experience these unpleasant reactions when informed of the potential risks that they may be faced with from testing. Research has suggested that, overall, people who experience such psychological reactions to their negative results do not see a decrease over time (Guyatt *et al.*, 1998, 694). It may be an indication of their risk perceptions and beliefs about the disease controllability but there is also the possibility that factors external to the tests themselves have

an impact on psychological state and reactions (Oliveri *et al.*, 2018, 3; Guyatt *et al.*, 1998, 694). Such factors include long-term decisions and the effects that these tests may have on family and community dynamics.

6.2.1 Collective Consent

Although genetic testing is, prima facie, an inherently individualized activity, it has far-reaching community and social implications. Despite these tests focusing on examining a single individual's genetic materials, those who share this genetic material are not and cannot be exempted from the implications of the results. With only one simple biological sample, all members of one's immediate and distant family can be identified, such as with the case of Lacks' family and descendants, whose entire lineage and genome is now accessible to everyone including any relatives.[7] This is especially the case for instances involving "proof of paternity", and revealing information about shared genetic traits, including predispositions and risks within the family (Clayton *et al.*, 2019, 23). In some cases, genetic information can even lead to the determination of other private data about the family of the tested individual, such as their insurance information (Magistro, 2021; Andrews *et al.*, 1994, 252). While the individual undergoing the test has assumedly been privy to some form of genetic counselling and comprehensive debriefing prior to providing their fully informed consent, this is not the case for the other members of their family or community. Despite their individual consent and privacy being taken into consideration, there is still a large negligence taking place. Not only did family members not consent to the disclosure of their intimately private information, they also did not consent to having these details communicated *to* them (Gilbar, 2007, 390). Sometimes, this

[7] It is worth noting that this is more of a major concern for people who already have relatives in any of the databases.

information can also be disclosed to family members without the patient's consent, especially in direct-to-consumer testing scenarios (Gilbar, 2007, 390-391; Phillips *et al.*, 2021).

Here, it becomes clear that there is some sort of tension between the individual interests and rights versus those of the collective, namely the *relative* collective. Even with the current laws protecting privacy and genetic information established worldwide, they are not broad enough to cover the wide expanses of patient and consumer interest beyond the individual themselves. Most of the fundamental laws protecting genetic testing and data do so only with regards to employment and health insurance, leaving a wide space of vulnerability outside of this focus. While it is certain that these laws are "necessarily narrower in scope" to accommodate for this delicate and specific area, it may be that the tunnel focus creates larger societal pitfalls that can go ignored – such as the rights of relatives (Clayton *et al.*, 2019, 8). As well, in focusing solely on health insurance and employment, individuals are left compromised to discrimination in other areas such as life insurance, disability, education, and in general social settings. There is also something to be said about the allusions that DNA testing and genetic data have on group identities, as well as the potential for genetic determinism within the nature versus nurture debate (Keogh, 2019; Chadwick, 2012; Kachanoff *et al.*, 2022). The arising stigmatization of genetic testing and the diseases have the potential to harm not only the individual getting tested, but their family as well (Sankar *et al.*, 2006). These kinds of attitudes conform to the general pattern of stigmatizing diseases and those who (may) possess the related "undesirable traits" that come with the disease or having genetic markers for it, which could impact the community (Markel, 1992, 209).

Though individuals may have a duty of care to disclose pertinent medical information to those family members who are impacted by it, it is not simply a matter of communicating with them. Since external persons are not legally or ethically protected, according to the current standards, there

must be some etiquette for how they are approached regarding these matters. Not only is it harmful for the adults in the family, but also any children in the family (Clayton *et al.*, 2019, 31). While a "plan of non-disclosure" could serve as a strong protection against harms to family dynamics, there may still be a duty to warn or inform related parties of potential risks (Botkin *et al.*, 2015, 15; Laberge & Burke, 2009, 657). This duty continues to clash with collective rights, including privacy, confidentiality, and consent rights, which can be undermined in the pursuit of empowering the individual counterparts. To alleviate this, there are measures to ease the conversation between family members, including letters provided by healthcare professionals outlining the risks and testing options for implicated relatives (Phillips *et al.*, 2021, 2038). Although this is conversation-starter, it does not answer the consent and privacy violation that family members will be faced with. It also raises the possible issue of "subtle" or "not-so-subtle" testing coercion for these family members, who may be forced to get genetic tests or disclose their private information to others upon receiving this kind of knowledge (Rego *et al.*, 2020, 3). Any kind of coercion would impact the "voluntary" contributions made by any individuals, thus diminishing their autonomy and the validity of their consent in that context (Toom *et al.*, 2016, 2). Not only would this be a severe ethical violation, but it could also come with legal repercussions, including setting a negative precedent for how genetic testing can be conducted.

Another weakness in the testing models is presented here in the form of lackluster support for families. Aside from the conversations regarding ownership and privacy, families may require some kind of support throughout the process of genetic testing due to the psychological experience going into the procedure, the experience itself, as well as the results. Though there are some services that aid in ensuring that the families of individuals being tested are "appropriately informed" of the relevant information, there are no counselling-like services to alleviate the specific pressures the

genetic testing have on dynamics and the individuals within them (Lucassen, 2007, 22). Other kinds of support that families may require include economic funding or education, but these resources are often scarce if at all available (Andrews *et al.*, 1994, 30).

This project does not aim to provide solutions for these problems. Aside from providing a systemic overview of the fatal shortcomings of the laws and policies governing genetic testing across context, there are yet to be any tangible resolutions that this chapter will contribute to. Some have suggested that the current individualistic model of informed consent, which favors the individual over the collective, is inadequate enough to be replaced by a more substantial and comprehensive model – at least in the case of genetic testing (Hallowell, 2009). So instead of viewing consent as private and personal to the individual, it should be treated as a matter that – rightfully – implicates a group of people that deserve to have their consent and privacy prioritized as well (Magistro, 2021; de Groot *et al.*, 2021, 789). This is a model that is still in the early stages of development, but has the potential to overcome many of the shortcomings of the widely used individualistic model. In this way, there is a sense of shared decision-making that does not require difficult conversations and tense relationships after-the-fact. It also respects the autonomy of all involved parties by allowing them to voice their opinion on the matter and how it will impact the long-term health and financial standing (among other things) of the family. The shared consent model would also conform to cultures that are more collective than individualistic, including families with strong multigenerational ties, or those with specific religious and culture practices (Pecotic, 2019; De Castro & Teoh, 2010).

Arguments for the recognition of health information and data as being property have been underway and are generally widely accepted. Establishing such notions is necessary, since there are very real concerns regarding "who is entitled to control, and benefit from" such property, as well as its exploitation (Montgomery, 2017, 82). As this project has previously discussed, ownership

concerns are necessarily ingrained into discussion of autonomy and privacy, so it should come as no surprise that genetic testing pushes the boundaries of ownership. From an ownership and property standpoint, the shared or collective consent model would hold that DNA is a "form of shared property" that could at once be attributed to the individual and the group (Magistro, 2021). They argue that it is an "individual's social embeddedness" that fosters their individual autonomy, so the collective ought not to be separated from the individual when they are implicated (Gilbar, 2007, 390). There is also a sense that certain patients feel that they are the "custodian[s] of the DNA" that has been passed down to them from their parents, thus indicating an inherent sense of shared ownership and oversight (Malakar *et al.*, 2023, 3). It is recognized as a precious "part of a family resource" that is accessible to all those who "contribute" to it (Montgomery, 2017, 85). Furthermore, just as there are measures in place for the protection of collective intellectual properties such as histories, traditions and knowledge, there may be space for allocating similar, relevant protections for the collective rights of genetically bound communities (Santilli, 2006, 2; Wallace, 2012).

Others have argued that this collective consent represents "logistical hurdles" that come with different contexts of testing, making it a rather difficult requirement to maintain (Pecotic, 2019). They also disagree with the definition of the collective, which could either be a "group," "community," or a "population", including subgroups like family and friends (Ganguli-Mitra, 2008, 122). These ambiguous definitions allow for volatile boundaries that may be "detrimental" to the research itself and to the rights of the individuals within the shared collective (Ganguli-Mitra, 2008, 122). It is at once an acknowledgement of the weak genetic laws that are currently used, and a commentary on how there might not be a possible solution for the weaknesses they present without instilling other major violations. In place of this collective or shared consent, they have advocated for a consideration of the context to determine whether collective consent is warranted or whether individual consent is

sufficient. There have also been some that maintain that individual consent remains the priority in these settings, because one's DNA is their own property and thus requires only their own permission.

Although ownership in the clinical and research contexts is *generally* given to the individual to whom the genetic sample belongs, there is some tension in completely assigning ownership and control when considering the benefits that such samples provide. In cases where research has led to leaps in medical treatment of certain ailments, some have suggested that the genetic data (and any products emerging from its analysis and use) belong to the "laboratory or the heath service" that generated it (Lucassen, 2007, 23). Sentiments such as this encourage relegating patients and research participants to means for the end of scientific advancement, a sordid utilitarian outlook that can be interpreted as being dehumanizing and predatory. This is especially the case in a progressively technological world that relies on commercialized big data and binary information. While individuals should have the right to "receive their genomic raw data" in order to empower their autonomy, understanding and awareness, it is unclear that this necessarily means that they in turn own this data (Schickhardt *et al.*, 2020, 3, 10). Rather, it is likely that they would be receiving a copy of their raw data to assuage their concerns and meet the ever-increasing demands to have access to their data. This is not necessarily the same thing as sole ownership and control over the future uses and distribution rights of their intimate genetic data. Even with the (limited) explicit legal recognition of "rights of ownership, possession, control, and privacy" of individual and familial genetic material, this does not entirely clarify the ambiguity that exists with regards to patient and participant ownership (Clayton *et al.*, 2019, 33). Some interpretations even go as far as stating that "there can be no single point of ownership" between the individuals, their families, governing bodies, and the scientific community or testing company (Malakaret *et al.*, 2023, 2).

Certain definitions of ownership hold it to be "both the possession and responsibility for information" (Belani *et al.*, 2021, 3). What this appears to mean is that aside from having a rightful sense of control and proprietorship of the property in question, in this case being the genetic material, the individuals are responsible for the maintenance and protection of their own data. This might include responsible action, such as ensuring that they are as informed as possible of procedures. It also means that they are owed a duty of care, including disclosure and confidentiality, where those handling this delicate data are responsible for ensuring its protection. While this sense of ownership might be successfully filled – under the current standards – in the research and clinical contexts, the direct-to-consumer genetic testing context is faced with other complications.

The purpose of this thesis is not to explicitly outline any frameworks for solutions but rather to provide examinations of the issues and potential *criteria* for solutions. Yet, there is something to be said about collective consent. It is clear that this notion of shared consent must be given just as much consideration as individual consent in genetic testing, because it implicates others outside of the individual. However, it may be more complicated than simply saying that collective rights should be taken into consideration. Although the aforementioned views of collective consent and DNA being a shared property might be novel to philosophy and bioethics, shared interests have long been fundamental for cultures with collective values, which in its self should render it a staple consideration in discussions of consent. But since it is not, there are still other reasons why incorporating collective consent is a necessary step forward, including the benefit it would provide for companies.

Basically, in order to avoid any potential legal or ethical qualms with groups who share an interest in a genetic sample or result, it would be wiser to implement considerations of collective consent as a standard procedure. This is regardless of whether that looks like a longer process for

obtaining informed consent from all relevant parties or implementing other forms for ensuring collective agreeance may take some time to establish. Furthermore, it seems like failing to incorporate collective consent in bioethical proceedings means that the gap towards ensuring ethical and equitable access to healthcare and research will continue to grow as new technologies develop. It also means that essential relational characteristics for social healthcare, like fostering autonomy and trust, will fall into the abyss of this gap. As such, it is not necessarily a matter of implementing a novel framework to disrupt a system in motion, rather incorporating measures of collective consideration into existing consent frameworks to ensure that *both* individual and collective consent and autonomy are being seriously taken into consideration.

6.3 Direct-to-Consumer Genetic Testing

The technology that alleged to solve many of these problems is the direct-to-consumer genetic tests that many independent companies developed. They sought to provide an advanced scientific tool that allowed people to access their most miniscule information at an affordable price point, and with full privacy and control over said data. At least, that is how they advertised their products. This democratized inquiry into the genome bypasses healthcare professionals by highlighting how individuals had all the power and authority to make decisions on their own behalf. On the surface, it seems like an excellent opportunity to bolster autonomy and encourage education on such technical matters in a way that is equitable and easily accessible since it does not require healthcare professionals. However, these technological marvels are not without their downsides (Panacer, 2023, 2).

In addition to the very many disadvantages to genetic testing that have been discussed throughout this chapter, including inaccuracy results, difficult interpretation (especially without the aid of a healthcare professional or genetic counsellor), privacy concerns, and potential psychological

impact, there are other more specific issues. These issues are just as prominent, if not of more concern in the context of direct-to-consumer testing, since these tests are not as specifically regulated as tests used in research or medical settings, as discussed in Chapter 3 (Cernat *et al.*, 2022, 155; CMA, 2017). Direct-to-consumer tests are, generally, regulated differently across regions, so the federal and national laws that bind these companies could be different to those laws in specific provinces or states. Not only is this lack of consistent regulation problematic for assuring the quality of the product itself, it also means that consumers have "no legal guarantee" that the products will work as described or that their information will stay private (Consumer Reports, 2020, 3). As these tests are not strictly regulated or bound by laboratory standards set by codes such as the *Clinical Laboratory Improvement Amendments* (CLIA), there is no way for individual consumers to ensure that these companies are meeting the same duty of care that other testing service providers are required to. It is also the case that these tests have a limited scope of testing, since they focus on very specific aspects of the genome – either searching for ancestry markers, rare diseases, or other targets, based on specialization and client needs.

While it may seem that these companies are meeting a need that the traditional testing routes are unable to, whether that be in specific versatility of target testing or affordability and variety, it is crucial to recognize that DTC companies are just that – companies. They are not necessarily working towards to the advancement of technology, but rather the increase of their profit margins in an innovative market niche that is estimated to "range from $600 million in to the billions," with an expected increase in coming years (Kliff & Bhatia, 2022). When developing their products, they are likely more focused on how their products can be differentiated relative to their competitors, rather than overall benefits to the consumers themselves. In order to put their best foot forward for potential customers, companies that offer DTC genetic tests may refrain from publishing numbers, from

providing objective framing for publicly accessible data, or providing warped study results as support for their success (Kliff & Bhatia, 2022). Of course, this is done with the purpose to ensure that their product is presented to be successful and reliable as possible. This kind of misleading marketing is usually gone "unquestioned by outside reviewers" and "unchecked by ethical considerations," making it easier to deceive consumers (Nill & Laczniak, 2022, 670; Nelson & Robinson, 2014, 114-116).

Since they operate as businesses rather than healthcare institutions, the shaky regulations governing DTC companies impact more than just the products themselves. Most companies offer some kind of informed consent, an agreement between consumer and company regarding the intricacies of the testing and bounds of protection offered through the service. While previous chapters discussed informed consent in depth, the most relevant issue is the inability of informed consent (as proffered by these companies) to protect privacy, confidentiality, as well as ownership of data. The information age is heavily characterized by data and in the emergence of over-present technology that enables faster and more-efficient data collection (Brown *et al.*, 2011, 1). What is of greater interest and concern is the commercialization of this information, often collected without full consent or transparency, and its distribution to third-parties for profit maximization (Davenport & Dyché, 2013, 8). Formally, economics is inextricably tied to "the analysis of large-scale data sets," which is part of what these DTC testing companies – as well as other genetic testing institutions – do (Einav & Levin, 2014, 716).

To provide a sense of comfort and protection for their users, many DTC testing companies have specific clauses addressing privacy and data in their informed consent agreements (The DNA Geek, 2017). On the surface, it appears that the wording is designed to protect any information that is disclosed to these companies, whether it is given to them explicitly through forms and registration and DNA samples, or unknowingly through internet access. This can include data about internet

activity on other websites, such as social media platforms (Colbert, 2018). It is of importance because, for many, the modern notion of privacy has more to with "being in control of the distribution and use by others" of one's information, especially with regards to health and finances (Clayton *et al.*, 2019, 2, 17). Upon closer look, however, these protections are weak and complete with loopholes that allow these companies to use, distribute, and profit off data in any way that they choose under the guise of it all being previously consented to. Where some legal jurisdictions happen to "prohibit" any explicit "collection and disclosure" of such information for the commercialization and distribution, there are loopholes that these companies take full advantage of to increase their profit margins (Gerards & Janssen, 2006, 367).[8] One such loophole is included in the tricky phrasing adopted in the agreements, which may allow consumers to retain ownership over the DNA samples they provide, but not the data that comes from the sample (The DNA Geek, 2017). For companies operating under for-profit models, the data is usually of "higher commercial interest" than the DNA samples themselves or the products (Vayena *et al.*, 2008, 32). By claiming that no data will be shared with third-parties without "explicit consent," individuals are lulled into a false sense of security that encourages them to pay for the genetic testing services (The DNA Geek, 2017; Magistro, 2021).

But it is the case that people have and continue to use direct-to-consumer genetic testing services to obtain more information about their genomic profile. The course of questioning, when faced with these issues, is what these companies plan to do with the information that they collect from individuals. While consumers are advised to "[s]crutinize each company's website for details about what they do with your personal data" and "read the company's privacy policy" prior to making any kind of commitment, it is not always apparent on the surface what these companies will really use the

[8] This is especially the case in Europe, as these kinds of provisions are not explicitly stated in North America regulations (Gerards & Janssen, 2006, 391).

data for (Colbert, 2018; Ravenscraft, 2019). DTC genetic testing companies claim to only share collected data on an "opt-in basis," meaning that they act only in accordance with the prescriptions of the agreement that consumers sign and share what consumers allow them to (i.e. the informed consent agreement). Regardless of the truth of this, reports claim that approximately 80% of consumers opt-in to freely share their data with these companies (Segert, 2018).

Many of the privacy provisions appear to rely heavily on consumers being unfamiliar with the language used in such agreements, and being unwilling to spend the time reading the long legal documents before agreeing to anything. So, another way that they appease to consumers is through the use of "click-wrap" or "browse-wrap" forms of agreement, which are short and easy to read (Hendricks-Sturrup & Lu, 2019, 2). This may be a convenient way for these companies to gain access to the information that they so seek, which they are very willing to share with third-parties, like consulting companies, data analysts, and research labs (Hendricks-Sturrup & Lu, 2019, 2). Even with these provisions and agreements in place, however, these companies may still be able to share data, including "deidentified" information and the results of the tests (Clayton *et al.*, 2019, 17). There is a wavering caveat to these privacy provisions that can allow genetic data to be disclosed and commercialized with all third-parties, except for law enforcement (Clayton *et al.*, 2019, 18; de Groot *et al.*, 2021, 789). Not only is this a way to "protect" the rights and privacy of the consumers who provide their data, but it is also a way to protect the company and its right to conduct business. This is not to say that law enforcement and governments alike are not making demands from DTC testing companies to provide information on individuals – it just so happens that the companies are less likely to comply with this form of data sharing.

When companies commercialize and profit off this genomic data, it also raises a question of ownership. Although companies do not usually claim explicit ownership over the genetic information,

assuring consumers that they retain these rights in their informed consent agreement, they often prefer to retain the "broad rights to commercialize the resulting data" after analysis (Clayton *et al.*, 2019, 17). Perhaps some of their motivation is to provide data for research purposes, since many people seem reluctant to join research studies, portraying the commercialization of data as an act for the greater good (Stoeklé *et al.*, 2016, 3; Raz *et al.*, 2020, 460; Hendricks-Sturrup & Lu, 2020). In the clinical and research contexts, there is a growing movement towards recognizing patient rights to data ownerships – this includes the raw genomic data and the results after analysis – however, there is no such advocacy for consumers (Malakar *et al.*, 2023). At the present time, this question of ownership hangs in the air, but it presents a critical need for clear and explicit definitions of genetic privacy, as well as the rights of patients and consumers in this ever-growing industry. It also calls for ensuring protections against the many violations that come with direct-to-consumer genetic testing, other than those previously mentioned.

Individuals providing DTC testing companies with their genetic data and personal information renders them as nothing more than figures in a large database. Despite the safety measures and the caution of the modern technological age, the interest in pursuing data by any means necessary leaves way for major compromises (Edge & Coop, 2020, 2). These data breaches can allow for the private information to be accessed by the wrong parties for the wrong reasons, thus weaponizing people's most intimate data against them (Belani *et al.*, 2021, 1). During the process of obtaining informed consent, individuals usually are not informed of these potential data breaches, leaving them even more vulnerable to surprise attacks should the company find itself compromised. Such cyber-attacks, while increasingly concerning, are also generally "preventable" by following a veritable set of techniques, including ensuring that consumers are informed of the possibility of such breaches (Edge & Coop, 2020, 13).

6.4 Implications for Future Scientific Discoveries

The ownership of genetic materials also has profound implications for future scientific discoveries. While companies can claim to share the data with third-parties that are involved in research for the purpose of scientific prosperity, there is no way to ensure that they are providing all the information, if any at all. By claiming ownership over the data, these companies can exert a certain amount of control over who has access to it – whether it be the consumers themselves, or other third parties. The main motivation for the commercialization and distribution of data is for monetary gain, and it may be unlikely that such a compensation will be reaped by these companies from disclosing data to research facilities. Once these facilities receive the information, however, it becomes theirs entirely since it is usually anonymized and deidentified (Montgomery, 2017; Clayton *et al.*, 2019, 6). And to that point, either party (the DTC genetic testing companies, or the third-parties that purchase the data sourced by the companies) may be eligible to patent and further profit from the results of the testing. Unfortunately, the consumers (or patients or research participants) are unable to patent their own genetic material or raw genomic data since current intellectual property laws prohibit "patentability of naturally occurring things on the basis that no intellectual capital has been invested in them" (Montgomery, 2017, 83). So simply providing the base genetic materials for any discovery is considered to be an insufficient contribution for intellectual proprietorship. This is likely to further deter people from participating in research or perhaps even completing direct-to-consumer genetic tests.

Despite genes themselves not being able to be patented, the arising inventions and discoveries can be. On one hand, this may be a positive thing – encouraging intellectual development that can benefit all, especially in cases of medical treatment. On the other hand, it can lead to certain negative outcomes, including the monopolization of subsequent treatments, which can limit access and drive costs. The biotechnology industry is a large monolith industry that brings in over $43 billion every

year, most of that based on patented products with a high price tag and an even higher profit margin (Roberts, 2018, 1108). While this may change as more people become cognizant of their rights to their own genetic material and any subsequent findings, regardless of whether the testing takes place in commercial or research settings, as it stands, there is a race towards ensuring that the science remains financially gainful above all else.

In spite of the emphasis on informed consent and debriefing patients and participants before completing any genetic testing, it appears that this burgeoning area of biotechnology is still rife with problems. Most of these problems can be condensed to the fact that the informed consent process is not nearly as complete as it should be and lacks sufficient transparency, especially in the commercial contexts. While companies are not bound to the same laws and regulations that research labs and healthcare institutions must conform to, they ought to follow some semblance of standards that organize more than just their business conduct. Without this, they will continue to prioritize data mining and commercialization for the sake of profit, over valid and efficient products that protect patient autonomy and privacy while also working towards furthering scientific discovery for the greater good. As it stands, there is still much work to be done.

Chapter 7:
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In pursuing the intricate depths of genetic testing, this thesis has grappled with different levels of ethical considerations. By exploring the plethora of issues surrounding informed consent for DNA testing, the privacy and ownership guidelines surrounding genetic testing, this project was able to compile a comprehensive profile on the complex web of ethical, legislative and policy, and social dimensions of this growing niche of biotechnology. The main task of this thesis was not to necessarily offer a new outlook, but rather demonstrate how the current ethical and legal structures operated in tandem to regulate this booming industry. It sought to demonstrate that, while vast and continuously growing, this web was not infallible, especially in light of the changing technological landscape.

As Chapter 4 demonstrated, the principle of informed consent is one of the fundamental pillars of bioethics in general, including genetic testing. This principle requires that individuals are provided a comprehensive understanding of the procedure itself, the benefits and risks, as well as any consequences that may arise as a result of their decision to get tested. It is upheld through various legal statutes and institutional policies that were extensively covered in Chapter 3. Furthermore, it imposes itself on the autonomy of individuals and those around them, thus elucidating the delicate balance between genetic testing and personal rights, a topic which Chapter 5 discussed extensively. However, even though it is heavily protected and cited across laws and policies, the reality of informed consent is that it cannot protect against everything individuals might face in their genetic journey. Some of the challenges include the commercialization of private information, considerations of collective rights and interests, as well as the validity and efficiency of tests, many of which were covered in Chapter 6 of this thesis.

Underlying this thesis is the poignant question of genetic data ownership, the implications of which extend beyond the healthcare context. Most importantly, data, in general, is the lifeblood of research and, by extension, future discoveries and innovation. However, in attempting to understanding commercialization, patenting and intellectual property, we can see just how contentious and vague the current frameworks of privacy and ownership are, and just how these ill-defined boundaries allow for trespasses on justice and rights. Not only are clear and well-defined description of both privacy and ownership required, especially for the purposes of genetic testing and genomic data, but so are consistent understandings and applications. This will guide the development of jurisprudence in this area of biotechnology and ensure that individuals are able to go in with a clear understanding of how they are protected when engaging with genetic testing.

An emerging topic that underlies this discussion is the tension between scientific autonomy and individual autonomy. Although both are necessarily valuable in their own right, a very delicate balance must be struck to ensure that one is not being prioritized or compromised for the prosperity of the other. While difficult, it is a consideration that must be engrained into the development of all legislations and policies that are relevant to genetic testing to guarantee constitutionally mandated rights. Without this kind of tenacious reform, the tension between protecting individual rights and equitable access to biocare such as genetic testing against the incentivization of innovative development may never be adequately resolved.

Though this thesis covered a large scope of this growing area, there were still many points that have not yet been considered. Such topics include the complexities surrounding genetic testing for minors and children, which come with their own specific set of analyses on parental ownership and rights over their children, or how minors are able to provide informed consent in such contexts. Another topic of interest that was not discussed is the impact of media representation on genetic

testing. Biotechnology is very much well and alive within the zeitgeist, so it is a requirement to acknowledge that at least some of the public perception of genetic testing is the result of pop culture knowledge. Not only is media a potentially accessible way to drive interest and drive people towards seeking out information, but it also creates a medium for economic incentive to push testing across contexts.

All of this is not to dismiss genetic testing or its benefits. Rather, it is a call for exercising diligence and caution when developing these technologies by ensuring that they are properly and consistently regulated without restricting access. It is also a call for drafting clear definitions for the most pertinent philosophical concepts that lie at the very center of these discussions, as otherwise, there is room for misconduct, frivolous trespass of personal rights, and taking advantage of patients and consumers. The merits of such investigation are the ethical utilization of genetic research output towards developing novel sciences that can be widely beneficial, and perhaps even encouraging business ventures that do not rely on data mining for profit.

There might be hope for a renaissance yet.

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