COMMISSION DE L’ÉTHIQUE DE LA SCIENCE ET DE LA TECHNOLOGIE

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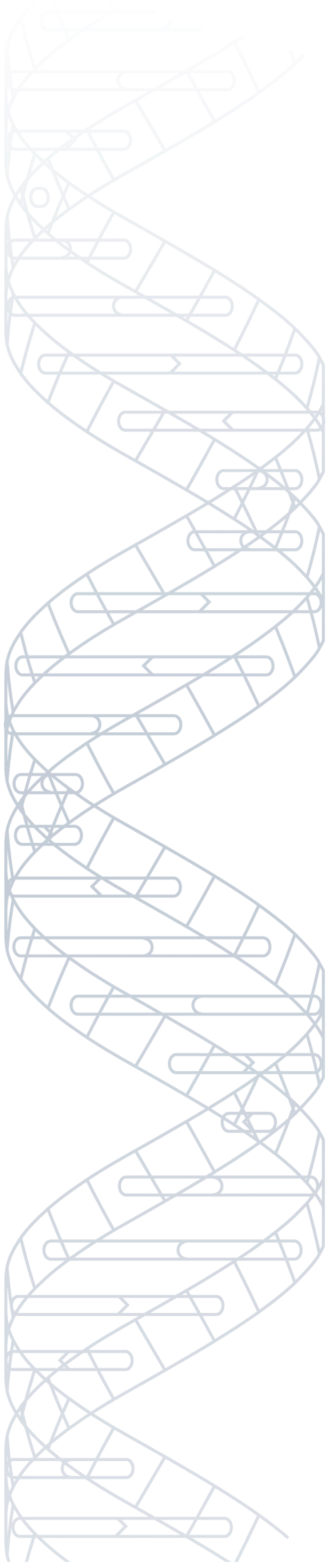
THE ETHICAL ISSUES OF GENETIC DATABASES:

Towards Democratic and Responsible Regulation



POSITION STATEMENT

Summary and recommandations

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Summary and Recommendations

This Position Statement is the response of the Commission de l'éthique de la science et de la technologie to a departmental mandate it received in January 2002. In essence, the Commission was responsible for examining the ethical questions raised by genetic databases and determining under what conditions a rigorous and open public consultation on the topic would be warranted. The four chapters and fifteen recommendations of the Commission's Position Statement summarize its conclusions, identify challenges, and suggest guidelines to clarify the complex and poorly understood issue of genetic databases, including their makeup, management, and use, as well as the necessity of a public debate on the matter.

The *first chapter* provides general background on genetic databases and positions them within the context of human genetics research and public views on the issue. The Commission discusses genetics as a field of study, explains the role genetic researchers play, and describes the benefits of new technologies developed as a result of genetic research, as well as the concerns it raises about personal and public wellbeing. It also takes stock of the increasing importance of genetic databases—whichever form they take—to researchers, defining genetic databases as follows: "A structured or non-structured collection of human specimens (DNA, cells, and tissues) or personal information of a genetic or proteomic nature from a variety of sources—including medical and other health files, and genealogical, socioeconomic, and environmental information—which is stored electronically as a single entity or as part of a larger database." By turning the spotlight on the various genetic databases in Québec, the Commission became aware of the difficulty—if not the impossibility—of accurately describing the situation. For the most part, genetic databases are neither held accountable nor subjected to controls regarding their purpose or how they are run. The chapter concludes with an overview of public opinion on genetics, which emerges from the findings of the studies consulted.

The *second chapter* describes how genetic databases are created and managed in a constantly evolving, research-focused setting where the roles and responsibilities of the private and public sectors increasingly intermingle. Such a situation creates tension between the values of pure research, which aims to further knowledge and share it with others, and those of industry, which seeks to put research to commercial use. Indeed, a large number of stakeholders are involved in various capacities and on many levels. The Commission has identified eight main stakeholders: the human subjects affected by genetic research, the researchers and research community, health care providers, research funders, regulating bodies, users of the results, special interest groups, and the media. These stakeholders do not work in isolation and sometimes their specific personal, professional, and institutional goals, as well as their various roles, may conflict with those of other stakeholders, thus creating tension. To alleviate and counteract this tension, the Commission has duly noted that measures are already in place to regulate the evolution of human genetic research and ensure that no one gets sidetracked by problems that may arise. These measures include international instruments, Canadian and Québec laws, and self-regulating institutional instruments. As an additional measure, the Commission recognizes the important role that Research Ethics Boards (REB) play in protecting research subjects and safeguarding the integrity of research while stressing the need to provide more support to these committees in hospital and university settings.

Chapter three gets to the heart of the issue of genetic databases, emphasizing the need to address the ethical concerns they raise for individuals, families, communities, and society in general. Given that genetic databases are situated within the larger context of human genetic research and that related issues not specific to genetic databases seem to create ethical problems, the Commission has taken the liberty of broadening its scope where necessary in order to address some of these issues. After looking at a number of values and principles of human genetic research that are common to both Québec and the international community, the Commission has tied a number of ethical issues to the following values: transparency, legitimacy, autonomy, confidentiality, equity, intellectual property, and solidarity. The Commission's analysis stresses the ethical significance of various situations and suggests ways to improve how they are dealt with. When it was deemed appropriate and essential, the Commission tailored its recommendations to the key stakeholders so as to effect quick and efficient changes in the field of genetics and genetic information for the common good.

Chapter four concludes the Commission's analysis by stressing the need for democratic management of the issues raised in the document. The Commission focuses on the importance of getting the public involved with issues that concern them and giving them the opportunity to take an informed stance and eventually influence decision making, which are key elements of any democracy. Its comments and recommendations answer the departmental question: "…not only does the collection, storage, use, disclosure, and marketing of genetic data require strict controls, the subject has not yet been debated publicly. In light of this, what conditions are necessary to ensure open and authentic public consultations?" For the Commission, it is obvious that these public consultations must help the government make the right decisions for all citizens. They should also follow the best practice guidelines laid out in this document. These consultations and a public debate on genetic information—specifically on the goals of genetic research and the methods used to attain them—should be initiated as soon as possible, with the ultimate goal of drafting a policy statement on genetic information to safeguard the personal and collective interests of all Quebecers. Such a statement should be drafted as soon as possible and include proactive guidelines for the makeup, management, and use of genetic databases, given that retroactive measures are much more difficult to implement.

The Commission has made the following recommendations on the various issues it has identified:

Recommendation no. 1

Given the operational difficulties Research Ethics Boards (REB) face and the Commission's expectations of them in terms of evaluating the ethics of research projects and consequently the creation or use of genetic databases,

The Commission recommends

That the Minister of Health and Social Services ensure

1) That Research Ethics Boards (REB) have the material and financial resources they need to operate and carry out their role effectively

2) That REB members undergo mandatory training and certification

3) That communication channels be established among REBs to facilitate discussion and increase consistency in decision making

4) That the study of REBs working in the private sector be continued

Recommendation no. 2

Given that the legitimacy of a population database depends on keeping the public sufficiently abreast of its makeup and characteristics and consulting them regarding their inclusion in the database and whether it should be set up,

The Commission recommends

That the Government of Québec ensure that all "population" genetic databases for mapping a population's genes or conducting research on population genetics first be submitted to an informed public to actively involve them in the decision-making process.

Recommendation no. 3

Given the current gaps between the social legitimacy and transparency of genetic databases in Québec and the risk that a proliferation of such research tools could pose to the public's expectation of confidentiality and privacy in the absence of sufficient control mechanisms or followup,

The Commission recommends

That the Government of Québec ensure the protection of its citizens and all information concerning them by

1) Changing the role of the Commission d'accès à l'information (CAI) in the short term and adjusting its budget accordingly to help it set up and manage a registry of genetic databases that

  a) Catalogs all existing databases in Québec

  b) Compiles the most information possible on these databases to increase understanding of their makeup and financial and operational structure, the legislation

as it applies to them and limits access to their content under the *Act to establish a legal framework for information technology* (2001, Chapter 32), and the organization's existing responsibilities regarding biometric databases

2) **Changing the role of the Agence d'évaluation des technologies et des modes d'interventions en santé (AETMIS) in the short term and adjusting its budget accordingly to help it evaluate the legitimacy of future genetic databases**
3) **Setting up an interdepartmental committee to evaluate the long term feasibility of creating a national agency that would incorporate the various roles of CAI and AETMIS with regard to genetic databases and provide an overview of human genetic research in order to regulate and monitor the creation and management of genetic databases and similar constructs**

Recommandation no. 4

Given the need to protect persons deemed incapacitated facing medical experiments and to ensure compliance with the *Civil Code* and its guiding values,

The Commission recommends

That the Government of Québec

1) **Require researchers to consult with and obtain the consent of research subjects who, although deemed legally incapacitated, are able to understand the nature and purpose of the experiment, in addition to the consent of their legal representative**
2) **Require that a mechanism be created to verify that the refusal of a person deemed legally incapacitated is respected**

Recommendation no. 5

Given that the role of the Public Curator is to protect the interests of persons deemed incapacitated,

The Commission recommends

That the Public Curator, as part of its mission to safeguard the wellbeing of Quebecers, create a registry of research participants - legally deemed incapacitated - who give their consent to scientific experiments, and obtain copies of their consent forms signed by their legal representatives or guardians

Recommendation no. 6

Given the omissions and ambiguities in the consent forms signed by people that are now deceased and the inconsistency this adds to the consent process,

The Commission recommends

1) **That a postmortem clause addressing the possibility of additional research other than that for which the consent was initially given be added to consent forms**
2) **That the spouse or closest relative of the deceased person who provided a biological sample complete another consent form in cases where the nature of the research was not yet determined when consent was given or the information obtained was not held in total anonymity**

Recommandation no. 7

Given the problems arising from consent forms when used for subjects participation in research of a yet undetermined nature,

The Commission recommends

That the consent clause explicitly state that no further research can be undertaken using the donor information obtained at the time of signing for a particular research. However, the consent form may include a clause allowing donors to be contacted again for the purpose of presenting a new research protocol and soliciting their participation, at which point they may accept or refuse to participate.

Recommendation no. 8

Given the need to protect the rights of subjects regarding their own genetic information and ensure they have access to advice from qualified specialists,

The Commission recommends

1) **That research subjects be able to meet with a genetic advisor not associated with the research team before signing the consent form**
2) **That a genetic advisor participate *de facto* in evaluating genetic research protocols submitted to the research ethics committee at his or her institution**
3) **That more genetic advisors be trained to provide sound advice to all Quebecers**

4) That until there are enough genetic advisors in the health care system, their duties be assumed by geneticists or other qualified professionals independent of the research team

Recommendation no. 9

Given the need to protect genetic information and material provided as samples or data to researchers outside Québec,

The Commission recommends

1) That only strictly anonymous data be allowed to leave Québec for research purposes and that recipient countries or institutions be obliged to guarantee the same level of protection and confidentiality as is required in Québec
2) That research subjects be informed that their genetic material and information may be used by researchers outside Québec

Recommendation no. 10

Given the risk of abuse inherent in using genetic information for employment, insurance, and financial purposes,

The Commission recommends

That the Government of Québec declare a five-year moratorium for employers, insurers, and financial institutions on the use of information obtained through genetic testing and that, during this period, the organizations involved be asked to draft and adopt a self-regulation policy regarding the use of genetic information in their evaluations. If the policies proposed at the end of this period do not agree with Québec's social values, the government should create legislation to set guidelines and restrict the use of genetic information in areas other than health.

Recommendation no. 11

Given the ethical issues raised by the advertising and over-the-counter availability of genetic tests, the interpretation of their results, and their possible effects on the people who use them,

The Commission recommends

That the Government of Québec

1) Take the steps necessary to prohibit the direct advertising of genetic tests as well as the over-the-counter availability of such tests
2) Require that genetic tests be conducted only under a physician's orders

Recommendation no. 12

Given that genetics will play an increasing role in the choices people make throughout their lives,

The Commission recommends

That the Minister of Education consider including basic human genetics in the high school curriculum to help tomorrow's citizens contribute to the public debate on the subject and make informed decisions for themselves and the common good

Recommendation no. 13

Given the likelihood that more and more Quebecers will ask for or turn to genetic testing and that it is essential they be well-informed about the nature, potential uses, and limitations of these tests when they visit their doctor,

The Commission recommends

1) That medical schools offer introductory genetics courses in all medical disciplines
2) That the Collège des médecins or any other qualified authority ensure that physicians in all health care settings have the same level of genetics expertise and provide ongoing training to meet future needs

Recommendation no. 14

Given that research decisions made by certain organizations may affect people, their families, their regions, and their communities,

The Commission recommends

That public representatives, if it is not already the case, be involved in the decision-making process of organizations that fund genetic research and the facilities for storing and operating genetic databases, as well as the institutional committees responsible for the ethics evaluation of these projects, and that representatives should receive training appropriate to their role

Recommendation no. 15

Given the need for Quebecers' democratic input on the creation of genetic population databases and on the delicate issues genetic information raises for everyone involved,

The Commission recommends

That the Government of Québec begin public consultations as soon as possible that include the following measures:

a) An initial survey of Quebecers

b) A Québec-wide public consultation

c) A call for submissions from interest groups and community organizations

d) The publication of a consultation report

e) A Québec Policy Statement on genetic information

The government may also consider any other measures that would guarantee open and thoroughgoing public consultations.

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* Until December 5th 2002