



***Protecting Genetic Information:
A Comparison of Normative Approaches***
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The increasing use of genetic information has emerged as an important concern worldwide as scientific and technological advances continue to advance at lightening speed and as governments struggle to develop appropriate policy frameworks. While most countries clearly recognize that genetic information warrants some form of privacy protection, the underlying rationale for providing that protection and the approach which is ultimately adopted vary significantly across the board. As a result, a medley of laws, policy statements and guidelines currently exist to protect genetic information, each with its inherent assumptions, concepts and terminology.

This second edition of **GenEdit** will briefly examine the broad policy directions that have been taken at international, regional and national levels to protect genetic information, commenting on different approaches and some of the normative challenges associated with each.

A. Use of Genetic Information in Health Care and Health Research

For decades, health care providers have relied on genetic information obtained through family histories to prevent, monitor and assess the development of hereditary disorders. Through recent advances in genetic testing, clinicians can now combine familial history with the specific genetic makeup of individuals in order to better diagnose a patient's existing disease or predict his/her risk of expressing a disease some time in the future. In some cases, such information can provide patients with the opportunity for earlier and more effective treatment, better information on which to base their reproductive choices, or the necessary incentive to change lifestyle factors that may contribute to the risk of onset of disease.

Understanding genetic information and its implications has also become a necessary and integral part of health research. For example, there are many important research studies that aim to:

- ❖ understand how genes account for different reactions to certain drugs;
- ❖ establish common genetic variation within a particular group or different groups through population health studies;
- ❖ find the genetic bases of diseases and develop new therapies;

- ❖ understand the interactions of genes with other genes or with external factors (e.g. environmental, socio-economic factors, etc); and
- ❖ evaluate the effectiveness of genetic testing in the delivery and organization of health services.

B. Regulatory Challenges

Regulating the collection and use of genetic information poses significant challenges for legislators and policy-makers. An international review of various policy instruments reveals that some jurisdictions have chosen to adopt special regimes tailored specifically to genetic information. Others have expressly expanded and adapted existing protections to cover this area. Others still have yet to determine the most appropriate policy direction. Several reasons may account for this difference in approaches.

i. Nature of Genetic Information

The first reason may be inherent to the nature of the information itself. There is something about genetic information and the human tissue that contains that information which seems, instinctively at least, to have special status worthy of distinct legal treatment and protection. Some of the arguments supporting the view that genetic information ought to be treated exceptionally are as follows:

- For some, genetic information is the most sensitive form of personal information that essentially defines individuals *qua* individuals. Through this lens, genetic information is regarded as having special status because it goes to the very core of our uniqueness as a human being and is the most intimate type of information about ourselves.
- While genetic information is specific to the traits of each individual, it is also revealing of common characteristics held by other family members. Hence, they too have a real interest in how genetic information about them is collected, used and disclosed. This challenges our traditional understanding of consent based on the principle of individual autonomy, since others who may also be affected by the individual's choice now factors significantly into the equation.
- Extending the latter point even further, genetic information may be revealing of common traits held by broader communities, groups and populations. The potential for discrimination and stigmatization of individuals, by sheer virtue of their association with a defined community, group or population that has a higher incidence of some genetic trait, whether or not the individuals themselves carry or express the gene, may negatively impact peoples' access to certain services, as well as their opportunity to participate in and contribute meaningfully to society.

- Another feature of genetic information is the fact that, in some cases, it may indicate an existing trait that actually manifests itself in the individual, while in other cases, it indicates only a probability that the individual may one day manifest that trait later in life. Some late onset conditions can be predicted with high certainty based on the presence of a single gene, while others depend on a host of other factors, including other genes, environmental influences, lifestyle choices, and socio-economic factors. Genetic test results are not always reliable, and even if they were, they do not lend themselves to easy interpretation. Hence, there is a danger that ill-informed decisions may be made about the fate of individuals, families and larger communities, impacting on their rights and interests, based solely on their genes which may, or may never, express themselves as a disorder.
- Finally, there are sometimes arguments made about the special status of genetic information that are related, not to the nature of genetic information *per se*, but rather, to the human tissue as a record of that information. Human tissue, or any human bodily substance - be it a skin or bone sample, a strand of hair, a drop of blood, or even nail clippings - contains a rather complete picture of who we are. Everything from one's gender, eye and hair colour, to one's predisposition towards certain behaviour or risk of developing certain diseases can be contained in a tiny biological specimen that can remain intact for years, decades and arguably centuries.

While many of these claims may be at the root of "genetic exceptionalism", arguments to the contrary have demonstrated persuasively that genetic information is in fact not exceptional at all. Genetic information raises, perhaps more acutely, many of the same issues raised by other types of personal information. We agree with this view for several reasons.

Sensitivity of personal information is a relative concept. For some, the fact that they carry an obscure gene that has no significant meaning to the average layperson, may not be nearly as sensitive to them as is information about their financial situation or personal lifestyle. In some circumstances, the fact that one family member suffers from an infectious disease or undertakes certain risky behaviour is information that can have profound impact on other family members, particularly dependents living in the same household. Moreover, there are unfortunately many examples of discrimination against individuals based merely on their association with communities or groups that have shown higher incidence of disease as a result of certain risk factors – be they genetic or non-genetic. There are other types of information, quite apart from genetic information, that can be just as predictive of future health outcomes, such as, infectious diseases in their early asymptomatic stages, addition to alcohol or drugs, high levels of cholesterol or propensity towards risk. Finally, the advent of

modern information technology has made it increasingly possible to electronically process and link all types of personal information originating from multiple different sources, including genetic information derived from human tissue, thus creating an even more complete record of who we are.

For these and other reasons, it is argued that there should not be a distinct legal regime to regulate the use of genetic data separately. Rather, existing frameworks governing other types of personal information should be re-examined to address, in a more coherent fashion, the complex issues raised by genetics, but which are not specific to genetics.

The difference in these views, that is, whether genetic information should be regulated distinctly or not, helps explain, in large measure, the difficult challenges faced by policy-makers in this area and the stark difference in directions they have taken to date.

ii. Proper Locus for Regulation

Another challenge raised by genetic information is the difficulty to identify the proper *locus* for regulation. Are there certain immutable principles we can agree to uphold at the international level and certain limits beyond which we all agree as a global society not to go? To what extent should the choice of legal norms be deferred to the national, or even local level, in accordance with local value systems and socio-cultural differences?

Moreover, what is it about genetic information that we wish to govern? Is it the need to regulate the collection, use and disclosure of genetic information? or the need to prohibit criminal abuses of genetic information? or the need to protect the fundamental human right to equality notwithstanding that genetic information? Are we most concerned about the public or the private sector? Does it, or *should it*, make a difference? Is it the use of genetic information in the context of health and health research, or is it its potential access and use by employers, insurers and law enforcers that requires closest scrutiny and regulation? Add to the mix federal-provincial division of legislative powers in a country like Canada, and other federal states, where each of these aspects and sectors of activity comes under different jurisdictions, and it is no wonder that policy-makers find this area challenging to regulate.

In the absence of statutory norms, some countries have resorted to self-regulation by professional corporations, governmental agencies and/or non-governmental organizations. Ethics guidelines or codes of conduct developed by such entities have the distinct advantage of being more flexible and closely connected to practical reality. These ethics norms also promote moral introspection and inculcate a sense of moral responsibility among users of genetic information, in a way which laws pronounced from “on high” may not. This being said, however, ethics norms also raise questions about legitimacy and

compliance. By virtue of what legal authority or mandate can these entities determine what is or is not “ethical” and effectively regulate the use of genetic information in the absence of law? In order to gain legitimacy under common law, ethics guidelines and codes of conduct have yet to demonstrate over time and usage that they indeed represent the standard of care that courts should expect of users of genetic information. Unfortunately, there is often no systematic evaluation of how well ethics guidelines or codes of conduct fare in practice, nor any substantial evidence of the extent to which they are adopted and implemented. Moreover, in cases of non-compliance, wrongdoers may not be as effectively sanctioned as they might otherwise be if these ethical norms had the force of law behind them.

iii. Other Challenges

Yet another challenge facing policy-makers is the rapid changing nature of genetic and information technologies. How can policy be designed to effectively regulate the known, yet be sufficiently adaptable to capture the unknown? Advances in our understanding of the human genome and development of the necessary technologies to support further enquiry into the study of genomics were never even dreamed of a few years ago. Likewise, what will be possible tomorrow likely bears no resemblance to what we can anticipate today. Adding to this is the continually expanding use of information technology and the Internet which makes it easier for many different custodians to access, store, link and analyze large amounts of genetic information with other personal information about individuals over time. All of this activity contributes significantly to the complexity of the rules needed to govern it.

Last, but not least, a major challenge facing policy-makers in the area of genetic information is the “yuk” factor. Genetics is the “stuff” of science fiction. For the average layperson, it engenders fears – fears that have been graphically depicted by Hollywood films and effectively amplified by newsy media headlines. These fears, whether or not they are justified or supported by broader public opinion, have tended to skew the policy debate. In some jurisdictions, these fears have been used to mount effective pressure on politicians to do “something”, but with no clear indication of what that “something” ought to be. As a result, policy-makers face the challenge of sorting through the rhetoric in order to disentangle the real “mischief” that legislation ought to address.

C. Different Normative Approaches

In light of all these challenges and confounding factors, it is not surprising to find that many of the countries whose laws we reviewed have adopted different approaches for protecting genetic information. Although the majority of jurisdictions recognize that genetic information needs to be protected, they have gone about ensuring that protection in a variety of ways. We can distinguish four

general approaches.

i. The Personal Information Approach [Table I](#)

The personal information approach encompasses genetic information within the broader definition of personal data (e.g. New Zealand) or nominative data (e.g. France). The reference to genetic information is either made expressly or impliedly. Jurisdictions may have specifically opted for this approach because they consider that the general regime they have in place, as is, provides sufficient protection to genetic information along with all other types of personal information. Alternatively, some jurisdictions may not yet have made a determination either way about how they intend to protect genetic information and resort to their general privacy regime in the meantime to provide some protection. Yet other jurisdictions (e.g. Canada) that include genetic information in their broad definition of personal information and subject it to the same rules, nonetheless build in a general provision calling for greater stringency in the application of those rules commensurate with the level of sensitivity of the data (leaving open to interpretation what is considered sensitive data depending on the type of information and the specific circumstances).

The personal information approach has the advantage of setting out a comprehensive, coherent and principled regime for privacy protection that focuses on those socially acceptable purposes for which personal information may be collected, used and disclosed, how that ought to be done, and under what conditions. It does not detract from that principled analysis by delineating different types or classes of personal information. Although the personal information approach may well provide adequate protection for genetic information, it centers primarily on a consent model grounded in the principle of individual autonomy and hence, does not take into consideration important familial and communal interests in that information.

ii. The Sensitive Information Approach [Table II](#)

The sensitive information approach expressly deems certain types of information to be sensitive based on the source of the information and the degree of intimacy related to it. Designated categories of sensitive data include data relating to health, ethnic origin, political, religious and philosophical beliefs, criminal records, and sexual orientation (e.g. European Parliament, France (bill), Iceland). Typically, the sensitive information approach reverses the default position that exists under the general personal information approach. That is, rather than allowing the processing of data subject to certain conditions, the sensitive data approach prohibits the processing for sensitive data unless it is required by law, it is for public health purposes, or if explicit consent is obtained.

While the sensitive information approach affords a higher level of protection to certain categories of personal information than does the general personal information approach, it is not altogether that clear when and if genetic data falls within a specified class of sensitive data. Moreover, even if genetic information

were deemed sensitive, either expressly or impliedly *via* the inclusion of health data, the sensitive information approach still does not take into account the familial or communal dimension of genetic data.

iii. The Health (or Medical) Information Approach [Table III](#)

The health (or medical information) approach provides a distinct normative regime for individually identifiable health or medical information (*e.g.* Australia, the U.S., some Canadian provinces (Alberta, Saskatchewan and Manitoba), World Medical Association and Council of Europe). For the most part, genetic information is covered either expressly or impliedly by the definitions of health or medical information. This approach often takes into consideration the interests and needs of family members who are involved in making decisions respecting the health of their loved ones. It also provides more detailed guidance on the conditions under which health or medical information may be used for care, education or research purposes - sometimes articulating special concern for the broader impact of research results on communities or groups.

While the health or medical information approach affords a good level of protection to the information covered, it is limited in its scope of application. Often this model will only cover information kept by specific entities (*i.e.* medical facilities, government funded entities, public institutions, health data custodians or trustees, etc). Once the information flows outside the walls of the covered entities, the protective rules cease to apply. Moreover, this model does not offer the advantage of overall coherence that the general personal information approach does. Because this model sets out a distinct set of rules and separate oversight mechanisms, a genetic research project that aims to study the influence and interaction of multiple health determinants (as discussed above), can be subject to conflicting rules and different oversight bodies. These differences from one regime to another add further to the already-existing jurisdictional differences that challenge national and international research.

iv. The Genetic Information Approach [Table IV](#)

Finally, some jurisdictions favour the genetic information approach. This approach creates a unique corpus of rules specific to genetic information (*e.g.* UNESCO, United Nations (draft), Israel). The genetic information approach has the obvious advantages of providing additional and more tailored protections specific to this type of information, while also addressing some of the familial and communal interests in that information.

However, by its very nature, this approach is limited. Indeed, by attempting to address the ethical, social and legal issues raised by genetic information only, it necessarily ignores equally important issues raised by other types of personal information. By affording special status to genetic information, this approach is then forced to define what constitutes genetic information and to distinguish it

from other types of data, namely general personal information and health information. This leads to unnecessary confusion and creates potential sources of controversy, if not additional stigmatization of persons with genetic conditions. Finally, the same difficulties facing health researchers looking to study the influence and interaction of several health determinants are further compounded by this piecemeal approach that, once again, focuses on the type of information, rather than those socially acceptable purposes for which personal information may be collected, used and disclosed, how that ought to be done and under what conditions.

D. Resolving the challenges

While each approach has its benefits and disadvantages, it is ultimately the comprehensive, coherent and principled approach of the broader regimes covering personal information generally that we favour the most. In our view, this approach appropriately organizes its rules according to purpose, rather than the type of information. Even though the rules for collection, use and disclosure of personal information may be the same for a given purpose regardless of the type of personal information, this approach does not preclude a more stringent application of those same rules when sensitive data is involved, such as genetic information for instance. We say “such as” because even if information is legally deemed to be sensitive under sensitive information approach, there may always be other types of information not formally recognized as such, but that are nonetheless sensitive in a given set of circumstances. And it is precisely in those circumstances that the application of the required standards, as on a sliding scale, should be more exacting.

Moreover, the personal information approach in no way forecloses the recognition of familial/community needs and interests in personal information. While some countries may be far away from formally entrenching these needs and interests into legal rights, they could nonetheless adapt their legal analysis that remains centred on individual autonomy, in a way that tempers that autonomy in view of the needs and interests of others.

In conclusion, we encourage jurisdictions to consider expanding the personal information approach to 1) build in a requirement calling for stricter application of the same rules when sensitive information, such as genetic information is involved, and 2) expressly take into account family/community interests in personal information that up to now is understood as being only about an identifiable individual. With the addition of these new concepts, jurisdictions may find that the benefits of a comprehensive, coherent and principled regime will displace the perceived need (as well as the political pressure) to treat genetic information distinctly from other types of data.

I. PERSONAL INFORMATION APPROACH

COUNTRY/ORGANIZATION	SOURCE
Canada	Canadian Government, <i>Personal Information Protection and Electronic Documents Act</i> , S.C. 2000, c.5, http://laws.justice.gc.ca/en/P-8.6/index.html (date accessed: September 10, 2003)
France	French Government, <i>Loi no 78-17 du 6 janvier 1978, Loi relative à l'informatique, aux fichiers et aux libertés</i> , http://www.cnil.fr/textes/text02.htm (date accessed: September 10, 2003). It is important to note that this act provides specific guidance for the use of nominative data in healthcare and health research.
New Zealand	New Zealand Government, <i>Privacy Act 1993</i> , Auckland, 1993 No 28, http://www.legislation.govt.nz (date accessed: September 10, 2003). New Zealand Privacy Commissioner, <i>Health Information Privacy Code</i> , Auckland, June 28, 1994, http://www.privacy.org.nz/comply/HIPCWWW.pdf (date accessed: September 10, 2003).

II. SENSITIVE INFORMATION APPROACH

COUNTRY/ORGANIZATION	SOURCE
European Parliament	<i>Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data</i> , 1995, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=FR&numdoc=31995L0046&model=guichett (date accessed: September 10, 2003)
Austria	Austria Government, <i>Federal Act concerning the Protection of Personal Data</i> , Austria, August 17, 1999, http://www.bka.gv.at/datenschutz/dsg2000e.pdf (date accessed: September 10, 2003)
Denmark	Danish Parliament, <i>Act on Processing of Personal Data</i> , Denmark, June 2, 2000, http://www.datatilsynet.dk/attachments/20001061548/ENGELSK%20LOV.doc , (date accessed: September 10, 2003).
Estonia	Estonia Government, <i>Personal Data Protection Act</i> , Tallinn, 1996, http://www.esis.ee/legislation/protection.pdf (date accessed: September 10, 2003)
Finland	Parliament of Finland, <i>Personal Data Act</i> , Finland, June 1, 1999, http://www.tietosuojafi/uploads/hopxtvf.HTM (date accessed: September 10, 2003)
France (bill)	French Government, <i>Projet de loi, modifié par le sénat, relatif à la protection des personnes physiques à l'égard des traitements de données à caractère personnel et modifiant la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés</i> , April 1 2003, http://www.cnil.fr/textes/docs/CNIL-Loi78-17_modSenat1-VI.pdf (date accessed: September 10, 2003).

Germany	German Government, <i>Federal Data Protection Act</i> , Germany, May 23, 2001, http://www.bfd.bund.de/information/bdsg_eng.pdf (date accessed: September 10, 2003)
Greece	Greek Government, <i>Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data</i> , Athens, April 9, 1997, http://www.dpa.gr/Documents/Eng/2472engl_all.doc (date accessed: September 10, 2003)
Iceland	Parliament of Iceland, <i>Act on Protection of Individuals with regard to the Processing of Personal Data No. 77/2000</i> , Iceland, January 1, 2000, http://www.mannvernd.is/english/laws/Act.DataProtection.html (date accessed: September 10, 2003). It is interesting to note that in Iceland the definition of sensitive data directly refers to genetic information.
Italy	Italian Data Protection Commission, <i>Protection of Individuals and Other Subjects With Regard to the Processing of Personal Data</i> , ACT no. 675, December 31, 1996, http://www.privacy.it/legge675encoord.html (date accessed: September 10, 2003).
Netherlands	Dutch Government, <i>Personal Data Protection Act</i> , 25 892, Netherlands, November 23, 1999, http://www.cbweb.nl/en/documenten/en_pdpa.htm (date accessed: September, 2003)
Norway	Norway Government, <i>Act of 14. April 2000 No. 31 relating to the Processing of Personal Data (Personal Data Act)</i> , Oslo, April 14, 2000, http://www.datatilsynet.no/lov/loven/poleng.html (date accessed: September 10, 2003).
Portugal	Portugal Government, <i>Act no 67/98 of 26 October - Act on the Protection of Personal Data</i> , Portugal, October 26, 1998, http://www.cnpd.pt/Leis/lei_6798en.htm (date accessed: September 10, 2003)
Spain	Spain Government, <i>Organic Law 15/1999 of 13 December on the Protection of Personal Data</i> , Spain, December 13, 1999, https://www.agenciaprotecciondatos.org/ley_15_ingles_v2_pdf.pdf (date accessed: September 10, 2003).
Sweden	Sweden Government, <i>Personal Data Act (1998:204)</i> , Sweden, April 29, 1998, http://www.datainspektionen.se/PDF-filer/ovrigt/pul-eng.pdf (date accessed: September 10, 2003)
Switzerland	Swiss Government, <i>Federal Law on Data Protection</i> , Switzerland, July 1, 1993, http://www.edsb.ch/e/gesetz/schweiz/dsge.pdf (date accessed: September 10, 2003)
United Kingdom	Parliament United Kingdom, <i>Data Protection Act 1998</i> , United Kingdom, July 16, 1998, http://www.legislation.hmso.gov.uk/acts/acts1998/19980029.htm (date accessed: September 10, 2003)

III. MEDICAL INFORMATION APPROACH

COUNTRY/ORGANIZATION	SOURCE
World Medical Association	World Medical Association (WMA), <i>Declaration on Ethical Considerations regarding Health Databases</i> , Washington, October 6, 2002, http://www.wma.net/e/policy/d1.htm (date accessed : September 10, 2003)
Australia	<p>Australian Government, <i>Privacy Act 1988 (Act No. 119 of 1988 as amended)</i>, Australia, 1988, http://austlii.edu.au/privacy/Privacy_Act_1988/index-Privacy.html (date accessed: September 10, 2003).</p> <p>National Health and Medical Research Council, <i>Guidelines Under Section 95 of the Privacy Act 1988</i>, 2000, http://www.nhmrc.gov.au/publications/pdf/e26.pdf (date accessed: September 10, 2003).</p> <p>National Health and Medical Research Council, <i>Guidelines Under Section 95A of the Privacy Act 1988</i>, 2001, http://www.nhmrc.health.gov.au/publications/pdf/e43.pdf (date accessed: September 10, 2003).</p>
Council of Europe	Council of Europe (CE), <i>Recommendation No. R (97)5 of the Committee of Ministers to Member States on the Protection of Medical Data</i> , 1997, http://www.coe.fr/cm/ta/rec/1997/97r5.html (date accessed: September 10, 2003).
The United States	Department of Health and Human Services, <i>Standards for Privacy of Individually Identifiable Health Information</i> , 45 C.F.R. §§ 160 & 164 (2002) http://www.hhs.gov/ocr/hipaa/finalreg.html (date accessed: September 10, 2003).

IV. GENETIC INFORMATION APPROACH

COUNTRY/ORGANIZATION	SOURCE
UNESCO	International Bioethics Committee, <i>International Declaration on Human Genetic Data</i> , Paris, October 16, 2003, http://unesdoc.unesco.org/images/0013/001312/131204e.pdf#page=27 (date accessed : October 29, 2003)
United Nations (Draft)	Economic and Social Council, <i>Argentina: Draft Resolution - Genetic Privacy and Non-Discrimination</i> , Geneva, July 27, 2001, http://www.un.org/documents/ecosoc/docs/2001/e2001-I24rev1.pdf (date accessed: September 10, 2003)
Israel	<i>Genetic Information Law, 5761-2000</i> , (2000), December 13, 2000, http://www.auco.justice.gov.il/MOJHeb/resources/genetic+information+law-edited_050901.doc (date accessed : September 10, 2003)