

-REPORT TO THE OFFICE OF THE PRIVACY COMMISSIONER OF CANADA-

**PROTECTING PRIVACY IN THE POSTGENOMIC ERA:
ENSURING RESPONSIBLE DATA GOVERNANCE BY EPIGENETIC,
MICROBIOMIC, AND MULTIOMIC DIRECT-TO-CONSUMER COMPANIES**

16 July 2020

Principal investigator: Yann Joly, LL.M., Ph.D. (DCL)
Co-investigator: Charles Dupras, Ph.D. (Bioethics)
Research Assistants: Elisabeth Beauchamp
Teres Knoppers



Centre of Genomics and Policy
Centre de génomique et politiques



McGill
UNIVERSITY

TABLE OF CONTENTS

INTRODUCTION	3
LITERATURE REVIEW OF PRIVACY CONSIDERATIONS IN OMICS	3
Epigenetics.....	3
Microbiomics.....	4
Multiomics	5
METHODS	5
FINDINGS	7
1. Consent - PIPEDA Principle 3.....	7
2. Openness - PIPEDA Principle 8	8
3. Accountability - PIPEDA Principle 1.....	11
4. Identifying Purposes - PIPEDA Principle 2	12
5. Limiting use, disclosure and retention - PIPEDA Principle 5	13
6. Safeguards - PIPEDA Principle 7.....	15
7. Individual Access - PIPEDA Principle 9.....	16
8. Challenging Compliance - PIPEDA Principle 10.....	18
DISCUSSION	18
1. Epigenetic and microbiomic data as “personal information/data”.....	18
2. Epigenetic and microbiomic discrimination.....	21
3. Anonymization and Aggregate Data	22
4. Other considerations for DTC-MoT companies	23
RECOMMENDATIONS	23
Best Practices Guidelines For DTC-MoT Companies.....	23
Information brief for the Canadian public.....	30
Note d'information à l'intention du public canadien.....	31
REFERENCES	33

INTRODUCTION

Over the past four years, private online companies have begun selling epigenetic and microbiomic tests to the public. Most of these tests are marketed as tools to provide customers increased control over their health and wellness. Companies offer tests for a wide variety of conditions, including biological aging, gut microflora composition, skin type and fertility. Many also provide health and lifestyle advice as part of their product. While health-related direct-to-consumer (DTC) testing is not a novel phenomenon in of itself, epigenetic and microbiomic tests constitute a shift into new omic territory that brings unique privacy considerations. Given the nature of the data they collect, these tests (DTC-MoT below)¹ present significant privacy challenges that fall outside the scope of currently existing regulatory frameworks. However, while considerable attention has gone towards the practices and policies of DTC genetic testing companies, these newer forms of omic testing have largely escaped scrutiny. In order to fill the gap in literature, we provide an overview of currently existing DTC-MoT companies and of their policies. We identify best practices for DTC-MoT companies and provide guidance for consumers when using DTC-MoT services.

LITERATURE REVIEW OF PRIVACY CONSIDERATIONS IN OMICS

Over the past decade, omic databases have increased in number, volume, and diversity. Today, these databases include not only significant amounts of genetic information about individuals and populations, but also other types of complementary data such as epigenetics, microbiomics, proteomics and metabolomics, among others (Jansson and Baker, 2016; Hasin et al., 2017). Among these complementary omic types, epigenetics and microbiomics have received the most attention. A number of concerns regarding privacy issues in epigenetic and microbiomic research have been identified in academic literature.

Epigenetics

Epigenetics is the study of heritable changes in gene function that do not entail a change in DNA sequence (Wu et al., 2001). Epigenetic modifications include DNA methylation, the chemical modification of histones and interference at the RNA level (Dupras, Ravitsky, and Williams-Jones, 2014). These modifications have a major influence on the variability of gene expression, protein synthesis, and disease development across individuals and situations. Epigenetic modifications have garnered a lot of attention in particular for the fact they are dynamic, reversible, and influenced by our physical and social environments.

One of the main questions related to the protection of epigenetic privacy is whether epigenetic data constitutes personally identifiable information (Backes, 2016). Privacy risks in epigenetic testing and research were initially disregarded in part because of the supposition that epigenetic data was de-identifiable, and as such, it did not warrant privacy protection (Philibert, 2014). However, studies published in recent years refute this assumption (Diemer, 2015; Philibert, 2014). For instance, it has been shown that methylation arrays can be used to infer smoking history and it is highly probable that the ability to assess additional substance consumption, such as that of cannabis use, will develop in the near future (Philibert, 2014). Epigenetics is still undefined in law and regulation; few of the privacy issues associated with the distinct characteristics of epigenetic information have been discussed, leaving the exact nature of privacy risks involved in epigenetic testing unclear (Diemer, 2015).

¹ The abbreviation “DTC-MoT” stands for “Direct-to-consumer Multi-omic Testing”. Although focusing on epigenetic and microbiomic testing, our report ultimately calls for greater attention to regulation of all OMIC-types as an alternative to the currently existing gene-centric regulatory framework.

Concerns have also been expressed in the literature regarding potential discrimination based on individuals' epigenetic profile. It is unclear whether current laws prohibiting genetic discrimination apply to epigenetic data (Dupras, 2018). Some authors have noted that justifications for prohibiting genetic discrimination - i.e., individuals' lack of control over the genes they inherit and the need to protect already vulnerable groups - may not be fully applicable to epigenetic data, since individuals have some control over their epigenetic profile (Dupras, 2018). However, others have written that control over one's epigenetic profile may be overstated or even wrongly assumed (Erwin, 2015). Epigenetic testing raises questions that remain unresolved about the applicable ethical, legal, and social protections against discrimination.

A third privacy concern in epigenetics is related to third-party privacy. Epigenetic data has been defined as both plastic and inheritable, meaning both that epigenetic variants may be acquired, prevented and/or reversed and that they can be transmitted intergenerationally (Dupras and Ravitsky, 2016; Rothstein, 2015). Epigenetic data can therefore reveal information about the lifestyle, exposure and substance use of the family as well as 'social-relatives' - individuals who have been exposed to the same environment - of the person undergoing testing (Kalapesi, 2013). Traditional methods of obtaining individual consent to undergo testing may be insufficient in the case of epigenetic testing and could potentially lead to a violation of third-party privacy (Diemer, 2015).

The question remains as to what data protection model or models should be applied to epigenetic data (Terry, 2015). The protection currently afforded to epigenetic data may need to be revisited. Epigenetic data may require exceptional legal treatment or, at least, protection that equal to the exceptional protection already given to genetic data (*ibid*; Rothstein, 2015).

Microbiomics

Microbiomics is a discipline that considers the role that the microorganisms that live in and on human bodies play in physiology, health, and disease (Rajendhran and Gunasekaran, 2009). These include bacteria, archaea, fungi, viruses and other microbes (NIH Microbiome, 2019). A microbiome comprises "all of the genetic material within a microbiota (the entire collection of microorganisms in a specific niche, such as the human gut)" (Nature, 2020). Common areas studied include the gut, skin, nose, mouth and urogenital and gastrointestinal tracts (NIH Microbiome, 2019). Human microbiomic research has gained a lot of traction in the public imagination because it promises 'natural' explanations and solutions for ailments and disease.

To a large extent, privacy considerations in epigenetics apply to microbiomic data. Similar to epigenetics, there is no consensus as to whether microbiomic information constitutes personally identifiable information. While researchers agree that the microbiome is unique to each individual, some researchers have found that features of the human microbiome (particularly that of the gut) to stably associate with individuals over substantial periods of time and others assert that microbiome stability is still not well understood (Franzosa et al. 2015; Hawkins and O'Doherty, 2011). At this time, it is not safe to assume that microbiomic data can be completely anonymized (Franzosa et al. 2015). Like epigenetic data, microbiomic data may allow access to sensitive information such as past exposures or locations an individual has visited (Hawkins and O'Doherty, 2011). Such information is not available from genetic analysis alone and may raise additional privacy concerns, for example, in the hands of forensic investigators, law enforcement or homeland security agencies (*ibid*). Neither privacy nor anti-discrimination statutes explicitly apply to microbiomic information. The regulatory framework governing the use of microbiomic information is still undefined.

Multiomics

Some DTC companies offer both genetic and complementary omic testing, thus accumulating multiomic data in their systems. The combination of genetic information with other type of omic information raises additional privacy concerns (Erich and Narayanan, 2014). The accumulation of multiomic data in repositories substantially increases the risk that an individual may be re-identified following anonymization of their data, notably through the use of triangulation and linkage methods (Rumbold and Pierscioneck, 2018; Zaaier et al., 2017; Zook et al., 2017). Triangulation is a process by which the combination of multiple indirect identifiers contained in a single database, can allow the deduction of a participant's identity by elimination. Linkage is a process by which coded data contained in a particular database (e.g. for research use) can be linked to identifying information contained in another database (e.g., for forensic use). This phenomenon calls for greater attention to and regulation of multiomic databases rather than simply assessing each dataset in isolation (Rumbold and Pierscioneck, 2018).

It is in this broader context of ethical and regulatory debates that we situate our presentation of the publicly available privacy practices of twelve current DTC-MoT companies. First, we outline our methodology and analytical framework. Then we present our findings followed by a discussion of key challenges and concerns. We conclude with recommendations informed by our findings and current literature.

METHODS

This report is a content analysis of twelve DTC epigenetic and microbiomic testing companies' publicly available privacy practices. We looked at the content of company websites as well as their posted Privacy and Terms of Service policies. Two researchers did separate analyses of the companies in order to validate our findings: the first researcher did analyses during July 2019 and October 2019 and the second researcher did analyses during January and March 2020.

Inclusion and Exclusion Criteria

Using a combination of key words comprising the terms “direct-to-consumer”, “epigenetics”, “epigenetic testing”, “microbiomics”, and “microbiomic testing”, we conducted a Google search and compiled a list of companies currently offering online direct-to-consumer epigenetic and/or microbiomic tests (July 2019). We found fourteen such companies. For the purposes of our content analysis of publicly available privacy practices, companies had to have a website and a posted privacy policy, which eliminated two companies from this analysis. Companies that offered both direct-to-consumer and physician-ordered testing were included, since these companies collected and accumulated data from some consumers. Companies that offered both epigenetic or microbiomic testing and genetic testing were also included. One company ceased to operate during the course of our study (October 2019, uBiome), however we kept it in our analysis in order to provide a comprehensive overview of privacy practices in the industry. For similar reasons we chose not to exclude one company that operates exclusively in the U.S. at the moment, but whose website states the aim of being made available “worldwide in the near future” (EpigenCare). Ultimately, five direct-to-consumer epigenetic companies and seven direct-to-consumer microbiomic companies were selected for the study. Three of these twelve companies can be considered multiomic.

Analytical Framework

Our analytical framework is structured according to the 10 fair information principles set out in Canada's Personal Information Protection and Electronic Documents Act (PIPEDA). As compliance with certain principles (4-Limiting Collection and 6-Accuracy) could not be reasonably evaluated by looking at companies' publicly available policies

and websites, we do not claim to present a full assessment of DTC-MoT companies' compliance with PIPEDA. Rather, we point out the most salient areas of concern as filtered through PIPEDA.

1. Consent - PIPEDA Principle 3

“The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information. To make consent meaningful, people must understand what they are consenting to.”

- a. Where is the company located and does it offer services to Canada?
- b. How does the company present its test on its website?
- c. How does the test as presented on the website align with the purpose of the test named in the Terms of Services Policy?
- d. What type of sample is collected?
- e. What type of data is analyzed?

2. Openness - PIPEDA Principle 8

“An organization must make detailed information about its policies and practices relating to the management of personal information publicly and readily available.”

- a. Does epigenetic or microbiomic data constitute personal information?
- b. Does the company mention the applicable privacy regulatory framework? If so, what is it?
- c. What, if any, mention does the company make of privacy and/or discrimination risks associated with undergoing their testing?

3. Accountability - PIPEDA Principle 1

“An organization is responsible for personal information under its control. It must appoint someone to be accountable for its compliance with these fair information principles.”

- a. What privacy standards are third-party service providers held to?
- b. Is the company still accountable for third-party uses?

4. Identifying purposes - PIPEDA Principle 2

“The purposes for which the personal information is being collected must be identified by the organization before or at the time of collection.”

- a. Are the purposes and uses of data collection identified?

5. Limiting use, disclosure and retention - PIPEDA Principle 5

“Unless the individual consents otherwise or it is required by law, personal information can only be used or disclosed for the purposes for which it was collected. Personal information must only be kept as long as required to serve those purposes.”

- a. How long does the company retain epigenetic and/or microbiomic samples and correlated data?
- b. Who else has access to consumers' epigenetic or microbiomic samples and/or correlated data?

6. Safeguards - PIPEDA Principle 7

“Personal information must be protected by appropriate security relative to the sensitivity of the information.”

- a. What safeguards are used to protect epigenetic and microbiomic data?

7. Individual Access - PIPEDA Principle 9

“Upon request, an individual must be informed of the existence, use, and disclosure of their personal information and be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.”

- a. Can customers access their own epigenetic and microbiomic data?
- b. Under what form can they access their data?

8. Challenging compliance - PIPEDA Principle 10

“An individual shall be able to challenge an organization’s compliance with the above principles. Their challenge should be addressed to the person accountable for the organization’s compliance with PIPEDA, usually their Chief Privacy Officer.”

- a. What recourses are offered to customers?

FINDINGS

1. Consent - PIPEDA Principle 3

- a. Where is the company located and does it offer services to Canada?

Seven companies that were reviewed are based in the USA, three in the UK, one in Canada, and one in Sweden. Eleven out of twelve companies offer services to Canada.

- b. How does the company present its test on its website?

Four out of five epigenetic companies advertise tests that provide consumers with results regarding their biological age (Chronomics, Muhdo, myDNAge, TruMe), with two also providing results and recommendations pertaining to general health and wellness (Chronomics, Muhdo). The final epigenetic test is specialized to skin profile information (EpigenCare). The seven microbiomic tests provide consumers with an overview of the composition of their intestinal microbiome, as well as some combination of diet, supplement, and lifestyle recommendations. One epigenetic testing company requires consumers to chat with staff before purchasing a test (Chronomics) and one microbiomic testing company offered both a direct-to-consumer and a physician-ordered version of its test (uBiome). We noted that as of March 2020, ten out of eleven operational companies recommend repeat testing to maximize utility of their product and further, that number represents a jump from only four companies recommending repeat testing as of October 2019. This increase suggests a new trend in the industry.

- c. How does the test as presented on the website align with the purpose of the test named in the Terms of Service document?

As these tests exist in the health or health-adjacent industry, we were curious about how the medical relevance of tests were presented and where disclaimers, if any, were located. We found that the majority of company websites present their tests as applicable to the personalized improvement of health and as scientifically validated. Disclaimers stating that tests were for ‘research, informational, and educational purposes only’ were located within Terms of Service documents and/or website footers.

- d. What type of sample is collected?

Three epigenetic companies use saliva samples, one a skin swab, and the fifth either a blood or urine sample. Six out of seven microbiomic companies use stool samples and seventh uses a blood sample.

- e. What type of data is analyzed?

Four epigenetic testing companies report analyzing DNA methylation levels. The type of data that microbiomic testing companies report testing is more varied: one company reports basing their results on 16s rDNA, one on metabolite levels, and another on metatranscriptomics. Five companies do not specify the type of data they analyze. Three companies combine epigenetics or microbiomics information with genetic information, accumulating multiomic data.

Table 1 – Overview of DTC-MoT companies

	Company (country)	Sample type	Genetic data	Omic data type	Test results	Presentation of medical relevance
Epigenetics	Chronomics (UK)	Saliva	Yes	DNA sequence and methylation	Biological age, smoke exposure, health and lifestyle recommendations	Yes: overstated ¹
	epigenCare (USA)	Skin swab	No	DNA methylation	Skin type, current skin quality	None found: only cosmetic utility is suggested
	Muhdo (UK)	Saliva	Yes	Not available	Biological age, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ¹²
	myDNAge (USA)	Blood or urine	No	DNA methylation	Biological age	None found
	TruMe (USA)	Saliva	No	DNA methylation	Biological age	Yes: overstated ¹ and contradictory disclaimer ²
Microbiomics	Atlas Biomed (UK)	Stool	Yes	Not available	Gut composition, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ²
	Carbiotix (Sweden)	Stool	No	Not available	Gut composition, health and lifestyle recommendations	None found
	Ixcela (USA)	Blood	No	Levels of 11 metabolites	Gut composition, health and lifestyle recommendations	Yes: overstated ¹
	Thryve (USA)	Stool	No	Not available	Gut composition, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ¹²
	uBioDiscovery (Canada)	Stool	No	16S RNA	Gut composition, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ²
	uBiome (USA)	Stool	No	Not available	Gut composition, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ²
	Viome (USA)	Stool	No	Metatranscriptomics	Gut composition, health and lifestyle recommendations	Yes: overstated ¹ and contradictory disclaimer ²

¹ Website; ² Terms of Service

2. Openness - PIPEDA Principle 8

- a. Does epigenetic or microbiomic data constitute personal information?

In their privacy policies, companies generally define personal information as registration information (name, date of birth, address, billing information etc.). Six companies do not indicate whether they consider the epigenetic and/or

microbiomic data they collect to be personal information and one company provides contradictory information (Carbiotix). In their Privacy Policy, Carbiotix writes: “Even though every person’s microbiome is unique, your Microbiome Information is not PHI [personal health information], for the reason that it is currently not possible to identify individuals based on their microbiomes.” However, in their Terms of Service policy, they write that microbiomic information is personal information because it can be used to identify an individual. Thus in total, seven of the twelve epigenetic and microbiomic testing companies do not specify whether epigenetic and/or microbiomic information constitutes personal information, and as such, is protected by the provisions contained in their privacy policies.

b. Does the company mention the applicable privacy regulatory framework? If so, what is it?

Eight out of twelve companies mention the applicable privacy regulatory framework in their policies.

Table 2 – Site by site findings regarding openness (1/2)

	Company	Is the omic data collected considered personal information?	Applicable Privacy Law/Norms
Epigenetics	Chronomics	Yes – epigenetic data constitutes personal data ³	Data Protection Act 2018 and the General Data Protection Regulation ((EU) 2016/679) ³
	epigenCare	Not available	Not available
	Muhdo	Yes – epigenetic data is “special category/sensitive personal data” ⁴	GDPR ³
	myDNAge	Not available	GDPR ³
	TruMe	Not available	California Code, Civil Code - CIV § 1798.83 ³
Microbiomics	Atlas Biomed	Not available	Data Protection Act 2018; General Data Protection Regulation (EU) 2016/679 (GDPR); and the Personal Information Protection and Electronic Documents Act (PIPEDA) ²
	Carbiotix	Contradictory. Microbiomic data is not personal health information ³ but microbiomic data is personal information ²	GDPR ³
	Ixcela	Not available	Laws of the State of Massachusetts ³
	Thryve	Not available	Not available
	uBioDiscovery	Yes – gut microbiome information is personal information ³	Not available
	uBiome	Yes – microbiomic data is personal information ²	Not available
	Viome	Yes- microbiomic data is “sample data”, and as such constitutes personal information ³	GDPR ³

¹Website; ²Terms of Service; ³Privacy Policy; ⁴Data retention policy. This legend applies to all tables.

c. What, if any, mention does the company make of privacy and/or discrimination risks associated with undergoing their testing?

No company mentions privacy and discrimination risks on their website. Three microbiomic testing companies mention the risks associated with sharing one’s microbiomic information in their terms of service policies (Carbiotix, uBioDiscovery, uBiome). No epigenetic testing company mentions the risks associated with sharing one’s epigenetic information.

Table 3 – Site by site findings regarding openness (2/2)

	Company (*=genetic test performed)	Privacy and Discrimination risks named
Epigenetics	Chronomics*	<i>Not available</i>
	epigenCare	<i>Not available</i>
	Muhdo*	<i>Not available</i>
	myDNAge	<i>Not available</i>
	TruMe	<i>Not available</i>
Microbiomics	Atlas*	<i>Not available</i>
	Carbiotix	“Microbiome Information you share with others could be used against your interests. You should be careful about sharing your Microbiome Information with others. Currently, very few businesses or insurance companies request microbiome information, but this could change in the future. You may want to consult a lawyer to understand the extent of legal protection of your Microbiome Information before you share it with anybody. Furthermore, Microbiome Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Microbiome Information that you share with family, friends or employers may be used against your interests. Even if you share Microbiome Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Microbiome Information about health conditions and you do not disclose this to them, this may be considered to be fraud.”
	Ixcela	<i>Not available</i>
	Thryve	<i>Not available</i>
	uBioDiscovery	“Bacterial Information you share with others could be used against your interests. You should be careful about sharing your Bacterial Information with others. You may want to consult a lawyer to understand the extent of legal protection of your Bacterial Information before you share it with anybody. For example, Canada does not currently have legislation that specifically regulates the use that can be made of your Bacterial Information by insurers, employers, and other organizations. It is possible that this Bacterial Information could be used against your interests. Furthermore, Bacterial Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Bacterial Information that you share with family, friends or employers may be used against your interests. Even if you share Bacterial Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Bacterial Information about health conditions and you do not disclose this to them, this may be considered to be fraud.” ²
	uBiome	“Microbiome Information you share with others could be used against your interests. You should be careful about sharing your Microbiome Information with others. Currently, very few businesses or insurance companies request microbiome information, but this could change in the future. You may want to consult a lawyer to understand the extent of legal protection of your Microbiome Information before you share it with anybody. Furthermore, Microbiome Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Microbiome Information that you share with family, friends or employers may be used against your interests. Even if you share Microbiome Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Microbiome Information about health conditions and you do not disclose this to them, this may be considered to be fraud.” ²
Viome	<i>Not available</i>	

²Terms of Service

3. Accountability - PIPEDA Principle 1

- a. What privacy standards are third-party service providers held to?

Six companies provide information regarding accountability for third-party breaches of consumer privacy. Four mention that third-party services providers are held to the same privacy obligations as the company itself.

Table 4 – Site-by-site findings regarding third party accountability

	Company	Third party accountability information
Epigenetics	Chronomics	“We require all third parties to respect the security of your personal data and to treat it in accordance with the law. We do not allow our third party service providers to use your personal data for their own purposes and only permit them to process your personal data for specified purposes and in accordance with our instructions.” ¹
	epigenCare	<i>Not available</i>
	Muhdo	“This policy applies to all personal data held by the Company and by third-party data processors processing personal data on the company's behalf.” ⁴
	myDNAge	<i>Not available</i>
	TruMe	“Company contractually prohibits its contractors, affiliates, vendors and suppliers from disclosing PII received from Company, other than in accordance with this Privacy Policy.” ¹
Microbiomics	Atlas Biomed	“We may employ third party companies and individuals to facilitate our service, to provide the service on our behalf to perform service-related services or to assist us in analyzing how our service is used. These third parties have access to your Personal Data only to perform these tasks on our behalf and are obligated not to disclose or use it for any other purpose.” ¹
	Carbiotix	<i>Not available</i>
	Ixcela	“We may share your personally identifiable information with third parties (collectively, the “Third Party Vendors”) to further the purpose for which you provided such information to us. For example, we may share your information with Elastic Email, for the purpose of sending emails. We urge you to read the privacy practices of all of our Third-Party Vendors before submitting any personally identifiable information through the Service.” ¹
	Thryve	<i>Not available</i>
	uBioDiscovery	<i>Not available</i>
	uBiome	<i>Not available</i>
	Viome	“Viome’s accountability for personal data that it receives in the United States under the Privacy Shield and subsequently transfers to a third party is described in the Privacy Shield Principles. In particular, Viome remains responsible and liable under the Privacy Shield Principles if third-party agents that it engages to process the personal data on its behalf do so in a manner inconsistent with the Principles, unless Viome proves that it is not responsible for the event giving rise to the damage.” ¹

¹ Website; ⁴ Data Retention Policy

- b. Is the company still accountable for third-party uses?

One company mentions that the company remains accountable for the protection of customers’ privacy while the data is under the control of third-party service providers. Another company states that they were not accountable for the use that third-party service providers make of customers’ data and information.

4. Identifying Purposes - PIPEDA Principle 2

a. Are the purposes and uses of data collection identified?

All companies made name the purpose for which information was collected in their Privacy Policy. In many cases however, companies do not make a clear distinction between the purposes of collection and the use of the information that they collect. In their Privacy Policies, many companies describe uses of information under the heading “purposes of collection”.

It should also be noted that due to the lack of clarity regarding whether companies consider epigenetic and microbiomic data to be personal information (see Openness – Principle 8), is it unclear whether certain provisions about purposes of collection apply to epigenetic and microbiomic data.

Table 5 – Site by site findings regarding purposes of collection

	Company	Purposes of data collection
Epigenetics	Chronomics	“We will use your personal data where it is necessary to perform our contract with you so that we can provide the DNA Services to you and/or pursue our legitimate interests (namely (i) troubleshooting, data analysis, testing, research, and statistical and survey purposes (ii) keeping our systems, customers and information secure, (iii) obtaining customer feedback, (iv) looking into, and responding to complaints, legal matters or (v) any other issues).” ¹
	epigenCare	“We only collect personally identifiable information on a voluntary basis. We do not require that you provide this information to gain access to our site, and we do not require you to disclose more information than is reasonably needed to participate in an activity on our site. [...] We collect personally identifiable information on a temporary basis to send your purchases and at times to communicate with you email updates and news. All information generated from any DNA-sourced testing shall never be disclosed or associated with personally identifiable information on a permanent basis.” ¹
	Muhdo	“Purpose of collection of biological data: “To provide nutrition, health and fitness recommendations to a person.” ⁴
	myDNAge	“We will use your sample to perform the Service and to report to you. By ordering our services you agree that we own and may use the sample material (DNA, RNA or protein) and data generated therefrom for any reason included but not limited to our internal uses which will include sharing with our Research Laboratory for improving the Services as well as making new services.” ¹
	TruMe	“Company uses the PII in the file to deliver the products, to manage the account, to communicate with you, to develop and display content, to resolve disputes, to customize your experience.” ¹
Microbiomics	Atlas Biomed	“We collect several different types of information for various purposes to provide and improve our Service to you: to provide and maintain our services, to notify you about changes to our services, to allow you to participate in interactive features of our services, to provide customer support, to gather analysis of information, to monitor usage of our services, to detect technical issues. We will use your raw data and the results of interpretation to provide you with the testing services that you requested from us.” ¹
	Carbiotix	“We collect information from you (“Personal Information”) and our other users in order to provide you with a personalized, useful and efficient experience.” ¹
	Ixcela	“We may use your personally identifiable information to respond to your inquires or requests. We may use your personally identifiable information to send you emails from time to time about our services, but we will not provide your personally identifiable information to third parties for them to contact you directly unless otherwise permitted by this Privacy Policy or you provide your consent.” ¹
	Thryve	“Our primary goals in collecting information are to provide and improve our services, to administer your use of the services, and to enable you to enjoy and easily navigate our services.” ¹

uBioDiscovery	“We use information in general (i) to provide, analyze and improve our Services, (ii) as we reasonably believe is permitted by laws and regulations, including for marketing and advertising purposes, (iii) to protect the security and safety of our company, employees, customers as we reasonably believe permitted by laws and regulations, (iv) to comply with laws and regulations we are subject to, and (v) when you consent, for research purposes, the results of which could be used to develop therapeutics”. ¹
uBiome	“To provide our service; to communicate with you; to market, promote and drive engagement with our Service.” ¹
Viome	“Viome shares your personal data with third parties as follows: [...] scientific research collaborators: to engage in scientific research regarding the human microbiome.” ¹

¹ Website; ⁴ Data Retention Policy

5. Limiting use, disclosure and retention - PIPEDA Principle 5

a. How long does the company retain epigenetic and/or microbiomic samples and correlated data?

Most companies do not make a clear distinction between retention length and secondary uses of the information that they collect, speaking to the two in tandem. The vast majority of companies do not specify an end point to retention of personal samples and data and grant themselves the right to use consumer samples and data for various secondary purposes beyond the test the consumer ordered. Only one company indicated a specific limited time period for which samples are retained (Carbiotix, up to 10 years) and one company does the same for personal data (Chronomics, up to 6 years after the account is closed). While most companies state that they retain personal samples and data for some combination of service provision and quality control purposes, three companies grant themselves extensive rights over the personal samples and data (myDNAge, Thryve, Viome) and another three companies give no information whatsoever on this front (epigenCare, Ixcela, TruMe).

Table 6 – Site-by-site findings regarding retention

	Company	Retention Information
Epigenetics	Chronomics	Sample and aggregate data: <i>Not available</i> Data: Up to 6 years after account closes. “In some cases, we may want to keep part of your data for research purposes, in which case we will ask for your explicit consent to retain it” ³
	epigenCare	Sample and aggregate data: <i>Not available</i> Data: “All information generated from any DNA-sourced testing shall never be disclosed or associated with personally identifiable information on a permanent basis” ³
	Muhdo	Sample: May store for quality control and optimization ² Data: May keep it for other scientific, research and statistical purposes ⁴ . Held until customer requests for the information about themselves to be deleted ⁴ Aggregate data: Stored for research and development ²
	myDNAge	Sample, data, and aggregate data: “By ordering the service you agree that we own and may use the sample material (DNA, RNA, or protein) and data generated therefrom for any reason” ³
	TruMe	Sample and data: <i>Not available</i> Aggregate data: Stored for research and development ³
Microbiomics	Atlas	Sample: 1 year, with right to store indefinitely ³ Data: Only for as long as necessary for the purposes set out in the privacy policy ³ Aggregate data: Stored for research and development ³
	Carbiotix	Sample: 1-10 years ³ Data: As long as account is open or as needed to provide services ³ Aggregate data: Stored for research and development ³
	Ixcela	Sample and data: <i>Not available</i> Aggregate data: “Non personally identifiable or aggregate information may be used by us for any purposes permitted by law” ³
	Thryve	Sample, data, and aggregate data: “Thryve and its licensors exclusively own all right, title and interest in and to the services, content, samples, and sample data, including all associated intellectual property rights” ²

	uBioDiscovery	Sample: Unidentified samples and DNA stored after the laboratory completes its work unless consumer asks for disposal ³ Data: “We will only retain your personal information for as long as necessary to fulfill the purposes we collected it for, including for the purposes of satisfying any legal, accounting, or reporting requirements” ³ Aggregate data: Stored for research and development ³
	uBiome	Sample: <i>Not available</i> Data: Retained for as long as account is active or as needed to provide services ³ Aggregate data: Unclear, they reserve the right to “share information in an aggregated and anonymous form” ³
	Viome	Sample, data, and aggregate data: At least 10 years, but may in its sole discretion, retain for longer. “By submitting a sample to Viome, you agree to, and hereby do, transfer and assign to Viome and its assigns and successors all right, title, and interest in and to the sample, self-reported information, analysis, test data, and other data derived therefrom” ²

b. Who else has access to consumers’ epigenetic or microbiomic samples and/or correlated data?

All companies require consumers to agree to disclose information to third parties. The most common mandatory disclosures are to law enforcement (as required by law) and to affiliated service providers. There is a variety of language used to describe the other third parties with whom information may be shared including vendors, affiliates, service providers, partners, private parties, associates, and agents.

Table 7 – Site-by-site findings regarding disclosure

	Company	Mandatory disclosure
Epigenetics	Chronomics	Data- employees, contractors, agents, external lawyers, cloud platform providers, third-party improvement providers, third party affiliates, clinics or distributors, third parties in the event of a sale, in connection with any legal proceeding, and as required by law ²
	epigenCare	Aggregate data- business partners and other third parties ²
	Muhdo	Data- as required by law ³ Aggregate data and self-reported information- third party non-profit and/or commercial research partners ³
	myDNAge	Data- as required by law and to associated companies, affiliates, agents, vendors, or service providers ²
	TruMe	Data- as required by law or to protect rights, third-party service providers ² Aggregate data- third parties; affiliates; advisors, advertisers and investors ²
Microbiomics	Atlas	Data- as required by law, service providers, analytics, referral marketing, payment processors, partner laboratories ²
	Carbiotix	Individual data- as required by law ³ Aggregate data and self-reported information- other users, affiliates, "may lead to and/or include commercialization with a third party" ²
	Ixcela	Data- third party vendors, affiliates, as required by law ² Aggregate data- “...may be shared with any number of parties, provided that such information shall not specifically identify you” ²
	Thryve	Data- third party service providers, third parties in the event of a merger or sale, “to cooperate with government and law enforcement officials or private parties to enforce and comply with the law” ² Aggregate data- “Third parties for industry research and analysis, demographic profiling and other similar purposes” ²
	uBioDiscovery	Data- as required by law or to protect rights ² Aggregate data- third parties: "We reserve the right to use such anonymous and de-identified data for any legitimate business purpose without further notice to you or your consent" ² In the event of a sale, merger, or bankruptcy ³
	uBiome	Data- service providers and as required by law ² Aggregate data- third parties ³ including non-profit and/or commercial research partners ³
	Viome	Data- partners, service providers and as required by law ² Aggregate data- research, may include commercialization activities ²

²Privacy Policy; ³Terms of Service

6. Safeguards - PIPEDA Principle 7

a. What safeguards are used to protect epigenetic and microbiomic data?

While all but one company brings up safeguards in their privacy policy, most companies do not give details regarding the manner in which safeguards are implemented. Muhdo is the main exception: providing detailed stages of data protection and naming that the data is encrypted with Md5. Thryve mentions HTTPS technology as a method they use to encrypt data. Other companies use more vague expressions such as “state-of-the-art encryption technology” or “reasonable measures”. Further, it is once again unclear whether these safeguard provisions apply to epigenetic and microbiomic data since companies may not consider it to be personal information.

Table 8 – Site-by-site findings regarding safeguards

	Company	Safeguards
Epigenetics	Chronomics	“We have put in place appropriate security measures to prevent your personal data from being accidentally lost, used or accessed in an unauthorised way, altered or disclosed. We update and test our security technology on an ongoing basis. In addition, we train our staff about the importance of confidentiality and maintaining the privacy and security of your personal data. Any payment transactions will be encrypted. Unfortunately, the transmission of information via the internet isn’t completely secure. Although we will do our best to protect your personal data, we can’t guarantee the security of your personal data transmitted to our site; any transmission is at your own risk. Once we have received your personal data, we will use physical, technical and administrative safeguards to try to prevent unauthorised access. Our cloud platforms use state-of-the art encryption technologies for data in transit and at rest and are among the most secure providers available in the market.” ¹
	epigenCare	<i>Not available</i>
	Muhdo	[Safeguards are extensive. Privacy Policy mentions a long list of specific actions that are taken to ensure security of data].
	myDNAge	“We use robust internal and third party physical and technical measures intended to safeguard your information and help protect this information from unauthorized access or loss. We use our best efforts and comply with US state and federal law and other law such as the GDPR for data security but cannot guarantee complete security.” ¹
	TruMe	“We take the security of your Personally Identifying Information seriously and use reasonable electronic, personnel and physical measures to protect it from loss theft, alteration or misuse. However, please be advised that even the best security measures cannot fully eliminate all risks. We cannot guarantee that only authorized persons will view your information. We are not responsible for third-party circumvention of any privacy settings or security measures.” ¹
Microbiomics	Atlas Biomed	"The data we collect from you will be stored at a destination within the UK. It will also be processed by our staff. This includes staff engaged in, among other things, the fulfillment of your order, the processing of your payment details and the provision of support services. By submitting you personal data, you agree to this transfer, storing or processing. We will take all steps reasonably necessary to ensure that your data is treated securely and in accordance with this privacy policy." ¹
	Carbiotix	"Carbiotix cares about the security of your information and uses commercially reasonable physical, administrative, and technological safeguards to preserve the integrity and security of all information we collect and that we share with our service providers in line with the EU's General Data Protection Regulation (GDPR). However, no security system is impenetrable and we cannot guarantee the security of our systems 100%. In the event that any information under our control is compromised as a result of a breach of security, we will take reasonable steps to investigate the situation and where appropriate, notify those individuals whose information may have been compromised and take other steps, in accordance with any applicable laws and regulations." ¹
	Ixcela	“We have put in place reasonable physical, electronic, and managerial procedures to safeguard the information we collect. Only those employees who need access to your information in order to perform their duties are authorized to have access to your personally identifiable information.” ¹

	Thryve	“We take reasonable administrative, physical and electronic measures designed to protect the information that we collect from or about you (including your PII) from unauthorized access, use or disclosure. When you enter sensitive information on our forms, we encrypt this data using HTTPS or other technologies. Please be aware, however, that no method of transmitting information over the internet or storing information is completely secure. Accordingly, we cannot guarantee the absolute security of any information.” ¹
	uBioDiscovery	“uBioDiscovery takes seriously the trust you place in us. To prevent unauthorized access or disclosure, to maintain data accuracy, and to ensure the appropriate use of information, uBioDiscovery uses a range of physical, technical, and administrative measures to safeguard your Personal Information.” ¹
	uBiome	“We take reasonable physical, administrative, and technological safeguards to preserve the integrity and security of your information. However, no security system is impenetrable and we cannot guarantee that your information is completely safe from intrusion. In the event that any information under our control is compromised as a result of a breach of security, we will take reasonable steps to investigate the situation and where appropriate, notify those individuals whose information may have been compromised and take other steps in accordance with any applicable laws and regulations. Where we retain information for improvement and development of our service, we take steps to eliminate information that directly identifies you as an individual. We retain information about your marketing preferences unless you specifically ask us to delete such information.” ¹
	Viome	“Viome shall take reasonable steps to protect personal data from loss, misuse, and unauthorized access, disclosure, alteration and destruction. Viome has put in place appropriate physical, electronic and managerial procedures to safeguard and secure the information from loss, misuse, unauthorized access or disclosure, alteration or destruction. Viome cannot guarantee the security of information on or transmitted via the internet.” ¹

7. Individual Access - PIPEDA Principle 9

- a. Can customers access their own epigenetic and microbiomic data?

Seven companies explicitly mention the right to access in their privacy policies. Most companies do not specify the type of information that consumers can access.

- b. Under what form can they access their data?

One company states that “raw genetic data (uninterpreted DNA which is received in their laboratories) can be downloaded by customers as a *.txt file or as a *.csv file” (Atlas). Another company limits form in which data can be accessed: “we will report the result of the myDNAge test determined by our analysis of your sample in a report comprising a biological age determination only. No other data related to the analysis of our methodology will be provided (ex. the DNA methylation value and CpG loci) used for our analysis will not be reported; no information on our algorithm will be reported” (MyDNAge).

Table 9 – Site-by-site findings regarding individual access

	Company	Information regarding individual access
Epigenetics	Chronomics	“In relation to personal data we hold about you, you have the right to: where we process your personal data based on your consent, to withdraw your consent easily and at any time; get access to your personal data that we hold and receive information about our processing of it; ask us to correct the record of your personal data maintained by us if it is inaccurate or to complete incomplete personal data; ask us, in certain instances, to erase your personal data or cease processing; object to us processing your personal data for direct marketing purposes; challenge us processing your personal data which has been justified on the basis of our legitimate interests.” ³
	epigenCare	<i>Not available</i>

	Muhdo	All rights guaranteed in GDPR ³
	myDNAge	"You may request a summary of information we hold about you, as well as corrections, updates or deletion of your information, by contacting us at info@myDNAge.com." ³ "We will report the result of the myDNAge test determined by our analysis of your sample in a report comprising a biological age determination only. No other data related to the analysis of our methodology will be provided (ex the DNA methylation value and CpG loci) used for our analysis will not be reported; no information on our algorithm will be reported." ²
	TruMe	<i>Not available</i>
Microbiomics	Atlas	"If you want to be informed of what personal data we hold about you and if you want it to be removed from our systems, please contact us. You have the rights at any time to access and receive a copy of the personal data we own about you, and to rectify any personal data held about you that is inaccurate. You have the right at any time to request that we remove your sample and we delete your personal data. Note that we aim to maintain our services in a manner that protects information from accidental or malicious destruction. Because of this, after you delete information from our services, we may not immediately delete residual copies from our active servers and may not remove information from our backup systems. We will aim to delete your personal data after your request within the shortest time possible and within the maximum period of one month. However, there may be some latency in deleting your personal information from our backup systems after it has been deleted from our production, development, analytics and research systems. Also, our partner laboratories may retain information they receive from us in order to comply with laws and regulations that may require them to do so." ³ "Raw genetic data (uninterpreted DNA which we receive from our laboratories and which is stored and displayed to you in your personal account) can be downloaded as a *.txt file or as a *.csv file." ³
	Carbiotix	<i>Not available</i>
	Ixcela	<i>Not available</i>
	Thryve	"We offer you choices regarding the collection, use and sharing of your PII and we'll respect the choices you make. Please note however that if you decide not to provide us with the PII that we request, you may not be able to access all of the features of the services." ³
	uBioDiscovery	<i>Not available</i>
	uBiome	"You may access and update your information. You may ask that we delete or anonymize certain information about you. Please note, however, that we may need to retain certain information for record keeping purposes, to complete transactions or to comply with our legal obligations. You may ask us to stop accessing, storing, using and otherwise processing your information where you believe we don't have the appropriate rights to do so. Where you gave us consent to use your information for a limited purpose, you may withdraw that consent, but this will not affect any processing that has already taken place at the time. You have a right to inspect and copy your information; to ask us to amend your health information; to receive an accounting of certain disclosure made by us or our business associates of your PHI. You have the right to request a restriction or limitation on the PHI we use or disclose about you, for example, with certain family members. We are not required to agree to your restriction request but will attempt to accommodate reasonable requests when appropriate. If you pay in full out-of-pocket, you can ask us to not share that payment information with your health insurer. We will say yes unless required by law to share the information." ³
	Viome	"Viome shall allow those individuals access to their personal data and allow the individual to correct, amend, or delete inaccurate information, except where the burden or expense of providing access would be disproportionate to the risks to the privacy of the individual in question or where the rights or persons other than the individual would be violated". Please contact privacy@viome.com to exercise these rights. Subject to the above terms and conditions, Viome will, within 30 days from the request of a consumer, delete the personal data concerning such customer and destroy all samples provided by such customer. Notwithstanding the above provisions, Viome shall be permitted to retain any and all anonymized, aggregate data." ³

²Terms of Service; ³Privacy Policy

8. Challenging Compliance - PIPEDA Principle 10

a. What recourses are offered to customers?

Ten companies provide consumers with information regarding steps they can take to challenge compliance or exercise their rights. Four companies provide general information email addresses and six companies provide privacy specific contact information.

Table 10 – Site-by-site findings about challenging compliance

	Company	Information about challenging compliance
Epigenetics	Chronomics	"If you would like to exercise any of these rights, please contact info@chronomics.com." ³
	epigenCare	Not available
	Muhdo	"The Company's Data Protection Officer is Dale Holdback, dale@muhdo.com. The data protection officer shall be responsible for overseeing the implementation of this Policy and for monitoring compliance with this Policy, the Company's other Data Protection-related policies, and with the GDPR and other applicable data protection legislation." ³
	myDNAge	"If you have any questions, concerns or complaints about this Privacy Policy or privacy-related practices, please contact Epimorphy by email at info@myDNAge.com or phone at 833-693-6243." ³
	TruMe	Not available
Microbiomics	Atlas	"You have the right at any time to request that: we remove your sample at any time by sending an e-mail to hello@atlasbiomed.com with the word 'Withdraw' in the email title; we delete your Personal Data, health information and individual level genetic data by sending an email to hello@atlasbiomed.com with the word 'Forget me' in the email title." ³
	Carbiotix	"If you have questions about this Privacy Policy, please contact us at: privacyofficer@carbiotix.com or by writing to us at: Attn: Privacy Officer, Carbiotix AB, Scheelevägen 22, 22363 Lund, Sweden." ³
	Ixcela	"For questions or concerns relating to privacy, we can be contacted atlegal@ixcela.com or by calling (781) 538-6614 between 8 am and 6 pm." ³
	Thryve	"Please contact us at contact@thryveinside.com if you have any questions about our Privacy Policy." ³
	uBioDiscovery	"If you have questions about this Privacy Statement, please email uBioDiscovery's Privacy Administrator at contact@ubiodiscovery.com." ³
	uBiome	"If you have any question about this privacy policy, please contact us at privacyofficer@ubiome.com. If you believe your privacy rights have been violated, please let us know immediately by contacting our HIPAA Privacy Officer at (760) 268 6200." ³
	Viome	"Viome shall allow those individuals access to their personal data and allow the individual to correct, amend, or delete inaccurate information, except where the burden or expense of providing access would be disproportionate to the risks to the privacy of the individual in question or where the rights or persons other than the individual would be violated". Please contact privacy@viome.com to exercise these rights." ³

³Privacy Policy

DISCUSSION

In this section, we discuss the main points of tension that emerge from our findings.

1. Epigenetic and microbiomic data as sensitive “personal information/data”.

As mentioned in the literature review section, one of the main considerations in relation to the protection of epigenetic and microbiomic data is whether such data constitutes identifiable information. The analysis of the practices of the DTC-MoT companies reveals the concrete relevance of this issue.

Only seven companies provide information about the type of data being collected and that information is fairly general (DNA methylation levels, 16S rDNA, metabolite levels, metatranscriptomics). Epigenetic and microbiomic data is highly diversified and heterogeneous (Jenuwein and Allis, 2001; Dupras et al., 2018). Different types of biological variants behave in different ways, which may impact the concomitant privacy concerns and protection. It is therefore essential to identify the precise nature of the data analyzed by DTC-MoT companies.

In addition, only five companies provide clear information regarding whether the biological data they collect constitutes ‘personal information’ or ‘personal data’ and as such is protected by their privacy policies.

Below is an overview of the definition of personal data in statutes that are cited as a regulatory framework in DTC-MoT companies’ policies (non-Canadian statutes are presented for comparison purposes).

Table 11 – Definitions of personal information in privacy statutes

Statute	Jurisdiction	Definitions
<i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i>	Canada	2(1) Personal health information: (a) information concerning the physical or mental health of the individual; (b) information concerning any health service provided to the individual; (c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual; (d) information that is collected in the course of providing health services to the individual; (e) information that is collected incidentally to the provision of health services to the individual.
<i>Regulation (EU) 2016/679 (General Data Protection Regulation)</i>	Europe	4. ‘Personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
<i>MGL c. 66A Fair Information Practices Act</i>	Massachusetts	1. “Personal data” , any information concerning an individual which, because of name, identifying number, mark or description can be readily associated with a particular individual; provided, however, that such information is not contained in a public record, as defined in clause Twenty-sixth of section seven of chapter four and shall not include intelligence information, evaluative information or criminal offender record information as defined in section one hundred and sixty-seven of chapter six.
<i>California Code, Civil Code - CIV § 1798.83</i>	California	6B. “Personal information” as used in this section means any information that when it was disclosed identified, described, or was able to be associated with an individual

The “identifiable” character of the data is key to its protection in all of the cited jurisdictions. Canadian courts have stated that the following criteria must be used to determine whether information should be considered “personal information”:²

1. The definition of personal information must be given a broad and expansive interpretation (*Dagg v. Canada (Minister of Finance)*, [1997] 2 S.C.R., dissenting, 403 at para 68; *Canada (Information Commissioner) v. Canada (Transportation Accident Investigation and Safety Board)*, 2006 FCA 157;

² Office of the Privacy Commissioner of Canada, “Personal Information”, October 2013 [online] https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/pipeda-compliance-help/pipeda-interpretation-bulletins/interpretations_02/#fn27.

Canada (Information Commissioner) v. Canada (Commissioner of the Royal Canadian Mounted Police), [2003] 1 S.C.R. 66, 2003 SCC 8, at para 23).

2. Information will be about an “identifiable individual” where there is a serious possibility that an individual could be identified through the use of that information, alone or in combination with other information (*Gordon v. Canada (Health)*, 2008 FC 258 (CanLII)).

In the health context, the Privacy Commissioner of Canada ruled that: “personal information that has been de-identified does not qualify as anonymous information if there is a serious possibility of linking the de-identified data back to an identifiable individual”.³

As discussed in the literature review, while there is considerable evidence that certain data types, such as DNA methylation arrays, can be used to identify individuals, other variants are still not well understood (Diemer, 2015; Philibert, 2014; Backes, 2016). Because the variants being tested are biologically distinct, it is currently difficult to draw clear lines in the sand for epigenetic or microbiomic tests.

There are two avenues of potential increased risk of re-identification that need to be addressed however: multiomic repositories and repeat testing. The advent of multiomic data repositories raises additional doubts regarding whether epigenetic and microbiomic information contained in such datasets can ever be completely anonymized (Zook et al., 2017 ; Zaaijer et al., 2017 ; Erlich and Narayanan, 2014; Rumbold and Pierscionek, 2018). Similarly, the emphasis on repeat testing raises the sensitivity of the data and the likelihood of re-identification as exposure, lifestyle and health information are accumulated and tracked over time. Overall, it is unclear whether epigenetic and microbiomic information – both in individual and aggregate/anonymized form – constitute ‘personal information’ under PIPEDA.

It should also be noted that it is currently unclear whether the results provided by DTC epigenetic and microbiomic testing companies should be considered to be ‘medical’ information. As noted in the context of DTC-GT, direct-to-consumer online testing no longer fits the traditional categories of “medical” and “non-medical” tests (Christofides and O’Doherty, 2015; Saukko, 2013). Although they use the language of ‘health’ as a means of advertisement, DTC-MoT companies often state that their results do not constitute medical advice and that people should not rely on their results to change their behaviour. Accordingly, the DTC-MoT industry should perhaps be considered as providing information pertaining to “wellbeing” rather than medical information (*ibid*). This distinction impacts the protection of the data collected by DTC-MoT companies and the results they provide, since they data and results may not constitute “information concerning the physical or mental health of the individual, or information that is collected in the course of providing health services to the individual”, and as such, constitute ‘personal health information’ under by *PIPEDA*.

In the absence of clear legislative protection awarded to epigenetic and microbiomic data, DTC-MoT companies should commit to the protection of epigenetic and microbiomic privacy by stating that this data constitutes protected personal information and as such is protected by their privacy policies. On a broader scale, however, this issue calls for an interdisciplinary inquiry on the identifiable nature of epigenetic and microbiomic data, so as to provide a clear normative framework within which companies will have to operate. Given the fact that this industry is rapidly diversifying, policy makers should perhaps anticipate future developments and decide on the protection awarded to complementary-omics data more broadly.

³ Office of the Privacy Commissioner of Canada, “PIPEDA Case Summary #2009-018 – Psychologist’s anonymized peer review notes are the personal information of the patient” [online] <https://www.priv.gc.ca/en/opc-actions-and-decisions/investigations/investigations-into-businesses/2009/pipeda-2009-018/>.

2. Epigenetic and microbiomic discrimination

Only a minority of DTC-MoT companies mention microbiomic discrimination risks to consumers, and no DTC-MoT company mentions risks of discrimination on the basis of one’s epigenome. Genetic anti-discrimination statutes in Canada and in the USA are currently formulated as follows:

Table 12 – Definitions of genetic information in anti-discrimination statutes

Statute	Jurisdiction	Definition
<i>Genetic Non-Discrimination Act, SC 2017, c 3.</i>	Canada	2. Genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (test génétique)
<i>Genetic Information Non-Discrimination Act (GINA), Public Law 110-233, 110th Congress</i>	USA	<p>5. The term ‘genetic information’ means, with respect to any individual, information about</p> <ul style="list-style-type: none"> (i) such individual’s genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual <p>7. A) The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.</p> <p>7. B) The term ‘genetic test’ does not mean</p> <ul style="list-style-type: none"> (i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or (ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

It is currently unclear whether the data collected by DTC-MoT companies meet these criteria.

Authors have noted that genetic non-discrimination statutes are formulated in narrow terms due to the notion of “genetic exceptionalism”, which refers to the position that genetics raise unique ethical and legal issues that they ought to be addressed separately from other health conditions and information (Rothstein, 2013). Among the reasons why genetics is said to be different include that genetic inheritance has implications for reproduction, family members, and members of the same ethnic group; genetic inheritance is immutable; genetic information is predictive of future health; there is a long history of misuse of genetics; and genetic information is regarded as distinct by many members of the public (Rothstein, 2013). According to other authors, the underlying rationale for genetic exceptionalism is the impossibility to completely de-identify genetic data (Knoppers, 2010).

There may be some debate over whether the rationale underlying the adoption of genetic anti-discrimination laws should apply to epigenetic and/or microbiomic information as individuals may have some degree of control over their profiles, and in the case of microbiomic information, is not human data (Dupras *et al.* 2018). Nevertheless, epigenetic and microbiomic data have the potential to expose lifestyle and exposure information directly subject to legal and moral regulation. Data that falls under what could be conceived of as ‘choice’ or ‘lifestyle’ is particularly vulnerable to discrimination (Dupras, Saulnier, and Joly 2019). In light of our results and of the fast diversification of the genetic

testing industry, policy-makers should consider the extent to which complimentary-omic data collected through DTC testing – or for research purposes – should be protected against discrimination.

In the meantime, given the absence of explicit legislative protection against discrimination based on epigenetic and microbiomic profile, DTC-MoT companies should clearly state potential discrimination risks in their policies. Companies should mention the lack of a legislative framework and the potential risks associated with it in order for consumers to make informed choices.

3. Anonymization and Aggregate Data

As we previously mentioned, the Privacy Commissioner of Canada ruled that in the health context “personal information that has been de-identified does not qualify as anonymous information if there is a serious possibility of linking the de-identified data back to an identifiable individual.”⁴ Many DTC-MoT companies state in their privacy policies that they may keep consumers’ data for indefinite periods of time or share it with third-parties provided that this data is anonymized (Carbiotix, EpigenCare, Ixcela, Muhdo, myDNAge, Thryve, TruMe, uBioDiscovery, uBiome). In light of recent findings regarding the increased difficulty of anonymizing multi-omic data, such practices may prove harmful to consumer privacy. It should be noted that it is often unclear whether these provisions apply specifically to epigenetic and/or microbiomic data, rather than usage data for example.

Some authors have noted that issues related to omic data storage and sharing can be addressed from two angles: first, the privacy of the individuals who contribute biological material such as DNA, and second, the ownership of data (Ozercan et al. 2019). As Christofides and O’Doherty noted in their 2015 Report, there is a great deal of disagreement on how direct-to-consumer genetic testing should be regulated, which has resulted in a lack of policy action (Christofides and O’Doherty, 2015; McGuire et al., 2009). This disagreement is based on the tension between the need for privacy protection and the ability of researchers to access data that could allow for scientific advances. The same tension is expected to dominate discussions related to regulation of DTC-MoT. In the context of DTC-GT, private companies have attempted to circumvent this debate by proposing a new paradigm to govern storage and sharing of genetic data online, based on user “control” of their data through blockchain technologies. Companies such as *Zenome* (<https://zenome.io/>), *DNAtix* (<https://www.dnatix.com/>), *Gene-chain* (<https://encrypgen.com/>), *Genecoin* (<http://genecoin.me/>), and *MyGenomeCoin* (<https://www.mygenomecoin.com/>) are proposing a model of omic data governance where consumers remain the owners of their genetic data. For instance, *Gene-chain* users freely upload their information to a blockchain. *Gene-chain* allows institutions to use the system to collaborate with other researchers, but for a licensing fee. Any research center or company that is interested with any user’s data reaches a financial agreement with the data owner (i.e., users), and the data owner grants temporary or permanent access to their data (Ozercan et al. 2019). Similarly, *Zenome* users register their data to the system, and the full data set is kept in a distributed framework. Computational nodes in the system perform bioinformatic analyses (i.e., mapping, variation calling, annotation, etc.) as necessary. Both computational and storage nodes earn rewards, called “Zenome DNA tokens” (ZNA). The users can buy computational and storage services from the relevant nodes, or they can sell the rights to their data to interested entities such as pharmaceutical companies. In short, both *Gene-chain* and *Zenome* have mechanisms to ensure that the ownership of the data belongs to the users. (Ozercan et al. 2019). According to the companies promoting it, this model of omic data governance can satisfy both individuals concerned

⁴ Office of the Privacy Commissioner of Canada, “PIPEDA Case Summary #2009-018 – Psychologist’s anonymized peer review notes are the personal information of the patient” [online] <https://www.priv.gc.ca/en/opc-actions-and-decisions/investigations/investigations-into-businesses/2009/pipeda-2009-018/>.

with privacy of omic data, and individuals who wish to ensure greater access to omic data to further research purposes. This could be a framework option to consider for policy-makers that aim to regulate DTC-MoT and for DTC-MoT companies themselves – although it may deprive companies of the profit they make off selling customers’ information (Hazel, 2018).

In any case, the nature of the data collected by DTC-MoT calls for great caution when it comes to data disclosure and retention. Greater transparency on the part of companies regarding the precise type of biological data they collect and the nature of the data they retain and disclose would be a first step in identifying the exact nature of privacy risks posed by companies’ current practices.

4. Other considerations for DTC-MoT companies

Apart from these three main concerns – identifiability, discrimination and anonymization – our findings demonstrate that DTC-MoT should take a number of steps to comply with the principles set out in *PIPEDA*. Third party service providers should be held to the same standards as the company itself (Principle 1). DTC-MoT should identify the purposes for which they collect epigenetic and microbiomic data (Principle 2). At the moment, many privacy policies only address purposes of collecting other personally identifiable information, such as registration information. DTC-MoT companies should not require consumers to consent to use or disclosure of information that is not necessary to satisfy the primary purpose of collection (Principles 3-4). For instance, consent to research should not be inferred by general consent to use the company’s services. Minimum and maximum periods of data and sample retention should be named. After such periods, data should be destroyed or erased (Principle 5). Many DTC-MoT lacked the crucial information needed for customers to make informed decisions about using their services (Principle 8). Many companies lacked a privacy-specific contact option through which consumers can challenge compliance (Principle 10).

RECOMMENDATIONS

Due to the uncertainty surrounding the legal framework governing epigenetic and microbiologic data, DTC-MoT companies should commit to the protection of consumer epigenetic and microbiomic privacy. Below are our recommendations to DTC-MoT companies in this regard.

Best Practices Guidelines For DTC-MoT Companies

1. DTC-MoT companies should name the specific type of data they analyze (aka the exact epigenetic variant(s) at what loci on the genome or which genomic markers of which species of microbes contained in the gut microbiota). This information should be found on company websites.

Rationale	Increased transparency on the part of DTC-MoT companies with regards to the type of data they collect and analyze may provide policy-makers with relevant information when designing a regulatory framework for DTC-MoT. This information should also be available to consumers for the sake of informed consent and so they can do additional research regarding scientific validation of the test type and any of risks associated with the collection of this type of data.
Support from literature	Dupras, C., Song, L., Saulnier, K. M., Joly, Y. (2018) Epigenetic Discrimination : Emerging Applications of Epigenetics Pointing to the Limitations of Policies Against Discrimination. <i>Front. Genet.</i> 9:202.

	<p>“In addition to the difficulty of delineating the frontier between epigenetics and genetics there exists perhaps an <u>even greater challenge: that of handling the potential normative implications of the high heterogeneity of the field of epigenetics.</u> As argued elsewhere, the <u>diversity of epigenetic mechanisms and variants</u> – and <u>different contexts under which epigenetic programming occurs</u> – can impact the attribution of moral epigenetic responsibilities to different actors.” (at 4)</p> <p>“It is not easy to determine whether DNA methylation and histone modifications, for instance, are conceptually equivalent and deserve equal protection against discrimination. In fact, the biological properties of methylated cytosins are considerably distinct from other epigenetic modifications, such as histone acetylation or histone phosphorylation. DNA methylation involves the creation of a relatively stable chemical bond between a methyl group and a nucleic acid (covalent bond). Histone modifications, in contrast, imply much weaker chemical bonds between histone tails and the DNA (hydrogen bonding). [...] Considering the lack of homogeneity among diverse types of epigenetic mechanisms and variants, it is unclear how one could imagine oversight applying similarly to all types of epigenetic information.” (at 4)</p>
Problematic provisions	Many companies provided no information regarding the type of data they collect and analyze.
Model provisions	“The technology Viome uses is called metatranscriptomic analysis. The reason metatranscriptomic analysis is so powerful is because it gives us a complete picture. Not only are we able to identify every active microbe, we can also identify the biochemicals that are being consumed and produced, and how the microbes are interacting with each other. This tells us what’s really going on.” (Viome, the website then goes on to explain more about what metatranscriptomic analysis can tell us, different types of microbes, and a brief history of microbiome testing).

2. DTC-MoT companies should provide a clear definition of personal information to which the privacy policy applies. Personal information should include:

- a. Biological material: the biological sample provided by consumers
- b. Epigenetic/microbiomic data: data derived from the biological sample
- c. Test results: test results as well as interpretation

Rationale	Given that current privacy laws do not explicitly apply to epigenetic or microbiomic data, companies should commit to the protection of consumer privacy.
Support from literature and relevant statutes	<p>Terry, N. (2015) Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces. <i>Behavioral Sciences & the Law</i> 33(5): 653-661.</p> <p>“It is to some extent unclear how well existing regulatory mechanisms and encryption algorithms developed for genetic information are suited for the protection of epigenetic [and microbiomic] information.”</p> <p><i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i></p> <p>Personal information: information about an identifiable individual</p> <p>Personal health information: (a) information concerning the physical or mental health of the individual; (b) information concerning any health service provided to the individual; (c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual; (d) information that is collected in the course of providing health services to the individual; or (e) information that is collected incidentally to the provision of health services to the individual.</p> <p>Christofides, E., O’Doherty, K. (2015) Privacy risks of direct-to-consumer genetic testing: How do consumers interpret the privacy risks associated with sharing their genetic material with private companies? <i>Report to the Office of the Privacy Commissioner of Canada.</i></p> <p>“It is important for the companies themselves, as the experts in genetic testing, to serve as proactive information sources for consumers. Personal information includes:</p>

	<ul style="list-style-type: none"> • Financial transaction information: name, address, credit card information • Health information: personal and family health history • Genetic material: the biological sample provided by consumers • Genetic testing results: genetic sequence, genetic test results as well as any interpretations • Online profile and communication” (at 62-63).
Problematic provisions	<p>“We are required by law to maintain the privacy of your individually identifiable health information. PHI is stored separately from and is treated differently than other information associated with you. Even though every person's microbiome is unique, your microbiome is not personal health information, for the reason that it is currently not possible to identify individuals based on the microbiomes.” (<i>Carbiotix</i>)</p> <p>“Personal data means data about a living individual who can be identified from those data (or from those and other information either in our possession or likely to come into our possession) [...] PII may include, but is not limited to: email address, phone number, address, cookies and usage data” (<i>Atlas</i>).</p>
Model provisions	<p>“Personal data includes your name, address, email address, date of birth, phone number, debit/credit card detail, genetic and/or epigenetic data” (<i>Chronomics</i>).</p> <p>“Special category/sensitive personal data” includes: “DNA and epigenetic profile, medical information, demographic and lifestyle data” (<i>Muhdo</i>).</p> <p>“Personal Information, that we can reasonably use to directly or indirectly identify you, such as your name, mailing address, e-mail address, telephone number, Internet protocol (IP) address used to connect your computer to the Internet, user name or other similar identifier, data from your use of our Services (i.e. Microbiome Data) and any other identifier we may use to contact you online or offline” (<i>uBioDiscovery</i>).</p>

3. DTC-MoT companies should post privacy policies that give clear and complete information about the manner in which customers’ personal information – including biological material and epigenetic/microbiomic data - is treated from collection to disposal including use, access, storage and any secondary uses.

Rationale	DTC-MoT companies should be transparent about their practices so that consumers can make informed decisions.
Support from literature and relevant statutes	<p>Christofides, E., O’Doherty, K. (2015) Privacy risks of direct-to-consumer genetic testing: How do consumers interpret the privacy risks associated with sharing their genetic material with private companies? <i>Report to the Office of the Privacy Commissioner of Canada</i>.</p> <p><i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 8 – Openness: An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information.</p> <p>Office of the Privacy Commissioner of Canada, <i>PIPEDA Self-Assessment Tool</i> “Your organization must: be open about its policies and practices relating to the management of personal information; make specific information about such policies and practices readily available in a form that is generally understandable to your clients and customers” (at 27).</p>

4. Customers should be asked for explicit consent for any use of their sample or data beyond those involved in delivering and improving the service they purchased. This includes external research and data sharing between companies and other organizations. Consumers should be allowed to refuse and still purchase services. Given the potential risk of re-identification associated with multi-omic data, DTC-MoT companies should not share anonymized or aggregate data with third parties without the express consent of customers.

Rationale	Customers should be provided with choices regarding the collection, use or disclosure of their information and should be made aware of those choices.
Support from literature and relevant statutes	<p><i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 3 – Consent: The knowledge and consent of the individual are required for the collection, use or disclosure of personal information, except where inappropriate.</p> <p>Office of the Privacy Commissioner of Canada, <i>PIPEDA Self-Assessment Tool</i> “You organization must never require an individual to consent, as a condition of supplying a product or service, to the collection, use, or disclosure of information beyond what is necessary to fulfill explicitly specified and legitimate purposes” (at 13)</p> <p><i>Philibert RA, Terry N, Erwin C, Philibert WJ, Beach SR, Brody GH. Methylation array data can simultaneously identify individuals and convey protected health information: an unrecognized ethical concern. Clin Epigenetics. 2014;6(1):28. Published 2014 Nov 19.</i> “Recent developments in bioinformatics have shown clearly that the assumption that genotype data in public repositories cannot be tied to identifiable individuals is not correct in all cases.”</p> <p><i>E. A. Franzosa, K. Huang, J. F. Meadow, D. Gevers, K. P. Lemon, B. J. Bohannon, and C. Huttenhower. Identifying personal microbiomes using metagenomic codes. Proceedings of the National Academy of Sciences, page 201423854, 2015.</i> “ [...] it is not safe to assume that microbiome data can be completely anonymized, as a nontrivial fraction of samples can be accurately traced back to their original sources, along with potentially sensitive metadata.”</p>
Problematic provisions	<p>“We may share information with other users in an aggregated form; with our affiliates and other companies owned by or under common ownership with Carbiotix, with third-party vendors. We may include your information in the aggregated microbiome and self-reported information we use to carry out research and development activities performed by Carbiotix and/or its affiliates. These activities may include, among other things, improving the services and/or offering new products or services to you; performing quality control and conducting data” (<i>Carbiotix</i>)</p> <p>“R&D” means research and development activities performed by uBiome on user data. These activities may include, among other things, improving our Services and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party” (<i>uBiome</i>)</p>
Model provisions	“Muhdo will never release individual-level genetic information and/or self-reported information to any third party without asking for and receiving your explicit consent to do so, unless required by law. Further, you acknowledge and agree that Muhdo is free to preserve and disclose any and all personal information to law enforcement agencies. If you have given consent for your genetic information and self-reported information to be used in Muhdo Research as described in the applicable consent document, we may include your information in the aggregated genetic information and self-reported information we disclose to third parties for the purpose of publication” (<i>Muhdo</i>).

5. In order for customers to make informed decisions regarding the purchase of DTC-MoT, companies should name the privacy and discrimination risks potentially associated with undergoing tests as well as the absence of anti-discrimination statutes clearly applying to epigenetic and microbiomic information.

Rationale	In the absence of clear anti-discrimination regulation applying to epigenetic and microbiomic data and as the experts in epigenetic testing/microbiomic testing, companies should serve as a proactive information sources for consumers.
Support from literature and relevant statutes	<p><i>Genetic Non-Discrimination Act, SC 2017, c 3.</i> “Genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis.”</p> <p>Terry, N. (2015) Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces. <i>Behavioral Sciences & the Law</i> 33(5): 653-661.</p>

	<p>“It is to some extent unclear how well existing regulatory mechanisms and encryption algorithms developed for genetic information are suited for the protection of epigenetic [and microbiomic] information.”</p> <p>Rothstein, M. A. (2013), Epigenetic Exceptionalism. <i>The Journal of Law, Medicine & Ethics</i>, 41: 733-736.</p> <p>“The key issue is whether genetic-specific nondiscrimination laws include epigenetics [...]GINA defines genetic information as information about “(i) such individual’s genetic tests, (ii) the genetic tests of family members of such individuals, and (iii) the manifestation of a disease or disorder in family members of such individual. This language strongly suggests that GINA does not apply to epigenetic information, unless “an analysis of human DNA” is broadly interpreted to include epigenetic marks associated with DNA.” (at 735).</p>
Problematic provisions	Most DTC-MoT companies’ policies made no mention of discrimination risks.
Model provisions	“Microbiome Information you share with others could be used against your interests. You should be careful about sharing your Microbiome Information with others. Currently, very few businesses or insurance companies request microbiome information, but this could change in the future. You may want to consult a lawyer to understand the extent of legal protection of your Microbiome Information before you share it with anybody. Furthermore, Microbiome Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Microbiome Information that you share with family, friends or employers may be used against your interests. Even if you share Microbiome Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Microbiome Information about health conditions and you do not disclose this to them, this may be considered to be fraud” (<i>Carbiotix</i>)

6. DTC-MoT companies should give customers access to their epigenetic and/or microbiomic raw data and test results.

Rationale	Individuals should have access to their individual information – including raw data - and own it, to ensure that they preserve control over it.
Support from literature and/or relevant statutes	<i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 9 – Individual access: Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal information and shall be given access to that information.
Problematic provisions	<p>“By ordering our services you agree that we own and may use the sample material (DNA, RNA or protein) and data generated therefrom for any reason included but not limited to our internal uses which will include sharing with our Research Laboratory for improving the Services as well as making new services [...]</p> <p>We will report the result of the <i>MyDNAge</i> test determined by our analysis of your sample in a report comprising a biological age determination only. No other data related to the analysis of our methodology will be provided (ex the DNA methylation value and CpG loci) used for our analysis will not be reported; no information on our algorithm will be reported” (<i>myDNAge</i>)</p>
Model provisions	“Genetic data: this is uninterpreted DNA data which we receive from our lab and which is stored and displayed to you in your personal account. The data can also be downloaded as a *.txt file or as a *.csv file” (<i>Atlas Biomed</i>)

7. DTC-MoT companies should destroy samples after they are done using them for the purpose for which they were collected. Privacy policies should state a clear timeframe for sample retention.

Rationale	Samples should be destroyed to ensure that companies do not use them for secondary purposes. Consumers should be made aware of what happens to their biological samples.
------------------	--

Support from literature and relevant statutes	<p><i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 5 – Limiting use, disclosure and retention: personal information shall be retained only as long as necessary for the fulfillment of the purposes for which it was collected.</p> <p>Office of the Privacy Commissioner, <i>PIPEDA Self-Assessment Tool</i> Your organization must retain information only as long as necessary to fulfil the purposes. Your organization should destroy, erase or anonymize any personal information that is no longer required to fulfil identified purposes; should develop guidelines and implement procedures with respect to the retention of personal information; include minimum and maximum retention periods in these guidelines. (at 19)</p> <p><i>Philibert RA, Terry N, Erwin C, Philibert WJ, Beach SR, Brody GH. Methylation array data can simultaneously identify individuals and convey protected health information: an unrecognized ethical concern. Clin Epigenetics. 2014;6(1):28. Published 2014 Nov 19.</i> “Recent developments in bioinformatics have shown clearly that the assumption that genotype data in public repositories cannot be tied to identifiable individuals is not correct in all cases.”</p> <p><i>E. A. Franzosa, K. Huang, J. F. Meadow, D. Gevers, K. P. Lemon, B. J. Bohannon, and C. Huttenhower. Identifying personal microbiomes using metagenomic codes. Proceedings of the National Academy of Sciences, page 201423854, 2015.</i> “[...] it is not safe to assume that microbiome data can be completely anonymized, as a nontrivial fraction of samples can be accurately traced back to their original sources, along with potentially sensitive metadata”.</p>
Problematic provisions	<p>“Biological samples are stored at our partner laboratories. We store the samples for 1 year, although we retain the right to store the samples for an indefinite period” (<i>Atlas Biomed</i>).</p>
Model provisions	<p>None available</p>

8. DTC-MoT companies should delete personal data after consumers close their accounts. They should not retain data in aggregate or anonymized form. Privacy policies should state a clear timeframe for which data is retained after accounts are closed.

Rationale	<p>Data should be deleted so as to ensure that companies do not use it for secondary purposes. Data should also be deleted to minimize risk of reidentification.</p>
Support from literature	<p><i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 5 – Limiting use, disclosure and retention: personal information shall be retained only as long as necessary for the fulfillment of the purposes for which it was collected.</p> <p>Office of the Privacy Commissioner, <i>PIPEDA Self-Assessment Tool</i> Your organization must retain information only as long as necessary to fulfil the purposes. Your organization should destroy, erase or anonymize any personal information that is no longer required to fulfil identified purposes; should develop guidelines and implement procedures with respect to the retention of personal information; include minimum and maximum retention periods in these guidelines. (at 19)</p> <p><i>Philibert RA, Terry N, Erwin C, Philibert WJ, Beach SR, Brody GH. Methylation array data can simultaneously identify individuals and convey protected health information: an unrecognized ethical concern. Clin Epigenetics. 2014;6(1):28. Published 2014 Nov 19.</i> “Recent developments in bioinformatics have shown clearly that the assumption that genotype data in public repositories cannot be tied to identifiable individuals is not correct in all cases.”</p> <p><i>E. A. Franzosa, K. Huang, J. F. Meadow, D. Gevers, K. P. Lemon, B. J. Bohannon, and C. Huttenhower. Identifying personal microbiomes using metagenomic codes. Proceedings of the National Academy of Sciences, page 201423854, 2015.</i> “[...] it is not safe to assume that microbiome data can be completely anonymized, as a nontrivial fraction of samples can be accurately traced back to their original sources, along with potentially sensitive metadata.”</p>

Problematic provisions	“The company shall not retain any personal data for any longer than necessary in light of the purpose for which data is collected. We may keep your personal data longer for scientific, research and statistical purposes” (<i>Muhdo</i>).
Model provisions	“We keep you data as long as your account remains open and up to 6 years thereafter. In some cases, we may want to keep part of your data for research purposes, in which case we will ask for your explicit consent to retain it” (<i>Chronomics</i>).

9. DTC-MoT companies should remain accountable for breaches of consumer privacy while personal information is transferred to third-party service providers. Third-party service providers should be held to the same privacy standards as the company itself.

Rationale	Where third party disclosure of personal information is necessary for service provision, consumer privacy should still be protected.
Support from literature and/or relevant statutes	<i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 1 – Accountability: An organization is responsible for the personal information under its control and shall designate an individual or individuals who are accountable for the organization’s compliance with the following principles. <i>Office of the Privacy Commissioner, PIPEDA Self-Assessment Tool</i> “Your organization must protect all information in the organization’s possession or custody including information that has been transferred to a third-party for processing; should use contractual or other means to ensure a comparable level of protection while personal information is with a third party for processing” (at 6).
Problematic provisions	“This policy does not apply to third-party service providers. We urge you to read privacy practices of all our third party vendors before submitting any PII to us” (<i>Ixcela</i>).
Model provision	“This policy applies to all personal data held by the Company and by third-party data processors processing personal data on the company's behalf”. (<i>Muhdo</i>) “We require all third parties to respect the security of your personal data and to treat it in accordance with the law. We do not allow our third party service providers to use your personal data for their own purposes and only permit them to process your personal data for specified purposes and in accordance with our instructions.” (<i>Chronomics</i>)

10. DTC-MoT companies should provide consumers with one or multiple privacy-specific contact options (email, phone number and mailing address) so that they can easily raise privacy questions or issues, or request access to their personal information.

Rationale	Companies should have people designated to supervise and maintain the organizations privacy practices and consumers need to be able to have concrete means of contact for their questions and concerns.
Support from literature and/or relevant statutes	<i>Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].</i> Principle 10 – Challenging compliance: An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization’s compliance. <i>Office of the Privacy Commissioner, PIPEDA Self-Assessment Tool</i> “Your organization must put in place procedures for receiving and responding to complaints or inquiries concerning the organization’s policies and practices relating to the handling of personal information; must establish complaint procedures that are easily accessible and simple to use; must inform inquirers or complainants of the existence of relevant complaint procedures” (at 33).
Problematic provisions	Incomplete-“You may request a summary of information we hold about you, as well as corrections, updates or deletion of your information, by contacting us at info@myDNAge.com ” (<i>myDNAge</i>).

Model provisions	<p>“Viome shall allow those individuals access to their personal data and allow the individual to correct, amend, or delete inaccurate information, except where the burden or expense of providing access would be disproportionate to the risks to the privacy of the individual in question or where the rights or persons other than the individual would be violated”. Please contact privacy@viome.com to exercise these rights” (<i>Viome</i>).</p> <p>“If you have any question about this privacy policy, please contact us at privacyofficer@ubiome.com. If you believe your privacy rights have been violated, please let us know immediately by contacting our HIPAA Privacy Officer at (760) 268 6200” (<i>Ubiome</i>).</p>
-------------------------	--

Information Brief for the Canadian public

What is epigenetic testing? Broadly defined, epigenetics is the study of how the reading of DNA is affected by its interactions with surrounding chemical compounds. Epigenetics is different from genetics in that it does not study the DNA sequence itself. Rather, it studies how the presence of other molecules impacts gene expression by activating or deactivating certain parts of DNA. When you undergo direct-to-consumer epigenetic testing, the company collects a biological sample from you (saliva, blood, urine, etc.) and analyzes data about one of the known epigenetic mechanisms. The company then provides results and recommendations based on inferences from epigenetic data.

What is microbiomic testing? Microbiomics is the study of the genomes of the microorganisms that live in or on the human body, such as bacteria and viruses. Currently, most direct-to-consumer microbiomic testing companies will provide you with some information about the microorganisms living in your gut. The company collects a biological sample from you (most often a stool sample) and extracts information about your microbiome. Some companies draw inferences about the diet that is best adapted to your microbiome.

What are the risks associated with direct-to-consumer epigenetic and microbiomic testing? Epigenetics and microbiomics are relatively new fields. The information that can be extracted from epigenetic and microbiomic data is changing rapidly and the exact nature of risks associated with epigenetics and microbiomics are still unknown. However, we do know that epigenetics and microbiomics can reveal sensitive information about you such as risk to some diseases, past exposure to trauma, smoking status, patterns of alcohol and drug consumption, or diet. At the moment, only one direct-to-consumer epigenetic test provides information regarding smoke and alcohol exposure, and one microbiomic test provides information on the ‘nationality’ of your gut microbiome. In the future it is possible that tests will reveal additional sensitive information about your disease risks, exposures and lifestyle.

What privacy laws apply? The *Personal Information Protection and Electronic Documents Act* [PIPEDA] (L.C. 2000, ch. 5) is Canada’s federal act for organizations that collect, use, or disclose personal information in the course of commercial activities. At the moment, most companies do not explicitly mention that they treat epigenetic or microbiomic information as personal information, making it unclear whether these companies’ data governance practices comply with the requirements of PIPEDA. There is increasing scientific evidence suggesting that epigenetic and microbiomic data should be treated as potentially identifying and sensitive data. We therefore recommend that consumers ensure DTC epigenetic and microbiomic testing companies will treat their data as personal information before using their services.

What non-discrimination laws apply?

Current genetic non-discrimination policies, such as the *Genetic Non-Discrimination Act* (S.C. 2017, c. 3) in Canada do not explicitly apply to epigenetic and microbiomic data. At the moment, Canadian employers, insurance companies, social services etc. typically do not ask you to disclose epigenetic and microbiomic information. However, this may change in the coming years and it is important to consider these new risks of discrimination.

Questions to ask the company

- What is/are the exact biological variant(s) that you test for, and using what type of arrays? Have these tests been scientifically validated? Have these tests been validated for clinical use?

- What personal information do you collect? Is epigenetic and/or microbiomic data protected as personal information under your privacy policy?
- With whom will the company share my test results (eg. researchers, marketers)? Is this sharing mandatory? *You are within your rights to refuse such disclosure.*
- How long will the company keep my sample and data? Why?
- Once I undergo testing, who owns my data?
- Can I access my epigenetic/microbiomic data? How? Under what format?
- Can I have my data completely deleted upon request?

Note d'information à l'intention du public canadien

Qu'est-ce qu'un test épigénétique? L'épigénétique est l'étude de la manière dont la lecture de l'ADN interagit avec d'autres composés chimiques qui affectent la manière dont l'ADN est traduit et transcrit. L'épigénétique se distingue de la génétique en ce que l'on n'y étudie pas la séquence génétique elle-même (A, T, C, G). On étudie plutôt de quelle façon la présence d'autres molécules impact sur l'expression des gènes, via l'activation ou la désactivation de certaines parties de la séquence d'ADN. Lorsque vous commandez un test épigénétique en ligne, vous soumettez à la compagnie un échantillon (généralement, de sang ou de salive). La compagnie examine les modifications épigénétiques à l'ADN dans cet échantillon. La compagnie fournit ensuite différents types de résultats fondés sur les inférences qu'elle tire à partir des données épigénétiques.

Qu'est-ce qu'un test microbiomique? La microbiomique est l'étude du génome des microorganismes qui vivent au sein du corps humain, comme des bactéries et des virus. À l'heure actuelle, la plupart des compagnies offrant des tests microbiomiques en ligne analysent les génomes des microorganismes se trouvant dans le système digestif. Lorsque vous commandez un test microbiomique en ligne, vous soumettez à la compagnie un échantillon de vos selles. La compagnie en extrait les données relatives à la composition de votre microbiome. Certaines compagnies obtiennent de ces données des inférences par rapport à la diète la mieux adaptée à votre microbiome.

Quels sont les risques associés aux tests épigénétiques et microbiomiques offerts en ligne? L'épigénétique et la microbiomique sont des domaines relativement nouveaux. L'information qui peut être extraite des données épigénétiques et microbiomiques change rapidement, et c'est pourquoi la nature exacte des risques associés à l'épigénétique et à la microbiomique n'est pas claire. Cependant, nous savons que l'épigénétique et la microbiomique peuvent révéler des informations sensibles à votre sujet telles que l'exposition au tabac, l'abus de substances, les traumatismes psychologiques, le stress et l'alimentation. À l'heure actuelle, un seul test épigénétique en ligne fournit des renseignements sur l'exposition au tabac et à l'alcool, et un test microbiomique fournit des informations relatives à la 'nationalité' de votre microflore intestinale. À l'avenir, il est possible que les entreprises puissent révéler d'autres informations sensibles sur vos expositions passées, votre mode de vie ou encore votre risque de développer certaines maladies.

Quelles sont les lois applicables en matière de vie privée?

La *Loi sur la protection des renseignements personnels et les documents électroniques* [LPRPDE] (L.C. 2000, ch. 5) est la loi fédérale du Canada pour les organisations qui recueillent, utilisent ou divulguent des renseignements personnels dans le cadre d'activités commerciales. À l'heure actuelle, la plupart des compagnies ne mentionnent pas explicitement qu'elles traitent les informations épigénétiques ou microbiomiques comme des informations personnelles, ce qui pose la question à savoir si les pratiques de gouvernance des données de ces entreprises sont conformes aux exigences de la LPRPDE. De plus en plus de preuves scientifiques suggèrent que les données épigénétiques et microbiomiques devraient être traitées comme des données potentiellement identifiantes et sensibles. Nous recommandons donc aux personnes de s'assurer que les compagnies de tests épigénétiques et microbiomiques offerts directement au consommateur traiteront leurs données comme des informations personnelles avant d'utiliser leurs services.

Quelles sont les lois applicables en matière de non-discrimination?

Les politiques existantes en matière de non-discrimination génétique, comme la *Loi sur la non-discrimination génétique* (L.C. 2017, ch. 3) ne s'appliquent pas explicitement aux données épigénétiques et microbiomiques. Pour le moment, les compagnies d'assurances canadiennes ne demandent pas à leurs clients de leur fournir leur information épigénétique ou microbiomique. Toutefois les pratiques pourraient changer au cours des prochaines années et il est important de considérer ces nouveaux risques de discrimination.

Questions à poser à l'entreprise :

- Quel est/sont le(s) variant(s) biologique(s) précis testé(s) par votre produit? Quel type de test/méthode utilisez-vous pour détecter ce variant? Cette méthode a-t-elle été validée scientifiquement? A-t-elle été validée pour une utilisation clinique?

- Quel type d'information personnelle récoltez-vous ? Les données épigénétiques et microbiomiques sont-elles considérées comme des renseignements personnels en vertu de votre politique de confidentialité ?
- Avec qui votre entreprise partagera-t-elle les résultats de mes tests ? (ex : chercheurs, agence de marketing). Suis-je obligé d'accepter une telle divulgation? *Vous êtes en droit de refuser.*
- Pendant combien de temps l'entreprise conservera-t-elle mon échantillon et mes données ? Pour quelles raisons ?
- Une fois que je subis le test, à qui mes données appartiennent-elles ?
- Pourrai-je avoir accès à mes données épigénétiques/microbiomiques ? Comment ? Sous quel format ?
- Mes données pourront-elles être détruites complètement si j'en fais la demande?

REFERENCES

PRIMARY SOURCES – COMPANIES’ WEB SITES AND POLICIES

- Atlas Biomed, online: <https://atlasbiomed.com/ca> [last accessed October 19, 2019].
- Atlas Biomed, “Information Governance Policy” (May 25, 2018) online <https://atlasbiomed.com/ca/privacy> [last accessed October 19, 2019].
- Atlas Biomed, “Terms and Conditions” online: <https://atlasbiomed.com/ca/rules> [last accessed October 19, 2019].
- Carbiotix, online: <https://carbiotix.com/> [last accessed October 19, 2019].
- Carbiotix, “Privacy Policy” (September 1, 2019) online: <https://carbiotix.com/assets/Carbiotix-Privacy-Policy.pdf> [last accessed October 19, 2019].
- Carbiotix, « Terms of Services » (September 1, 2019) online: <https://carbiotix.com/assets/Carbiotix-Terms-of-Service.pdf> [last accessed October 19, 2019].
- Chronomics, online: <https://www.chronomics.com/> [last accessed October 19, 2019].
- Chronomics, “Privacy Policy” online: <https://www.chronomics.com/legal/privacy-policy> [last accessed October 19, 2019].
- Chronomics, “Terms and Conditions” online: <https://www.chronomics.com/legal/terms-conditions> [last accessed October 19, 2019].
- EpigenCare, online: <https://www.epigenCare.com/> [last accessed October 19, 2019].
- EpigenCare, “Privacy Policy” (April 15, 2018) online: <https://www.epigenCare.com/privacy-policy> [last accessed October 19, 2019].
- EpigenCare, “Terms & Conditions” (April 17, 2018) online: <https://www.epigenCare.com/terms/> [last accessed October 19, 2019].
- Ixcela, online: <https://ixcela.com/> [last accessed October 19, 2019].
- Ixcela, “Privacy Policy” (May 30, 2017) online: <https://ixcela.com/privacy-policy/> [last accessed October 19, 2019].
- Ixcela, “Terms of use” online: <https://ixcela.com/terms-of-use/> [last accessed October 19, 2019].
- Muhdo, online: <https://muhdo.com/> [last accessed October 19, 2019].
- Muhdo, “Privacy Policy” (May 16, 2018) online: <https://muhdo.com/privacy-policy/> [last accessed October 19, 2019].
- Muhdo, “Data Retention Policy” (May 16, 2018) online: <https://muhdo.com/data-retention-policy/> [last accessed October 19, 2019].

Muhdo, “Terms & Conditions” (February 5, 2019) online: <https://muhdo.com/terms-conditions/> [last accessed October 19, 2019].

MyDNAge, online: <https://www.mydnage.com/> [last accessed October 19, 2019].

MyDNAge, “Privacy Policy” online: <https://www.mydnage.com/privacy> [last accessed October 19, 2019].

MyDNAge, “Terms of Services” online: <https://www.mydnage.com/termofservice> [last accessed October 19, 2019].

TFTAK, online: <http://www.microbiome.ee/> [last accessed October 19, 2019].

TFTAK, “Terms and Conditions” (April 28, 2017) online: https://www.microbiome.ee/docs/Kasutajatingimused_en.pdf [last accessed October 19, 2019].

Thryve, online: <https://www.thryveinside.com/> [last accessed October 19, 2019].

Thryve, “Privacy Policy”, online; <https://drive.google.com/file/d/0B-bzApZXCpbjOTRURHgyNTFSc1k/view> [last accessed October 19, 2019].

Thryve, “Terms of Services” online: <https://drive.google.com/file/d/0B-bzApZXCpbjZmNQdU5vLTFFWGc/view> [last accessed October 19, 2019].

Trume, online: <https://trumelabs.com/>. [last accessed October 19, 2019].

Ubiodiscovery, online: <https://ubiodiscovery.com/> [last accessed October 19, 2019].

Ubiodiscovery, “Privacy Policy” (April 3, 2017) online: <https://ubiodiscovery.com/privacy/> [last accessed October 19, 2019].

Ubiodiscovery, “Terms of Services”, online: <https://ubiodiscovery.com/privacy/> [last accessed October 19, 2019].

Ubiome, online: <https://ubiome.com/> [last accessed September 17 2019].

Ubiome, “Privacy Policy” online: <https://ubiome-assets.s3.amazonaws.com/doc/privacy-policy.pdf> [last accessed September 17 2019].

Ubiome, “Notice of Privacy Practices” online: http://cdn.shopify.com/s/files/1/0208/9228/files/HIPAA-15-ATT-B_Notice_of_Privacy_Practices_2.0_1.pdf?17422066647075382299 [last accessed September 17 2019].

Ubiome, “Terms of Services” online: https://cdn.shopify.com/s/files/1/0208/9228/files/HIPAA-15-ATT-A_Terms_of_Service_for_www.ubiome.com_3.1.pdf?141 [last accessed September 17 2019].

Viome, online: <https://www.viome.com/> [last accessed October 19, 2019].

Viome, “Privacy Policy” (January 25, 2019) online: <https://www.viome.com/privacy-policy> [last accessed October 19, 2019].

Viome, “Terms of Services” (January 25, 2019) online: <https://www.viome.com/terms> [last accessed September 17 2019].

Zenome, online: <https://zenome.io/>. [last accessed September 17 2019].

DNAitix, online: <https://www.dnatix.com/> [last accessed September 17 2019].

Gene-chain, online: <https://encrypgen.com/> [last accessed September 17 2019].

Genecoin, online: <http://genecoin.me/>. [last accessed September 17 2019].

MyGenomeCoin, online: <https://www.mygenomecoin.com/> [last accessed September 17 2019].

Let's Get Checked, online: <https://www.letsgetchecked.com/ca/en/> [last accessed October 19, 2019].

Everlywell, online: <https://www.everlywell.com/> [last accessed October 19, 2019].

LEGISLATION

Personal Information Protection and Electronic Documents Act, SC 2000, c 5 [PIPEDA].

EU General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1.

Fair Information Practices Act, MGL Part I, Title X. c. 66A

Genetic Non-Discrimination Act, SC 2017, c 3.

Shine the Light Law, California Code, Civil Code - CIV § 1798.83

JURISPRUDENCE

Canada (Information Commissioner) v. Canada (Transportation Accident Investigation and Safety Board), 2006 FCA 157

Canada (Information Commissioner) v. Canada (Commissioner of the Royal Canadian Mounted Police), [2003] 1 S.C.R. 66, 2003 SCC 8.

Dagg v. Canada (Minister of Finance), [1997] 2 S.C.R.

Gordon v. Canada (Health), 2008 FC 258 (CanLII).

Morgan v. Alta Flights Inc, 2006 FCA 121.

SECONDARY SOURCES - ARTICLES

Backes, M., Berrang, P., Hecksteden, A., Humbert, M., Keller, A. (2016) Privacy in epigenetics: temporal linkability of MicroRNA Expression Profiles. *USENIX Security Symposium* 1223-1240.

- Christofides, E., O’Doherty, K. (2015) Privacy risks of direct-to-consumer genetic testing: How do consumers interpret the privacy risks associated with sharing their genetic material with private companies? *Report to the Office of the Privacy Commissioner of Canada*.
- Christofides, E., O’Doherty, K. (2016) Company disclosure and consumer perceptions of the privacy implications of direct-to-consumer genetic testing. *New Genetics and Society* 35(2): 101-123.
- Diemer K., Woghiren M. (2015). Epigenetic privacy: hacking your health? in *Epigenetics in Society*, ed. Crawford M., Windsor: Epigenetics Study Group, 279–301.
- Dupont C., Armant D.R., Brenner C.A. (2009) Epigenetics: definition, mechanisms and clinical perspective. *Semin Reprod Med.* 27(5): 351–357.
- Dupras C., Song L., Saulnier K.M., Joly Y. (2018) Epigenetic Discrimination: Emerging Applications of Epigenetics Pointing to the Limitations of Policies Against Genetic Discrimination. *Front Genet.* 9: 202.
- Dupras C., Ravitsky V. (2016) The ambiguous nature of epigenetic responsibility. *Journal of Medical Ethics* 42: 534-541.
- Dupras, C., Ravitsky, V., and Williams-Jones, B. (2014). Epigenetics and the Environment in Bioethics. *Bioethics* 28(7): 327-334
- Erlich, Y., Narayanan, A. (2014). Routes for breaching and protecting genetic privacy. *Nature reviews Genetics* 15(6): 409–421.
- Franzosa, E. A., et al. (2015) Identifying personal microbiomes using metagenomic codes. *Proceedings of the National Academy of Sciences* 201423854.
- Hasin, Y., Seldin, M., Lusk, A. (2017) Multi-omic approaches to diseases. *Genome Biol.* 18(1): 83.
- Hawkins, A. K., and O’Doherty, K. C. (2011) Who Owns Your Poop?: Insights Regarding the Intersection of Human Microbiome Research and the ELSI Aspects of Biobanking and Related Studies. *BMC Medical Genomics* 4: 72.
- Hazel, James and Slobogin, Christopher, “Who Knows What, and When?: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies”. *Cornell Journal of Law and Public Policy*, 2018; Vanderbilt Law Research Paper No. 18.
- Jansson, J.K. and Baker, E.S. (2016) A multi-omic future for microbiomic studies. 1 *Nat Microbiol.* 16049.
- Jenuwein, T., and Allis, C. D. (2001) Translating the histone code. *Science* 293: 1074–1080.
- Knoppers B. M. (2010) Consent to 'personal' genomics and privacy. Direct-to-consumer genetic tests and population genome research challenge traditional notions of privacy and consent. *EMBO reports* 11(6): 416–419.
- Ma Y., Chen H., Lan C., Ren J. (2018) Help, hope and hype: ethical considerations of human microbiome research and applications. *Protein Cell.* 9(5):404–415.
- McGuire, A.L., Diaz, C. M., Wang, T. & Hilsenbeck, S.H. (2009) Social networkers’s attitudes toward direct-to-consumer personal genome testing. *The American journal of bioethics: AJOB*, 9(6-7): 3-10.

- Nature (2020) Microbiome. *Nature.com* online: <https://www.nature.com/subjects/microbiome>
- NIH Microbiome Portfolio Analysis Team (2019). A review of 10 years of human microbiome research activities at the US National Institutes of Health, Fiscal Years 2007-2016. *Microbiome*, 7(31) online: <https://microbiomejournal.biomedcentral.com/articles/10.1186/s40168-019-0620-y#Abs1>
- Ozercan, H.I., Ileri, A.M., Ayday, E., Alkan, C. (2019) *Realizing the potential of blockchain technologies in genomics*. *Genome reseach* 28: 1-9.
- Philibert, R. A. et al. (2014) Methylation array data can simultaneously identify individuals and convey protected health information: an unrecognized ethical concern. *Clinical epigenetics* 6(28).
- Rajendhran, J., Gunasekaran, P. (2010). Human microbiomics. *Indian journal of microbiology*, 50(1): 109–112.
- Rothstein, M. A. (2013), Epigenetic Exceptionalism. *The Journal of Law, Medicine & Ethics*, 41: 733-736.
- Rumbold, J., Pierscionek, B. (2018) Contextual Anonymization for Secondary Use of Big Data in Biomedical Research: Proposal for an Anonymization Matrix. *JMIR Med Inform.* 6(4): e47.
- Saukko, P. (2013) State of Play in Direct-to-Consumer Genetic Testing for Lifestyle-related Diseases: Market, Marketing Content, User Experiences and Regulation. *Proceedings of the Nutrition Society* 72 (1): 53–60.
- Terry, N. (2015) Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces. *Behavioral Sciences & the Law* 33(5): 653-661.
- Wu C.t., Morris J.R. (2001) Genes, genetics, and epigenetics: a correspondence. *Science* 293(5532): 1103–1105.
- Zaaijer S., et al. (2017) Rapid re-identification of human samples using portable DNA sequencing. *eLife* 6.
- Zook M., et al. (2017) Ten simple rules for responsible big data research. *PLoS Comput Biol.* 13.

SECONDARY SOURCES – WEBSITES

- Office of the Privacy Commissioner of Canada, “Direct-to-consumer genetic testing”, December 2017 [online] https://www.priv.gc.ca/en/privacy-topics/health-genetic-and-other-body-information/02_05_d_69_gen/.
- Office of the Privacy Commissioner of Canada, “Personal Information”, October 2013 [online] https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/pipeda-compliance-help/pipeda-interpretation-bulletins/interpretations_02/#fn27.
- Office of the Privacy Commissioner of Canada, “PIPEDA Case Summary #2009-018 – Psychologist’s anonymized peer review notes are the personal information of the patient” [online] <https://www.priv.gc.ca/en/opc-actions-and-decisions/investigations/investigations-into-businesses/2009/pipeda-2009-018/>.