

Final Report
Advisory Group on a

**GOVERNANCE
FRAMEWORK FOR DATA
BANKS AND BIOBANKS
USED FOR HEALTH
RESEARCH**

FONDS DE LA RECHERCHE EN SANTÉ DU QUÉBEC (FRSQ)

Final Report
Advisory Group on a Governance Framework
for Data Banks and Biobanks
Used for Health Research

The translation of this report was supported by the
Canadian Institutes of Health Research (CIHR)



French version submitted to FRSQ Board of Directors, December 8, 2006

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1. BANKS AT THE CORE OF RESEARCH

The quest for knowledge is a human endeavour serving the development and betterment of society. Scientific research advances the social good, as well as population health and well being. A wide range of disciplines are currently instrumental in producing scientific knowledge in the health field.

Research generates data that investigators use to produce scientific knowledge. Collecting, organizing and examining those data are activities that probably date back as far as scientific investigation itself. Furthermore, data storage media have evolved over time in tandem with technical and technological development.

All research is dependent on the collection and organized storage of observations and various materials, including biological material. Although some types of biological material have always been preserved, recent major breakthroughs in science and technology have considerably extended storage capabilities¹.

All research on human tissues involves the creation of some repository in which to store them. We are currently seeing unprecedented proliferation in the number and capacity of these biobanks, whether in terms of storage duration, quantities of banked specimens, bank sites or related financial issues. In addition, the convergent development of electronic data processing and biological material preservation methods is giving rise to large-scale storage and leading-edge human tissue studies.

Data banks and biobanks are a valuable resource providing knowledge that far exceeds the anecdotal knowledge culled from limited quantities of information or biological specimens. Their scientific value lies in the possibility of collecting data or specimens from hundreds or even thousands of individuals. Analysis of large amounts of data and specimens increases the statistical power of research outcomes and thereby enhances their validity. Banks owe their considerable worth to these larger quantities.

The possibility of correlating banked data and also correlating those data and biological material multiplies research resources and improves the chances of gaining new knowledge. While this technical capability allows for many such correlations, it also puts respect for privacy and personal autonomy at greater risk.

1. The Ethics Unit of the Québec department of health and social services has posted a paper on biobank governance titled *Encadrement des banques de données et de matériel biologique* on its Web site. The passage below is taken from that paper.

“Research is inherently tied to the collection of data and biological material. Information technology has provided for accumulating information and has greatly increased research opportunities. Recent years have seen the creation of increasingly voluminous information banks used for health research purposes.” [translated from the French]

See at: <http://ethique.msss.gouv.qc.ca/site/112.0.0.1.0.0.phtml>

The use of data banks and biobanks lies at the core of research practices, which explains their critical importance for scientific advancement. Alongside this is the imperative to pursue research under conditions respectful of the human subjects, especially where their autonomy and right to privacy are concerned². **We will therefore undertake to develop an approach that recognizes the legitimate needs of research initiatives and is predicated on respect for the rights of all concerned.**

2. The National Consultative Bioethics Committee for Health and Life Sciences (CCNE) describes the conjunction of two valid concerns: the optimal use of biological specimens and respect for the rights of the persons concerned. *“For optimal use, biological specimens must be capable of association with medical data, and in some cases, partial or complete lineages concerning the donors and their families. The scientific and medical value of such collections, in association with medical and genetic data drawn from previous studies, must not be reason for forgetting the extreme sensitivity of such material as regards the ethical principles involved – individual rights of privacy, autonomy, and dignity.”* CCNE, *Ethical Issues Raised by Collections of Biological Material and Associated Information Data: “Biobanks,” “Biolibraries,”* Opinion 77, 2003, p. 14. See at: <http://www.ccne-ethique.fr/english/start.htm>

2. ADVISORY GROUP MANDATE AND MEMBERSHIP

The Fonds de la recherche en santé du Québec (FRSQ) and the ministère de la Santé et des Services sociaux du Québec – MSSS (department of health and social services) established this Groupe-conseil sur l'encadrement des banques de données et des banques de matériel biologique à des fins de recherche en santé (advisory group on a governance framework for data banks and biobanks used for health research). They tasked our Advisory Group with examining the current status and foreseeable evolution of data banks and biobanks and then producing a report that proposes a) guidelines that would be integrated into the FRSQ *Standards* and b) amendments to applicable administrative standards and current legislation. This final report by the Advisory Group deals with the collection, processing, utilization, storage and management of data banks and biobanks for health research purposes.

The Advisory Group comprises the following members (institutional affiliations are given in Appendix 1):

Dr. Marie-France Raynault, Co-chair
Mr. Claude Dussault, Co-chair
Ms. Gillian Bartlett
M^{ce} Mylène Deschênes
Ms. Sabrina Fortin
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Ms. Béatrice Godard
Ms. Michèle S. Jean
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Mr. Jack Siemiatycki
M^{ce} Marie-Hélène Vachon

Many data banks are created in the public and private sectors for purposes other than health research. They are concerned with the life sciences and address issues as wide-ranging as consumerism, taxation, drug prescription, motor vehicle use, schooling, workplace injuries, professional activity and personal finance. Such banks are liable to be used for health research and thus fall within our purview. In light of this, we decided to broaden our terms of reference and examine how data banks and banks of biological material created for reasons other than health investigation should be governed when they are tapped for health research purposes. As members of the Advisory Group, we realized the critical importance of fulfilling our mandate with utmost attention to the protection of research subjects.

Having completed its task, the Advisory Group is making a series of recommendations, some of which are intended for legislators and others for Québec's department of health and social services or the FRSQ. Several of them address both legislators and the FRSQ.

The Advisory Group is grateful to Michel T. Giroux, the specialist who researched and prepared this document. Mr. Giroux is director of the Institut de consultation et de recherche en éthique et en droit (ICRED) (institute for consultation and research in ethics and law) and FRSQ ethics advisor.

3. DEFINITIONS

It would be appropriate to define a number of key terms for the sake of clarity and proper understanding of this report.

- Data

Representation, in any form, of information or concepts pertaining to the characteristics of an individual or a population³.

Explanation

Health research has either an individual or a group dimension, meaning that data may pertain to one person or an entire population⁴. The dimension of interest should always be specified so as to avoid mistaking one for the other. A data bank contains only data.

- Biological material

Any substance of human origin (e.g. organs, tissues, cells or serum).

- Analysis of a biological specimen may produce data.

Explanation

The term “substance” appears broad enough to include all possible forms of matter and types of specimens, provided those specimens come from humans.

The terms “analysis” and “specimen” pertain more to research than to therapeutics.

Proper understanding of research activities supposes clear explanation of the link between biological material and data.

We use the term “may” in connection with the data derived from specimens to indicate the possibility that some specimens do not produce data, are now producing data or will produce data later on.

- Bank

A systematic collection of data or biological material that may be used for health research.

Explanation

The term “collection” designates a series of items gathered and organized with a specific purpose in mind. Examples include items gathered for their historical value, administrative role or scientific interest.

Owing to the expression “may be used for,” this definition covers systematic collection of data or biological material intended for health research purposes or other purposes. It also covers present or future uses of such collections.

3. This definition borrows from the definition of “data” in section. 31 of the *Personal Information Protection and Electronic Documents Act* (2000, ch. 5): “Representations of information or concepts, in any form.”

4. For the purposes of this report, we chose the word “population” over “community” so as to better reflect health research terminology.

A data bank contains only data. A biobank contains specimens, specimen-related data and data derived from those specimens.

- Applicable administrative standards

Rules of conduct that apply to research involving human subjects and are designed for the protection of those persons. These are rules, not laws, and their content draws on research ethics. Rules of conduct can become accepted practice, however, and are rightly part of the normative landscape.

Explanation

There are federal and provincial laws governing various aspects of research involving human subjects. By way of example, section 20 of the *Civil Code of Québec* states that “a person of full age who is capable of giving his consent may submit to an experiment,” provided the experiment meets certain conditions. There is also a body of rules of conduct – applicable administrative standards – adopted by international organizations, as well as federal and provincial agencies. Even a partial list of these rules gives some idea of their scope and particularity⁵:

- a) *Nuremberg Code*, 1947.
- b) World Medical Association, *Declaration of Helsinki*, 1964, 1975, 1983, 1989, 1996, 2000, 2004.
- c) International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use, *Good Clinical Practice: Consolidated Guidelines*, Health Canada, 1997.
- d) Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, 1997.
- e) World Medical Association, *Declaration on Ethical Considerations Regarding Health Databases*, Washington, 2002.
- f) HUGO Ethics Committee, *Statement on Human Genomic Databases*, 2002.
- g) Council for International Organizations of Medical Sciences (CIOMS), World Health Organization (WHO), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2003.
- h) UNESCO, *International Declaration on Human Genetic Data*, 2003.
- i) UNESCO, *Universal Declaration on Bioethics and Human Rights*, 2005.
- j) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002 and 2005 amendments).
- k) Canadian Institutes of Health Research, *Best Practices for Protecting Privacy in Health Research*, 2005.
- l) Ministère de la Santé et des Services sociaux du Québec, *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (departmental action plan for research ethics and scientific integrity), 1998.
- m) Fonds de la recherche en santé du Québec (FRSQ), *Standards en éthique de la recherche et en intégrité scientifique du FRSQ* (FRSQ standards for research ethics and scientific integrity), 2nd edition, *in Guide d'éthique de la recherche et d'intégrité scientifique* (guidelines for research ethics and scientific integrity), August 2003.

5. The MSSS offers an online tutorial in research ethics. That Web site provides an extensive list of references. See at: <http://ethique.msss.gouv.qc.ca/didacticiel/mod/resource/view.php?id=27>

This list should include the internal rules of conduct made by universities and health care institutions. Those rules cover the scientific and ethics review of research projects, grievance management, institution/private sector partnerships and data bank and biobank governance.

- Personal information

The expression “personal information” designates information protected by Québec law: the *Civil Code of Québec* (ss. 35-41), the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*⁶ and the *Act Respecting the Protection of Personal Information in the Private Sector*⁷. It further pertains to information deemed confidential under section 19 of the *Act Respecting Health Services and Social Services*⁸.

Explanation

The *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*⁹ has a twofold purpose. First, it guarantees every person the right to examine documents held by public agencies. This answers concerns regarding governmental transparency and citizen participation in democracy. Second, this legislation protects the personal information in the hands of the public administration. In other words, it safeguards the privacy of persons and certain information. Access to personal information for study, research or statistical purposes without the consent of those concerned must be regarded as an exception and a privilege. Consequently, access to the documents held by public bodies and access to personal information are to be handled in different ways.

It should further be mentioned that implementing public health surveillance and research activities¹⁰ requires access to personal information:

“In the area of public health, surveillance activities (as well as research activities) are largely predicated on rapid access to data (health data and other population data). These useful data include information obtained through surveys on health and social services and information found in hospital registers, medical and laboratory files, birth and death registers, and so on¹¹.” [translated from the French]

6. R.S.Q. c. A-2.1.

7. R.S.Q. c. P-39.1.

8. R.S.Q. c. S-4.2.

9. *Supra*, footnote 6.

10. Cf. *Public Health Act*, R.S.Q. c. S-2.2.

11. Comité d'éthique de santé publique, *Atteinte à la vie privée, confidentialité et protection des renseignements personnels* (public health ethics committee: violation of privacy, confidentiality and protection of personal information), 2003, p. 5.

See at: <http://msssa4.msss.gouv.qc.ca/fr/subjects/ethiqSP.nsf/22f2ea9b71e5846d85256d0a00761591/35570c61afcd97568>

4. TYPES OF HEALTH RESEARCH

The world of health research encompasses an array of different disciplines and methods for developing knowledge. The Canadian Institutes of Health Research (CIHR) categorizes health research in four broad themes:

- biomedical research, also called basic research;
- clinical research;
- research on health systems and services;
- research on population health, societal and cultural dimensions of health, and environmental influences on health¹².

In introducing these themes, CIHR states that these research areas are not mutually exclusive and that the proposed definitions are meant to be guidelines, not hard and fast categorizations.

Our Advisory Group uses the CIHR taxonomy because it wins broad consensus in the scientific community. Furthermore, information and biological material can be banked to deal with all four health research themes.

Because of the observable differences in practices specific to the various types of research, the rules for accessing data and biological material may differ accordingly. This refers, for one, to the consent process when necessary, depending on whether the research is more or less invasive¹³ where the subject is concerned. An intervention carried out as part of a research project may be invasive, both psychologically and physically.

12. Cf. Appendix 2 for the CIHR description of these themes.

13. The term “invasive” describes an exploratory or diagnostic procedure that calls for penetrating the body. With respect to the care contemplated in the *Code*, “invasive” is clearly the appropriate term in light of the provisions dealing with care, including experimentation (cf. Title Two, Chapter 1 “Integrity of the Person”).

5. OUR RECURRING THEME

The spirit that has guided the work and proposals of this Advisory Group is driven by one objective, that of reconciling recognition of the social value of health research and the protection of research subjects¹⁴. This recurring theme implies that health research should be encouraged through the creation and use of data banks and biobanks, a vital resource for the advancement of knowledge.

Respect for research subjects requires recognizing and protecting human rights, especially the rights to autonomy and privacy. **We do not believe that scientific advancement and basic rights protection are necessarily opposed.**

On October 19, 2005, the 33rd Session of the UNESCO General Conference adopted the *Universal Declaration on Bioethics and Human Rights*. The preamble to this *Declaration* forcefully states that developments in science and technology produce substantial benefits and should be pursued while respecting basic rights. We fully espouse the following statement from the introduction to the *Declaration*:

“Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms¹⁵ . . .”

In Québec, the FRSQ *Standards* state expectations bearing on the protection of participants and the scientific validity of research. The FRSQ lays emphasis on the expression “overall quality of health research” to mean all the qualities of research consistent with scientific standards and the standards governing ethics and integrity:

“The expectations of the FRSQ extend far beyond the dimension of the scientific validity of research to include protecting the dignity of persons who agree to participate as subjects, respect for the persons associated with performing the research, and proper management of all research resources. In short, the overall quality of health research will be assessed with reference to two classes of standards: scientific standards and standards governing ethics and integrity¹⁶.”
[translated from the French]

14. In his introductory remarks to the MSSS *Action Plan*, the Québec Minister of Health and Social Services states that protection of persons involved in research is an “inescapable imperative.” Cf. Ministère de la Santé et des Services sociaux du Québec, *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, 1998, Message from the Minister.

15. UNESCO, *Universal Declaration on Bioethics and Human Rights*, 2005.

See at: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

16. Fonds de la recherche en santé du Québec (FRSQ), *Standards en éthique de la recherche et en intégrité scientifique du FRSQ*, 2nd edition, in *Guide d'éthique de la recherche et d'intégrité scientifique*, Montreal, August 2003, p. 18.

The thrusts of this final report by the Advisory Group bear mainly on research subjects, researchers, research ethics boards, research bank operators, institutions¹⁷, administrators and all other persons involved in collecting, processing, utilizing, storing and managing data and biological material.

17. *Supra*, footnote 14, p. 11. According to the MSSS Action Plan, the institutions and agencies of the health and social services network are obliged to implement a regulatory framework for research activities. That framework must include standards governing various aspects of research, including database management.

6. THE ISSUES BROUGHT TO LIGHT

We conferred with diverse health research stakeholders: research subjects, REB (Research Ethics Board) members, administrators and investigators. The outcomes of those consultations deserve our attention, though they were not obtained scientifically. They represent, instead, empirical data culled from the experiences of those stakeholders.

6.1 By Researchers, REBs and Other Research Stakeholders

The research stakeholders whom we consulted expressed many different concerns. However, they all mentioned their distress at the shortcomings and uncertainties – the normative haze, as it were – which complicate their activities. Besides federal and Québec legislation, research stakeholders must contend with a slew of applicable administrative standards¹⁸. These international, Canadian, Québec and institutional standards are oftentimes difficult to interpret¹⁹.

Research Banks

- Which definitions of “data bank” and “biobank” does the Advisory Group use?
- Does the production of conclusive data justify the development of banks for health research purposes?
- What are the implications of correlating clinical and epidemiological data in multidisciplinary research?
- Can previously banked biological material be regarded as a potential resource for research? If so, how can interested parties access it?
- Should one press to have data banks and biobanks “unlocked” to give all researchers access to them?

Access to Personal Information

- The issue of access to personal information stirs debate over privacy protection. Does this debate concern health research?
- Is there any obligation to share banked data, whether among researchers or among institutions?

18. We mentioned a few of these administrative standards in the section on definitions.

19. The comments about this “normative haze” heard from researchers, REB members and other stakeholders confirm one of the main conclusions reached by the authors of a Law Commission study. Cf. Michael McDonald et al., *The Governance of Health Research Involving Human Subjects*, a study commissioned by the Law Commission of Canada, 2000, Executive Summary, pp. vii and viii:

“Canada’s complex, decentralised, multi-sources arrangements for governing HRIHS (health research involving human subjects) poses major ethical challenges in terms of consistency, transparency of the provisions made and accountability. This is due in part to the complexity of the health research process and the complicated ways in which socially constructed scholarly and ethical parameters influence the research process. This complex research process is very much affected by four pervasive international factors:

- *Rapid scientific and technological innovation and advances;*
- *Multi disciplinary and interdisciplinary research modalities;*
- *Commercialization and privatization;*
- *Globalization and harmonization.”*

See at: <http://www.lcc.gc.ca/pdf/MACDONALD%20FRE%20OCT%2017%202000%20FINAL.pdf>

Consent

- How should the persons concerned be approached for their consent to use previously banked data or biological material?
- How valid should substituted consent be once a minor reaches age 14 or 18? What should be done with collected data or biological material once a minor reaches full age?
- What are the advantages and disadvantages of consent forms that offer several options? Can this solution be considered for Québec as a whole?
- What are the pros and cons of unconditional donation of specimens (e.g. organ donations)?
- How should the family factor be included in consent to research?
- What place should genetic counselling have in the banking of data or biological material?
- Should consent always be needed before using tissues for research purposes?

Use

- Concerning the use of data and biological material, should there be an “ethics culture” transcending legal rules and administrative standards?
- What type of framework should be developed for:
 - transferring data and material among researchers nationally and internationally? between hospitals and universities? between researchers and private enterprise?
 - properly monitored access to data and material?
 - ensuring the quality of data and material?
 - safely destroying data and material?
- What are the implications of harmonizing existing administrative standards pertaining to data banks and biobanks?

Storage and Mandatory Destruction

- How appropriate are the mandatory storage and destruction times for data and biological material?

Management

- What are the responsibilities of granting agencies, hospitals, research centres and networks, researchers and REBs with regard to data banks and biobanks?
- How should these responsibilities be incorporated into a management system?

Commercialization

- What factors are involved in commercializing data and biological material?

Research Ethics Boards

- What are the pros and cons of turning to private-sector REBs?
- Is there a need to harmonize ethics reviews of research projects that require creating banks?
- Is the subject’s autonomy considered during the ethics review?

Risks

- How can the different perceptions of risk be reconciled (perspectives of the research subject, researcher, REB and society)?
- Can the risks be divided among the stakeholders?

Funding

Does the funding source influence the way the bank trustee discharges his duties?

6.2 By Research Nurses

Research nurses had two reasons for asking to meet with the Advisory Group members: (1) to introduce us to the Association des infirmières et infirmiers en recherche clinique (AQIIRC) (*clinical research nurses association*) and (2) to inform the Advisory Group of the concerns that nurses have about data banks and biobanks. At the time of that meeting, held November 29, 2004, most research nursing coordinators had apparently not been advised that research centres have an administrative obligation to implement a database policy. The AQIIRC feels, however, that the policies currently in effect are adequate.

The content of the consent form is a concern because subjects may unwittingly consent to procedures that violate their right to privacy. Active monitoring of research projects is marginal, ruling out any rigorous evaluation of research practices. Nursing staff need to be properly informed, for they are the link between the research subject and the institution hosting the project – where pharmaceutical trials are concerned, in any case.

The AQIIRC representatives submitted several issues for the Advisory Group's attention.

- Research centres are heavily regulated, but how do private research interests handle information about patients?
- Should there be stricter rules regulating genetic data and specimens giving access to genetic data?
- Some data banks were not created for research purposes, but for quick access to information about a patient or group of patients, for recognizing trends or for statistical uses. Can that banked information be used if it seems helpful for research purposes?
- Should data banks created prior to a research project be considered on a par with banks created specifically for research purposes? How can the confidentiality of those banked data be guaranteed?
- Should the public be told how data banks are used? If so, how?
- The protection of information on file is a concern, given its possible use. Is legislation needed to keep insurance companies from having access to the complete history of patients, including genetic information?
- Research nurses are worried about the management of data stored on electronic information media since it seems possible to alter those data without a coordinator's authorization. Those coordinators should be the only ones authorized to alter those data, just as with data recorded on paper.
- It is often very hard to clearly see a promoter's intent when the consent form mentions the preservation of specimens (e.g. blood or plasma) for future analyses. Where do the promoters' true interests lie?
- How can one be certain that specimens and data are destroyed at the end of the planned storage time?
- In theory, participation in a genetic study is not recorded in a patient's medical file and so this information is not available to the patient's employer or insurer. Still, some patients feel uneasy about "hiding" information that is accessible for research

purposes only. Should a clear distinction be made between information available for diagnostic purposes and information accessible for research?

- How can one be certain that information will be used solely for the research initiative for which collection was authorized?

6.3 By Research Subjects

Our meetings with individuals who have participated in clinical trials heightened our awareness of the research subject's perspective. We conferred with women diagnosed with breast cancer and males with cystic fibrosis. Those persons share two concerns. First, they are keenly interested in knowing whether they will be in the placebo group when the research protocol goes on stream. Needless to say, they would rather receive the active substance. Second, they are equally interested in knowing the outcomes of the study in which they participate. We use the term "outcomes" to mean the research conclusions and the new knowledge produced by the study.

The women with cancer told us they had consented to use of their personal information for breast cancer research. They had also agreed to provide biological samples. Naturally, they expect the researchers to use their data and biological material for the advancement of knowledge, to the extent possible. This is in hopes of possible benefits for themselves, for all women suffering from cancer and for future generations.

Those women cannot understand why administrative standards and rules of ethics founded on respect for personal autonomy and privacy oblige researchers to limit use of their data or tissues to the one project known at the time consent is obtained. They understand even less why certain administrative standards oblige researchers to destroy those data and biological material after a certain time – sometimes three, five or even twenty years after the project. They see this as squandering valuable resources. They believe that an approach emphasizing respect for personal autonomy and privacy and personal rights protection should be adopted. That approach should also promote the secondary use of data and biological material – for the same disease in any case.

6.4 Special Observations about Epidemiological Research

Investigators in the field of epidemiology informed the Advisory Group of certain observations and drew our attention to problems encountered in epidemiological research. As they see things, an ethics culture characterized by a narrow, unyielding view of the need for consent is worming its way into some circles. That culture would require epidemiology researchers to obtain the consent of all persons whose records were consulted, and this would apply for all research initiatives. This requirement evidently results from a narrow interpretation of the applicable administrative standards. The Advisory Group realizes that this requirement goes far beyond legislation governing personal information protection. If this ethics culture does indeed exist, it could put epidemiology research in jeopardy.

The Advisory Group learned of a research undertaking that rendered great service. That study explored exposure to asbestos fibre. It is now well-known that exposure to this material can cause certain types of cancer. Epidemiology researchers believe that such

studies might no longer be possible given the way personal information protection laws and the applicable administrative standards are sometimes interpreted.

Our understanding of the relationship between asbestos exposure and cancer results from a series of studies conducted on cohorts of asbestos workers in the 1960s and 1970s. The researchers conducted the studies from lists of workers obtained from employers and trade unions. Some of those lists dated back 20, 30 or even 40 years, and the cohorts often included thousands of workers. The researchers traced the workers identified in those cohorts by combing through national death or cancer registers.

It was suggested to the Advisory Group that those studies would never have materialized if researchers back then had been bound by certain present-day readings of the principle of respect for privacy. For, the employers made no attempt to contact each of the 20,000 people who had worked in the asbestos industry during the twentieth century. This means they did not seek their consent to give researchers their names, dates of birth and other personal information. Nor did the researchers contact the workers to obtain their consent prior to examining State death records.

6.4.1 Emerging trends

The Advisory Group was also told that the need to work within the parameters of one specific project of defined or definable duration limits the possibility of exploring a theme as opposed to testing a hypothesis. The Framingham Heart Study, one of the best known and most productive studies in the history of biomedical research, would have been impossible under those conditions since its objectives were initially imprecise and its duration unpredictable²⁰.

Health research has thus far taken place within the framework of a setup known as a “research project.” Traditionally, a research project is conducted to validate a specific research hypothesis concerning a specific disease. Emerging trends are proposing a new, “research theme” approach. This approach allows researchers to explore different hypotheses using the same database. Various factors have made the thematic approach possible:

- the concentration of major government files at a limited number of sites;
- the development of computer processing capabilities;
- the compatibility between banks.

When all three of these factors converge, billions of items of personal information can be quickly processed and made available for large-scale research programs or themes. The thematic approach and the creation of research infrastructures, as opposed to the project-driven approach, brings new realities into play. The present legal framework was designed to accommodate and manage traditional research projects, meaning studies testing one particular hypothesis for a defined period of time.

20. The Framingham Heart Study deals with the causes of cardiovascular disease. It commenced in 1948 under the direction of the National Heart Institute, now the National Heart, Lung and Blood Institute (NHLBI). The first cohort of subjects consisted of 5,209 women and men aged 30 to 62 from Framingham, a city in Massachusetts. The objective of the study was to identify the factors responsible for the onset of cardiovascular disease and to observe the course of the diseases over a long period of time. Since 1948, the subjects have been meeting with the research team every two years to record their medical history and undergo a physical examination and laboratory tests. In 1971, the study enrolled a second generation of subjects comprised of 5,124 persons. The Framingham Heart Study is still in progress.

In November 2002, the Commission d'accès à l'information du Québec (CAI) published a paper titled *Une réforme de l'accès à l'information: le choix de la transparence* (reforming access to information: the transparency option). In the section on emerging trends, the CAI mentions how difficult it is to fit current legislation into the new research landscape. In the paper's conclusion, the CAI recommends debating the matter through a parliamentary commission:

"The wording of section 125 of the Act Respecting Access is predicated on the specific concepts of research, record, duration and consent. In other words, that section, as worded, provides but an awkward, flawed way of dealing with these new realities.

"The issues raised by these scientific and technological developments extend far beyond just protecting personal information to embrace ethical or moral considerations. The Commission d'accès à l'information therefore recommends a broader debate concerning what could well become societal issues.

"In this regard, the Commission would hail the appointment of a parliamentary commission characterized by transparency and giving stakeholders opportunities to affirm their interest and advocate for the principles they espouse²¹." [translated from the French]

The mention of this CAI paper in no way suggests that the Commission shares the Advisory Group's opinion on any particular matter. We will discuss section 125 at greater length in another chapter. At that point, we will consider the possibility of accessing personal information without the consent of the persons concerned, but with authorization from the CAI or an institutional director of professional services.

Like the CAI, the Advisory Group finds that present legislation on personal information protection is ill suited to emerging research trends, which often favour studies that explore themes rather than test specific hypotheses.

6.4.2 Recruitment of research subjects

Researchers raised the issue of who is authorized to solicit potential subjects. According to one interpretation of the applicable administrative standards, the attending physician – to the exclusion of all other stakeholders – should be the one who initially contacts the potential participant and obtains that person's agreement to have his name and other particulars submitted to the researcher. As far as researchers are concerned, this interpretation makes it virtually impossible to recruit subjects for many studies.

The FRSQ *Standards* broach the matter of soliciting potential subjects. They make it clear that the means used to solicit a subject must not raise the slightest doubt as to the voluntarism of consent. Subjects must not be put under duress or in a dependent relationship vis-à-vis the researcher. From this perspective, there is a risk when the attending physician, a person whom the potential subject should trust, is also the researcher or shares in soliciting his own patient. Such situations should be avoided. For various reasons, however, the attending physician may be the only person who can approach the potential subject or else participation in an experiment may be the only available therapeutic procedure. If so, the *Standards* allow attending physicians to solicit their own patients under the following conditions:

21. Commission d'accès à l'information du Québec, *Une réforme de l'accès à l'information: le choix de la transparence*. November 2002, p. 113-114.

“The attending physician of a person shall not participate in soliciting that person, unless the physician has shown to the satisfaction of the REB that his participation is necessary. Once the REB has acknowledged that necessity, the attending physician shall explain his dual role to his patients²².” [translated from the French]

Besides the attending physician, who should be authorized to approach potential subjects? All persons who have access to a patient’s confidential information in the course of their duties can participate in soliciting that patient. This description applies to the members of the health care team and record keepers, as well as researchers working in or outside an institution. The best strategy must be determined in light of the nature of the research initiative. For example, the validity of certain studies depends on the most painstaking and representative solicitation of a pool of patients. That recruitment may call for considerable effort that needs to be supported. In deciding on recruitment conditions, the REB must weigh how the recommended procedures will affect the validity of the research initiative. Indeed, the participation of subjects in an activity tainted by methodological bias is far from desirable, ethically speaking.

Reading the applicable administrative standards to mean that the attending physician, to the exclusion of all other stakeholders, should make the initial contact with a potential research subject is inconsistent with the FRSQ *Standards*. The perspective of the *Standards* is that the freedom of potential subjects is better protected if the patient is approached by someone other than the attending physician.

6.4.3 Respect for persons and individual consent

The Advisory Group heard it explained that respect for the individual can take different forms reflecting a variety of practices. Respect for persons may take the form of a rule making it mandatory to obtain consent. However, serious, beneficial research that is not structured to allow for individual consent can also be respectful of persons.

We humans cannot live as though we are alone in the world or as though history has not preceded us. Like all their fellow citizens, research subjects benefit from the knowledge amassed through research. That research is based on data from individuals who also reaped the benefits of knowledge acquired by previous generations. Some researchers whom we consulted underlined the importance of seeing that this chain is not broken by rules that are needlessly or inordinately restrictive.

6.5 New Purpose for Banks

A number of public agencies in Québec maintain and operate databases containing information on the identity and health of individuals and the care they receive. These databases are operated in compliance with the terms of reference of the responsible organization. Those organizational mandates relate to the delivery of therapeutic care. However, research has created a new purpose for the databases, and that purpose has some people concerned about safeguarding public trust in our health care system. That trust is apparently being compromised through the use of highly sensitive health information for research purposes, something that exceeds the clinical or therapeutic mandates for those particular databases.

22. *Supra*, footnote 16, p. 24.

The Advisory Group is of the opinion that conducting health research through the use of databases created for other purposes is legitimate, as long as the research provides privacy safeguards. Our position is explained by the possibility that access to clinical or other data could help advance health knowledge and thus contribute towards improving clinical procedures and prevention.

The World Medical Association addresses this issue head-on in a declaration adopted in 2002. It sees delivery of health care as the foremost purpose for collecting information. The WMA recognizes, however, that medical advances depend, *inter alia*, on research, including retrospective epidemiological studies making use of information about individuals, communities and societies. Databases are thus seen as vital sources of information:

“The primary purpose of collecting personal health information is the provision of care to the patient. Increasingly, this information is held in databases. The database might hold the patient's health record or specific information from it, for example in the case of disease registries.

“Progress in medicine and in health care is contingent upon the conduct of quality assurance and risk management activities and health and medical research, including retrospective epidemiological studies, which use information concerning the health of individuals, communities and societies. Databases are valuable sources of information for these secondary uses of health information²³.”

Using databases created for the delivery of care for the secondary purpose of health research does not betray the loyalty that the health care system and professionals owe to patients. **Clinical purposes and health research purposes are not incompatible. Indeed, improvement in the quality of clinical intervention hinges on advances in research.**

6.6 Unknown Risks and Hasty Conclusions

Certain stakeholders and a few authors make an argument based on the presumption that creating and operating banks entail risks that are unknown at this time. Their argument rests on these two premises:

- We cannot identify all the risks that access to data banks and biobanks will create over the next 25 years.
- The personal information in the banks is private, and right to privacy protection should be energetically addressed.

The conclusion of this argument is that we should prioritize a restrictive approach at all stages of initiatives involving banks: creation, operation and access. Apparently, the unpredictability of progress in science and technology means that we do not know the specific purposes for which biological material may be used a few years hence. Given our ignorance, we cannot even imagine the risks that will arise in the medium and long term. The impossibility of anticipating the purposes of research and the risks for subjects

23. World Medical Association, *Declaration on Ethical Considerations Regarding Health Databases*, Washington, 2002, art. 4 and 5, p. 1. See at: <http://www.wma.net/e/policy/d1.htm>

should make us fear the worst as regards respect for privacy and prompt an attitude of mistrust about this venture into data banks and biobanks.

It is true that we cannot accurately predict the future directions of technological development, which will help determine the evolution of data banks and biobanks²⁴. Still, construing that future as threatening solely on the likelihood of unknown risks does not seem reasonable. In restricting the development of banks for fear of unknown risks, one foregoes the possibility of significant gains in all areas of health research. In answer to valid concerns about risks, the bank governance framework must scrupulously protect subjects' rights. It will need modifying to minimize risks and avoid dangers as soon as they arise. Lastly, the REBs will continue their work of reviewing and monitoring research initiatives.

The known risks associated with data banks and biobanks do not justify prohibiting their creation and operation. Still, our lack of knowledge about all the long-term risks should encourage ongoing review and vigilance regarding these banks.

24. Daryl Pullman uses familiar situations to illustrate the difficulty of anticipating how a technology will make its way into society: "Accurately describing a rapidly developing and expanding technology and simultaneously anticipating the future trajectory of technological innovation is notoriously difficult. . . . The advent of the automobile was predicted to all but eliminate pollution as the massive quantities of horse manure in the streets would disappear. Nuclear technology was trumpeted as an inexpensive source of electrical power. Talk of the 'paperless office' in the new age of information technology has now all but disappeared. The common lesson here is that what is presented as fact is often mere speculation, and the results are often dramatically different from what was anticipated. The manner in which technological uptake occurs in a society is highly unpredictable and often defies logic." Pullman, D. (main author), Study commissioned by the Canadian Biotechnology Advisory Committee (CBAC), *Biotechnology Innovations and Institutional Transformations in Health: Issues in Public/Population Health – A Summary and Synthesis with Recommendations*, 2003, p. 3.
See at:[http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/Research-2003_PullmanFinal_e.pdf/\\$FILE/Research-2003_Pullman-Final_f.pdf](http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/Research-2003_PullmanFinal_e.pdf/$FILE/Research-2003_Pullman-Final_f.pdf)

7. GUIDING PRINCIPLES

The Advisory Group predicated its work and proposals on seven interrelated, complementary guiding principles. Any reading of this document that would prioritize these principles or rank one above the others would betray the spirit in which it was produced.

7.1 Simplicity, Transparency and Sound Judgment

Two attitudes were consistently labelled unacceptable throughout our consultations: the culture of ambiguity and the absence of justification. The persons with whom we conferred perceive a culture of ambiguity in the use of undefined key terms, conflicting or incompatible proposals, and what they see as an inundation of applicable administrative standards. What is more, those who adopt and enforce rules – lawmakers, government departments, granting agencies, universities and institutions – should be able to justify the suitability of those rules for protecting research subjects.

Simplicity is the quality of a thing that is easily understood and convenient to use. Transparency refers to the clarity of the information and arguments that underpin our conclusions. The exercise of sound judgment requires lucid assessment that has regard for place, circumstance and persons concerned. Sound judgment can make all the difference given the risk that a researcher or REB could wander off track.

All stakeholders in the research sector should display these three qualities: simplicity, transparency and sound judgment.

7.2 Social Value of Health Research

All of research contributes to the public good, population health and well being, and economic development. Health research in particular seeks to produce new knowledge contributing to the health and welfare of populations and individuals. **An undertaking of this kind derives its social value from the good it produces for human beings.**

The Advisory Group identifies with this passage from the *Tri-Council Policy Statement* (TCPS) recognizing that research involving human subjects is necessary to advance knowledge for the welfare of humankind:

“Research involving human subjects is premised on a fundamental moral commitment to advancing human welfare, knowledge and understanding, and to examining cultural dynamics. Researchers, universities, governments and private institutions undertake or fund research involving human subjects for many reasons, for example: to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze policy, and to understand human behaviour and the evolving human condition²⁵.”

25. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, TCPS: *Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002 and 2005 amendments), p. i.4.

7.3 Respect for Persons and Populations

Respect for persons requires regard for their full autonomy. The autonomy of research subjects is manifested chiefly through consent, where required.

Additionally, the collection of personal information must be carefully supervised and carried out with respect for the rights to professional privilege and confidentiality. The need to respect professional privilege and confidentiality is based on three factors: protecting the right to privacy, safeguarding the trust relationship and forestalling risks of discrimination against research subjects and populations. Likewise, the autonomy and particularity of communities also need to be considered, for once a population is identifiable, there is a risk of discrimination against the target community and its individual members²⁶.

Research activities involving persons who live outside of the country must respect the historical, cultural and other particularities likely to affect the contemplated activities.

7.4 Shared Responsibility

Health research involves a number of stakeholders – researchers, research workers, managers, institutional boards of directors, granting agencies, sponsors, REB members and decision makers – who are responsible for promoting quality research and protecting the rights of research subjects. These stakeholders must take the necessary measures associated with their respective responsibilities²⁷. Responsibility has to do first and foremost with controlling a situation. Responsible individuals have control over their actions and are able to fulfil the duties of their position²⁸.

The term “responsibility” also denotes accountability, which is the obligation to answer for one’s own actions and those of one’s organization. We must see that the involvement of several stakeholders does not diminish or confuse their individual responsibility and accountability. This applies not only to data banks and biobanks, but to all research involving human subjects.

Shared responsibility means that all banks earmarked for health research will be subject to standards of good practice.

The core responsibilities of bank operators should be set out in a specific mandatory law or regulation. This will keep the consent form brief and centred on the concerns of the research subject.

26. The publication of research outcomes may harm the reputation of some persons, even those belonging to a social group. Cf. Martyn Hammersley and Paul Atkinson, *Ethnography: Principles in Practice*, New York: Routledge, 1993, p. 263-287.

27. *Supra*, footnote 14, Message from the Minister.

28. Blais, M., *Une morale de la responsabilité*, Montréal, Fides, 1984, p. 54.

7.5 Distribution of Benefits and Burdens

Personal well being and knowledge development through research are interdependent. Health research concerns all citizens, whether directly or indirectly. To further their endeavours, the various categories of health research have need of people who agree to be research subjects.

The knowledge gained through all of research on the whole fosters the well being of individuals and society. Anticipation of the advantages that can reasonably be expected to result from research should encourage citizens to participate as voluntarily as possible.

Sustained participation in research would maximize the benefits for citizens, society and future generations. To the extent possible, researchers should encourage that type of involvement by disclosing the outcomes and main spinoffs of their investigations to the subjects and others concerned.

The benefits from research are useful for everyone. On the other hand, society must take steps to minimize the burdens borne by research subjects and spare them serious harm or denial of their rights because of their contribution to the advancement of health knowledge.

A number of people who spoke with the Advisory Group voiced serious concern about possible forms of discrimination, especially in the insurance and employment sectors. Article 20.1, paragraph 2 of the *Charter of Human Rights and Freedoms*²⁹ states with reference to insurance contracts that “the use of health as a risk determination factor does not constitute discrimination within the meaning of section 10.” Our stakeholders are afraid that this provision authorizes insurance companies to regard participation in research and individual research outcomes as risk determination factors.

The principle of equitable distribution of benefits and burdens is especially desirable when it comes to protecting participants from these kinds of discrimination. **The legislation should effectively protect research subjects against discrimination, especially in the areas of insurance and employment.**

The Advisory Group suggests that the new legislative provisions establish these rules: participation in a health research project should be confidential; it should be unlawful to request any such information in relation to insurance or employment; and reluctance or omission to declare or provide such information has no legal consequences.

29. R.S.Q. c. C-12.

Recommendation 1

With respect to research participation, that appropriate legislation establish the following two standards:

- Participation in a health research project is confidential, and any request regarding that participation in relation to insurance or employment is unlawful.
- Reluctance or omission to declare or provide such information has no legal consequences.

7.6 Proportionality of Risks and Protective Measures

Equitable treatment of research subjects means balancing the risks and benefits associated with their participation. This rule is found in several normative documents. For one, section 18 of the *Declaration of Helsinki* compares the importance of the research objective and the risks incurred by the participant. The sought-after objective must be preponderant:

“Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers³⁰.”

Besides setting out this principle, which safeguards the integrity of research subjects, article 16 of the *Declaration of Helsinki* maintains that the investigation should be painstakingly assessed to match its foreseeable benefits against the associated burdens and risks:

“Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available³¹.”

Section 20 of the *Civil Code of Québec* refers to the necessary proportionality between the risks incurred and anticipated good of the experiment: “A person of full age who is capable of giving his consent may submit to an experiment provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.”

The competent REB is responsible for making this determination. If it gives a project the green light, it must ensure the proportionality of the means used to protect the research subjects. **Given a minor risk, only limited precautions are needed. Given the possibility of greater risk, greater precaution should be taken and call on appropriate resources.** In section 8.2.1 of this final report, we propose a model of proportional review making reference to several customary criteria.

30. World Medical Association: *Declaration of Helsinki*, October 2000, art. 18.
See at: <http://www.wma.net/f/policy/b3.htm>

31. *Idem*, art. 16.

7.7 Receptiveness and Collaboration

Everyone wants to be in good health, and health is a personal good in this sense. Still, society as a whole has a stake in seeing all its citizens in good health. In this light, this is a public issue and health research should provide for innovative solutions accessible to everyone. **Health research using banks can only contribute effectively to the public good if it is driven by the willingness to share knowledge and by receptiveness to local and international cooperation.**

Article 18 of the *International Declaration on Human Genetic Data* encourages the flow of data and international cooperation. States should regulate this activity in a manner that protects subjects' rights when the receiving party has obtained specimens.

“18 (a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration”³².”

Considering the act of generosity giving rise to the donation³³ of biological material, we believe it essential that a similar philosophy preside over all research using human tissues. **The data and biological material found in banks are entrusted to them without donors receiving any material or monetary benefit. Consequently, the principle of non-commercialization of biological material is vital to show respect for the donation of that material.** Québec society has chosen not to reduce the human body or its parts to mere commodities, and this basic orientation must be reflected in research activities. However, researchers and bank trustees can acquire intellectual ownership of discoveries stemming from biological material and data.

The principle of non-commercialization of biological material does not mean that the banks need to provide their services free of charge. It is reasonable for bank users to cover the costs incurred by the professional, technical and administrative aspects of banking, storage and utilization.

32. UNESCO, *International Declaration of Human Genetic Data*, October 16, 2003.

See at: http://portal.unesco.org/fr/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

33. According to two authors, the gratuity of the procedure clearly makes this a donation: “*Section 19 C.c.Q. sets out the principle that a competent person of full age may, under certain conditions, alienate a part of his body while still alive. (...) In addition, according to the terms of section 22 C.c.Q., it is possible to use for purposes of research any substance, organ or tissue removed in the context of care. Although these body parts, once alienated from the person, are in commercium or possibly subject to a juridical act, the Québec lawmaker has eliminated any element of mercantilism by affirming the gratuity of that alienation, so that it can be said that use of the word ‘donation’ in this context is not a misnomer.*” Kouri, R. P. and S. Philips-Nootens, *L'intégrité de la personne et le consentement aux soins*, 2^e éd., Cowansville, Éditions Yvon Blais, 2005, p. 19-20.

8. PROTECTION OF RESEARCH SUBJECTS

We stated at the beginning of this report that our Advisory Group seeks to reconcile protecting research subjects and recognizing the social value of health research. We will now explore the ways in which research subjects can be protected in the context of health research, especially when the research involves data banks and biobanks.

Maintaining and developing an ethics culture among research practitioners is the first means to prioritize for protecting research subjects and safeguarding the good reputation of scientists. The protection gradually established for research subjects over the past 60 years consists of two core mechanisms: approval of every research project by a REB and the subject's expression of free and informed consent. We find that these mechanisms are still adequate and will now consider how they should be deployed with respect to data banks and biobanks.

8.1 Ethics Culture

Researchers on the whole seem to pursue their activities as responsible individuals respectful of the dignity and rights of their fellow humans. **The most effective way to protect research subjects is to develop an ethics culture and entrench it in the health research community.**

Still, we cannot overlook certain behaviours that are clearly unacceptable, though somewhat marginal in our view. The prevention of other untoward occurrences is one reason why a formal ethics culture has taken shape. The existence of a formal ethics culture also improves the overall quality of health research in the everyday.

International, Canadian and Québec organizations have expended considerable resources to strengthen the ethics culture. Researchers nowadays are keenly aware of the ethical issues raised by health research. Their awareness should be further encouraged by promoting student training and ongoing researcher training. In 2002 and 2003, the deliberations of a committee chaired by Dr. Claude Morin³⁴ brought to light the need to organize activities to support and enrich the ethics culture. That committee's final report paints a distressing picture of ethics training for graduate students:

“Most students whom we met are satisfied with their research training and with the recognition and appreciation of their work. Paradoxically, all of the students whom we met had been trained in animal protection, whereas more than half of them had received no ethics training for research involving humans? Few research centres offer such training other than what supervisors provide³⁵.” [translated from the French]

The Morin report further notes that research ethics training for researchers, REB members and all personnel varies from one centre to the next and is a matter left to local initiative³⁶.” The Advisory Group believes that this situation could stand considerable

34. Le Comité du FRSQ sur les bonnes pratiques de la recherche et de l'éthique de la recherche chez l'humain (Comité Morin) was established by the FRSQ Board of Directors. Its final report dated back to February 2004.

35. *Idem*, p. 7.

36. *Ibid*, p. 8.

improvement. Having the health research sector affirm the importance of ethics does not make this a reality where the behaviour of research teams is concerned. Sustaining and bettering an ethics culture require serious training at the very least.

In concluding its report, the Morin committee made the following recommendation to the FRSQ with respect to the development of training programs:

“Provide leadership for the governance of good research practices and determine the reach of the responsibilities which the FRSQ intends to assume in the following areas:

“Support for the development of training programs for:

- researchers, especially new researchers;*
- REB members;*
- research support staff;*
- students (by asking the universities to provide research ethics training programs³⁷).”*

Innate common sense and personal decency can be relied on to rule everyday conduct. We can take it for granted that common sense and decency make for natural ethics. It seems, however, that research undertakings involving human subjects require knowledge and sensitivity that natural ethics do not always fully provide. Knowledge and sensitivity with respect to ethics are necessary in health research because researchers often have access to personal information about a research subject and could possibly harm that subject, whether intentionally or unintentionally.

A straightforward illustration of this is seen in the seven guiding principles stated in the previous section. Those principles were formulated through brainstorming by the Advisory Group members. That followed upon a search of the extensive documentation on the subject. We could not have produced that statement of principles based solely on the natural ethics of a few individuals. This prompts our conclusion that sustaining and furthering an ethics culture require participation in organized forums for information interchange and discussion.

Ethics training for graduate students³⁸ is still a serious concern owing to the findings of the Morin committee. The Advisory Group recommends that the FRSQ adopt a policy requiring that its funded graduate students receive appropriate research ethics training. A mere few hours of training would be ridiculously inadequate in light of all that needs to be learned and would discredit research ethics.

Obviously, graduate students are not the only ones who do research. Continuing ethics training should also be provided for individuals seeking research privileges and access to institutional user files. They could be granted research privileges upon displaying a basic knowledge of ethics.

37. *Ibid*, p 12-13.

38. These graduate students are enrolled in master's, doctoral and postdoctoral programs of study.

Recommendation 2

That the FRSQ adopt a policy requiring that its funded graduate students receive appropriate research ethics training. The FRSQ should also assess the basic training needs of research milieus (researchers, students and research personnel) in this respect. That basic training should carry over into continuing training. Furthermore, health care institutions should limit research privileges and access to user records to individuals who display a basic knowledge of ethics.

8.2 REB Approval

Under section 21 of the *Civil Code of Québec*, research projects that include experimentation involving minors or incompetent subjects must be approved and monitored by a research ethics board. There is no Québec legislation³⁹ requiring that research projects targeting persons of full age be approved and monitored by an REB. Still, the FRSQ's basic standard in the area of research ethics and scientific integrity is that every research project involving human subjects must be approved and monitored by an REB. Here is how the *Standards* justify the need for REB review:

“Subjects, even competent persons of full age, are ordinarily ill equipped to judge the accuracy and precision of the information provided to obtain their consent. In addition, those persons ordinarily lack the scientific knowledge needed to assess the possible effects of the experiment. Lastly, REB review of research projects targeting competent persons of full age is instrumental in protecting the dignity, well being and rights of all subjects⁴⁰.” [translated from the French]

Prior REB approval is essential for all research projects involving human subjects. This should be a legal requirement so that all research subjects are properly protected. It is noteworthy that the concept of “research” does not address quality control of clinical interventions.

The FRSQ *Standards* describe research involving human subjects as follows:

“Research involving human subjects consists of:

- *research using living human subjects;*
- *research using human cadavers and remains, including tissues, biological fluids, gametes, embryos or foetuses;*
- *research based on personal information filed in user records⁴¹.”*

[translated from the French]

The Advisory Group endorses this description of research involving human subjects, as well as the position statement contained in the FRSQ *Standards* whereby every research project using human subjects should have the prior approval of an REB. We should point out that research involving human subjects includes studies that call for examining user records. We are in agreement with the reasons given in the *Standards*. We also

39. However, a federal regulation requires REB approval of Phase I to Phase III clinical trials. Cf. *Regulations Amending the Food and Drug Regulations*, SOR/DORS/2001-203.

40. *Supra*, footnote 16, art. 1, p. 19.

41. *Supra*, footnote 16, art. 2, p. 20.

realize that it is common practice to require REB approval and monitoring for academic research. In conclusion, we propose that the current legislation be amended to ensure that all research projects involving human subjects have the prior approval of an REB.

Recommendation 3

Every research project involving human subjects must have the prior approval of an REB, and current legislation should be amended accordingly. This measure would be universal and therefore applicable to health research initiatives requiring authorization from the Commission d'accès à l'information du Québec or a director of professional services.

8.2.1 Model of proportionate review

This section provides guidelines for REBs in two areas that closely relate to their terms of reference: risk assessment for research subjects and determination of the criteria that should be addressed in the consent form. The criteria mentioned in this model can be used to estimate risk levels for research projects that include the banking of personal information or biological material. The consent form need not include all of these criteria, but only those germane to the situation at hand.

1. Relationship between research activity and subject

- Direct intervention comprising a health risk (e.g. clinical trial or surgery).
- Direct collection of biological material for research purposes (e.g. drawing blood, lumbar puncture)
- Direct collection of information from a subject (e.g. oral questionnaire)
- Indirect collection of biological material (e.g. pathological specimens, biopsies)
- Indirect collection of personal information from medical/research records

The more the research impinges on the subject's privacy, the more invasive it is and the greater the ethical imperatives. The level of risk also varies depending on whether the intervention is direct or indirect. Information that is gathered indirectly creates several levels of risk contingent on the pathology under study and the persons concerned (personal, family or other information). If data banks and biobanks are involved, the risk assessment must examine the level of data storage security and the fairly real eventuality of a breach of confidentiality.

2. Recruitment of subjects

- Within the public or private health sector
- Outside the health care system (in shopping malls, for example)

Within the health care sector, the relationship of trust built between patient or research subject and researcher calls for close examination of the freedom that a research participant actually has. The clinical context may reduce a person's freedom to refuse participation. There is less risk of feeling coerced when the person is recruited as a control case.

3. Institutional proximity

- Within the institution
- Outside the institution

Researchers affiliated with, or working in, an institution may have easier access to the data banks and biobanks since those investigators are known to management and are bound by the rules of the institution (e.g. a researcher working in a public agency may enjoy easier access to personal information). The greater the distance between the institution and the researcher, the greater the risks become since the institution has less control over the scientist's activities.

4. Researcher's geographical situation

- Québec
- Canada
- Mixed
- Other

The more legal jurisdictions the project spans, the more carefully the protocol should be reviewed. The more the standards of the researcher's home country differ from Québec standards, the more attention is needed to ensure that Québec participants enjoy legal and ethical protection equivalent to the protection prescribed in Québec⁴². The consent form must inform subjects that their data and biological material could be used by researchers outside Québec.

5. Subjects' geographical situation

- Québec or Canada
- Outside Canada
- Both

The risk level is assessed in terms of how easily data or biological material can be linked to the subject. It is important not to impose our cultural values on people from other cultures, meaning that risk assessment must be tailored to the local context.

6. Number of institutions involved

- One
- Several

If the ethics review is conducted properly and the research project is skilfully carried out, the number of institutions involved does not alter the risk level represented by a research project.

7. Funding source

- Public or philanthropic
- Private, possible commercialization
- Mixed

42. The Commission de l'éthique de la science et de la technologie made the following recommendation to ensure the protection of genetic material and information when samples are provided to researchers outside Québec: "That only irreversibly anonymized data may be transmitted outside 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; That research participants be informed that their genetic material and information may be used by researchers outside Québec." *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation*, 2003. Recommendation 9. The Advisory Group endorses the recommendation to ensure the same level of protection as exists in Québec, but not the recommendation requiring the data to be irreversibly anonymized.

The funding source in itself does not guarantee protection of the subject's rights. Nor is it a reliable indication of a higher risk level. In the event of possible commercialization, however, there is a greater risk that the subjects and the REB could lose control over the data and biological material. The risk level is also greater when the funding source is not accountable to an independent body, such as an REB.

8. Research involvement of the attending physician

- Active researcher (e.g. seeks to recruit subjects from among his patients)
- Passive researcher (e.g. is an intermediary providing access to data)
- Not applicable (e.g. survey, data bank)

The more the attending physician has personal or financial interests in a research project or an enterprise involved in a research project, the higher the risk level and the more rigorous the ethics review must be.

9. Research hypothesis

- Precise or specific
- General or thematic

The nature and broad traits of the research hypothesis do not affect the level of risk posed by a research project. The risk level varies instead with the research specification employed to test the hypothesis.

10. Known project duration or completion date

- Definite, foreseeable
- Indefinite, undetermined

The degree of protection afforded subjects should not depend on the duration of the research initiative. The risk level is tied more to the set-up of the initiative, the rules for its implementation and the conduct of the research team. The REB should know whether the duration of the initiative is definite or indefinite in order to schedule renewals of the certificate of ethical approval. Renewal frequency should be tagged to risk level.

11. Primary or secondary use of data and biological material

- Primary
- Secondary

The risk level depends on whether or not the data and biological material are nominative and whether or not the participant has consented to their secondary use. **In general, maximum use of data and biological material should be encouraged.** This applies in particular to the secondary use of data and biological material. In each case, researchers must honour their obligation to obtain consent or authorization. The new research initiative requires approval by a competent REB.

12. Possibility of anonymizing data for its use⁴³

- Yes
- No

43. "Denominalized data allow for tracing a person through an identifying code. Anonymized data are totally unlinked from the person concerned, meaning there is no way to associate the data with the person." Centre for Interdisciplinary Research in Rehabilitation of Metropolitan Montreal (CRIR), *Politique sur la constitution de banques de données de recherche et la gestion des dossiers de recherche dans les établissements du CRIR*, section A, article 3(b).

There is less risk of violating privacy if the data used have been anonymized.

13. The participant's option to withdraw

- Yes
- No

The risk level drops when the participant has the option of withdrawing at any time. The right to withdraw data or biological material can be exercised in cases where consent has been given. However, the research team must explain that the subject can no longer exercise this right once the data or biological material have been anonymized.

14. Identifiable population or group

- Easy to identify
- Difficult to identify

The more easily a population or group can be identified from the way the research outcomes are presented, the greater the risks of labelling and stigmatizing.

15. The subject's competence to consent

- Yes
- No

The risk level is greater when participants are not competent to consent on their own. Given two very similar research projects, the ethics review should be more rigorous when the targeted participants are minors or incompetent persons of full age. Under section 21 of the *Civil Code of Québec*, minors or incompetent persons cannot be subjected to an experiment that puts their health at serious risk⁴⁴.

16. Relevance of benefits for the subject and the study population

- Immediate benefit
- Future benefit
- No direct benefit

The greater the risk level for the participants, the greater the benefits they can expect to receive. The accepted risk level depends on the anticipated benefit. Additionally, the societal benefits resulting from breakthroughs should be considered.

17. Scientific evaluation

- With peer review
- Without peer review

One role of REBs is to see that projects undergo scientific evaluation. This evaluation can be done by various bodies, such as a peer review committee, a funding agency or an REB, provided that board has the requisite scientific expertise. **Evaluation of the scientific quality of a research project is essential for protecting the participants.**

44. The FRSQ *Standards* suggest an integrated interpretation of the concepts of serious risk and minimal risk. *Supra*, footnote 16, p. 22-24.

18. Commercialization

- Individual data (data, specimens)
- General outcomes (patents, intellectual property)

The potential for commercializing products or services stemming from individual data or general outcomes raises the risk level since the investigator and other research stakeholders factor possible financial gain into their project involvement. REBs should require research officers to inform them of any circumstances likely to jeopardize protection of the participants, such as situations in which researchers have a conflict of interest. They should keep a close eye on contracts having terms and conditions that could prove detrimental to participants. Furthermore, the possibility of commercializing products or services should be clearly stated in the consent form.

8.2.2 Clarifying section 21 and amending if needed

As was mentioned earlier, section 21 of the *Civil Code of Québec* includes a clause on experimentation involving incompetent persons or minors. That provision establishes, for one, that experimentation involving an incompetent person or a minor “must be part of a research project approved and monitored by an ethics committee.” As for the kinds of interventions involved, section 21 refers to three concepts: “research project,” “experimentation” and “innovative care.” Interventions referred to as “experimentation” and “innovative care” must be distinguished from other interventions mentioned in the *Code* – care required by a person’s state of health, for example. There is no legislation that defines or describes “research project,” “experimentation” or “innovative care.” The definition and application of these concepts are therefore a conundrum for health research stakeholders, especially the members of research ethics boards.

In law, the concepts of “experimentation” and “innovative care” are pivotal in that intended interventions classed as experimentation will be subject to different legal standards than those classed as innovative care. These legal distinctions have considerable consequences with respect to the expression of consent by potential subjects, risk assessment, and the need for experimentation involving incompetent persons or minors to take place within REB-approved research projects.

For historical reasons, research involving humans has been tied almost exclusively to the field of biomedical research. However, recent rapid growth in psychosocial research and public health research has significantly altered the general picture of health research. Increasingly, the development of these two fields of investigation is raising the question of whether or not certain research projects constitute experimentation within the meaning of the *Civil Code of Québec*.

At times, certain authoritative bodies enforce on research projects limited to observation the same restrictive legal and ethical rules applicable to invasive research. In other words, the rules pertaining to experimentation are applied to purely observational research. Clearly, the Advisory Group finds, not all research is experimentation. A study that consists simply of examining records, with the authorization of the institutional director of professional services, may indeed be research, but it is not experimentation. Conversely, a research project using human subjects to explore the practicability of a new surgical procedure is unquestionably experimentation. Would that all research undertakings were this easy to categorize.

Researchers and REBs should be working with concepts that more clearly identify certain interventions as research projects, experiments or innovative care. For instance, making this distinction in epidemiological research would provide for realistic assessment of the risks to participants, as well as a proportionate approach to consent and monitoring. For, a research project involving behavioural observation does not entail the same risks as research testing a new drug. Establishing proper distinctions for basic legal concepts is greatly to be desired. Discrete application of the *Civil Code* provisions, especially those governing forms of consent, would then be possible.

The MSSS *Action Plan*⁴⁵ published in June 1998 already anticipated the need for a clear distinction between “experimentation” and “innovative care.” It tasked certain authoritative bodies with clarifying the notion of “innovative care.” That process never materialized, however.

The need for distinguishing between experimentation and innovative care has grown and taken on greater urgency in recent years. It is no longer simply a matter of differentiating between the two, for the emphasis is now on providing operational definitions for these concepts in order to enlighten researchers, REBs, subjects and other health research stakeholders. The proposed definitions must have all due regard for the context of the *Civil Code of Québec*, a basic piece of legislation. One must also bear in mind that research which is not experimentation within the meaning of the *Civil Code of Québec* is nevertheless subject to ethical, administrative, legal and practice standards framing the protection of subjects.

It would probably suffice to produce definitions when the context and nature of a research project do not render them ambiguous. However, elements other than definitions must come into play when the situation is not clear enough for straightforward use of those definitions. The growing complexity and diversity of the fields of health research suggest the need for further elements to determine whether an intervention should be categorized as experimentation or innovative care. The suggested elements will need to apply to all fields of research involving human beings.

Implementing this proposal will require extensive study, documentation and compilation aimed at general interpretation of the *Civil Code* division entitled “Care,” the background and substance of the concepts of “research project,” “experimentation” and “innovative care,” and the production of operational definitions. The representatives of the organizations concerned will also need to be consulted. The person tasked with this work might also conclude that section 21 should be amended or revised.

Recommendation 4

The ministère de la Santé et des Services sociaux or, failing that, the FRSQ should take the initiative of tasking someone with producing a document that clarifies the following three concepts mentioned in section 21 of the *Civil Code of Québec*: “research project”, “experimentation” and “innovative care.” That person will consult the organizations concerned and will further suggest suitable amendments to section 21.

45. *Supra*, footnote 14, p. 26.

8.3 Free and Informed Consent

As a rule, subjects must give their free and informed consent before research can begin. Despite exceptions to this rule, free and informed consent is an effective mechanism for protecting those subjects. The Advisory Group enthusiastically endorses the use of free and informed consent as a means of protecting research subjects. However, such consent does more than protect subjects. It also signifies their agreement with, and support of, the researcher's initiative. In other words, they share in the researcher's intention.

The TCPS gives an inspiring description of free and informed consent as a continuum in a project in which the subject joins with the researcher:

“Free and informed consent lies at the heart of ethical research involving human subjects. It encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves⁴⁶.”

One international instrument applies the need for consent to genetics research. Article 5(b) of the *Universal Declaration on the Human Genome and Human Rights* stipulates that research on a subject's genome may be initiated after the person concerned has consented:

“In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest⁴⁷.”

Section 20 of the *Civil Code of Québec*, which uses the term “experimentation” rather than “research,” permits a competent person of full age to consent to an experiment “provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.”

Many more authoritative declarations and provisions – from the *Nuremberg Code* (1947) to current normative documents – endorse this general rule of the need to obtain free and informed consent. This report does not challenge the relevance of this general rule, and we will therefore not elaborate further on this matter.

However, the matter of consent takes on a new and exceptional complexion where data banks and biobanks are concerned, and it merits our special attention. Considerations about consent are crucial in this context since our conclusions will prove decisive with respect to the more or less open use of bank contents. Data and biological material are much alike when contemplated in terms of scientific methods and objectives. Access to personal information and sampling of a person's biological material for research purposes are subject, nonetheless, to separate and distinct legal rules, especially when it comes to whether consent should be mandatory or not. Indeed, consent may not be necessary and research may be undertaken upon authorization from a legally appointed

46, *Supra*, footnote 25, comment re 2.1, p. 2.1.

47. UNESCO, *Universal Declaration on the Human Genome and Human Rights*, 1997, article 5(b).

entity, such as the Commission d'accès à l'information du Québec or the director of professional services of a health and social services institution.

8.3.1 The right to withdraw

Section 24 of the *Civil Code of Québec* mentions that consent to an experiment “may be withdrawn at any time, even verbally.” Pursuant to this provision, persons who consent to an experiment do not lock themselves in for the entire duration. Signing a consent form differs from entering into a customary contractual arrangement in that subjects retain the right to withdraw from research projects.

Article 22 of the *Declaration of Helsinki* spells out the information that the subject must be given. That list includes the right to withdraw consent, the subject being free “to withdraw consent to participate at any time without reprisal⁴⁸.” Article 2.1 of the TCPS cited earlier conveys the same idea in saying that consent needs to be reiterated throughout the project. Such considerations, grounded in personal autonomy, portray consent as continuous, as opposed to time-limited:

“By not withdrawing the consent he has given, the subject reaffirms at any given time his willingness to participate in the experiment. Conceptually, not withdrawing consent equates with reiterating the implicit giving or renewal of consent so that it continues. This expression of consent is implicit because it stems naturally from the behaviour of the subject, who abstains from retracting his initial willingness⁴⁹.”
[translated from the French]

The existence of consent goes hand in hand with existence of the right to withdraw from a data bank or a biobank. Article 9 of the *International Declaration on Human Genetic Data* proposes a process applicable in cases where subjects wish to withdraw data or specimens they have provided for purposes of scientific research:

“9 (a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.

“(b) When a person withdraws consent, the person’s genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

“(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person’s wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed⁵⁰.”

48. *Supra*, footnote 30, art. 22.

49. Giroux, M.T., *L’experimentation auprès des personnes atteintes de maladie neurodégénérative*, médecine/sciences, No. 10, Vol. 19, October 2003, p. 1017.

50. *Supra*, footnote 32, art. 9.

In sum, subjects are entitled to withdraw from a research initiative at any time without that decision entailing any disadvantage whatsoever. They are further entitled to require the destruction of their data or biological material.

Exercise of the right to withdraw supposes a link between the person concerned and the data or biological material. During the consent process, the subject must be informed that, for all practical purposes, anonymizing data or biological material voids the right to withdraw. The decision to anonymize data or biological material may be made at the time of consent or later when the research begins.

9. COLLECTION AND USE OF BIOLOGICAL MATERIAL

The legal framework for collecting biological material is addressed in provisions of the *Civil Code of Québec*. The secondary use of biological material is not expressly contemplated in the *Code* and therefore requires studied consideration, for which we will refer to the relevant articles of the TCPS.

9.1 Legal Rules for Collecting Biological Material

The principle of personal autonomy taking the form of free and informed consent is made crystal clear in section 10 of the *Civil Code of Québec* which mentions the rights to inviolability and integrity. No one may interfere with a person's inviolability without his free and informed consent:

*“Every person is inviolable and is entitled to the integrity of his person.
“Except in cases provided for by law, no one may interfere with his person without his free and enlightened consent.”*

Section 11 of the *Code* establishes the principle that the person subject to an act must have first consented to that act on his own or by consent by a proxy.

“No person may be made to undergo care of any nature, whether for examination, specimen taking, removal of tissue, treatment or any other act, except with his consent.

“ If the person concerned is incapable of giving or refusing his consent to care, a person authorized by law or by mandate given in anticipation of his incapacity may do so in his place.”

Section 22 of the *Code* provides that a part of the body removed from a person as part of his care may be used for research with the consent of that person:

“A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research.”

Section 22 dispels any uncertainty as to whether tissues collected as part of care⁵¹ can be used for research purposes. The legislator says that they can, provided the person concerned has consented⁵².

Section 24 of the *Code* prescribes the form that consent to removal of a part of the body or to experimentation must take. The consent of the person concerned must be given in writing and can always be withdrawn, even verbally:

51. These tissues may have been collected at the time of diagnostic testing. A second example would be diseased tissue collected through excision.

52. *Supra*, footnote 33, p. 37.

*“Consent to care not required by a person’s state of health, to the alienation of a part of a person’s body, or to an experiment shall be given in writing.
“It may be withdrawn at any time, even verbally.”*

The sample of material removed from a person may be used for research purposes, provided the person concerned has first given his free and informed consent. Section 22 of the *Code* does not mention whether that consent must pertain to only one research project or whether it can cover a research theme or infrastructure.

9.2 Secondary Use of Biological Material

To clarify the meaning of “secondary use of biological material,” we need to look at the part of the TCPS dealing with the secondary use of data:

“Secondary use of data refers to the use in research of data contained in records collected for a purpose other than the research itself. Common examples are patient or school records or biological specimens, originally produced for therapeutic or educational purposes, but now proposed for use in research. This issue becomes of concern only when data can be linked to individuals, and becomes critical when the possibility exists that individuals can be identified in the published reports⁵³.”

For the purposes of this definition, the TCPS likens biological specimens to data. Based on the suggested definition, biological material collected for therapeutic purposes is used secondarily when used for research purposes. According to the TCPS, the secondary use of collected biological material becomes a concern when that material is linked to a person⁵⁴.

As can be seen, the TCPS broaches consent to the secondary use of tissues from the standpoint of whether or not the person concerned can be identified by means of those tissues. Section 22 of the *Civil Code of Québec*, on the other hand, makes no distinction between a specimen that allows for identifying the person who provided it and a specimen that has been anonymized. Two commentators opine that section 22 of the *Code* is intended to give the subject control over how the collected biological material will be used:

“Although, the collecting of samples does not, strictly speaking, violate the physical integrity of the person concerned since it is done within the bounds of care provided in the person’s own interest, the use that may be made of those samples could nevertheless offend the person’s concept of his dignity, not to mention the significant economic benefits that may sometimes accrue to the researcher or the institution in which the researcher works. ... In these circumstances, it seems normal for the person concerned to be allowed control over the collected products, which implies that he has been informed of, and consented to, their use⁵⁵.” [translated from the French]

53. *Supra*, footnote 25, art. 3.3, introduction, p. 3.5.

54. Readers will recall that the Advisory Group encourages the re-use of data and biological material for research purposes other than the original purpose.

55. Deleury, E. and D. Goubau, *Le droit des personnes physiques*, Cowansville, Éditions Yvon Blais, 2002, p.139-140.

It is plain that subjects should give their consent to the use of biological material taken from them. The question we need to ask ourselves at this point is how precisely should the potential use of that biological material be described.

The TCPS asks researchers to seek re-consent when previously collected tissues allow for identifying the subjects. However, the subjects' consent is not required when the tissues are anonymous or anonymized and the project does not risk harming the subjects:

“(a) When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue. The provisions of article 10.2 also apply here.

“(b) When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires⁵⁶.”

The approach favoured by the TCPS sheds interesting light on possible interpretations of sections 11 and 22 of the *Civil Code of Québec*. Restrictive interpretation of these provisions would allow subjects' consent to use of their biological material within the bounds of a specific research project of definite or definable duration. Less restrictive interpretation of sections 11 and 12 would allow subjects' consent to various secondary uses of their biological material, provided that material is anonymous or anonymized. Broad interpretation gives subjects the freedom to qualify their willingness much more. By comparison with restrictive interpretation of sections 11 and 12, a broad reading is more respectful of the subjects' autonomy.

56. *Supra*, footnote 25, art. 10.3, p. 10.4.

10. ACCESS TO PERSONAL INFORMATION AND DATA USE

Access to personal information is regulated by provisions of the *Civil Code of Québec* and the *Act Respecting Health Service and Social Services*⁵⁷ and by legislation on the protection of personal information in the public and private sectors⁵⁸. Additionally, section 132 of the *Public Health Act*⁵⁹ deals with the communication of information and makes reference to sections 17 to 28 of the *Act Respecting Health Services and Social Services*. It should be remembered that these statutes were enacted by the Québec National Assembly and therefore take precedence over the administrative standards pertaining to research.

Some banks are earmarked solely for the storage and processing of data. In light of this, a biobank containing no data is conceivable. But this is unlikely in this day and age since biological material is useful only if closely linked to data, whether those data are used to study the biological material or derived from its study. Knowing only this close link between data and biological material in the research sector, we can deduce **the need for harmonizing the administrative standards applicable to the storage and use of data with the corresponding standards applicable to the storage and use of biological material**. For example, Chapter 3 of the TCPS deals with access to personal information and data management⁶⁰ and chapter 10 with the collection and management of human tissues. Given the recent major expansion of banks as research resources, it would prove helpful to integrate the rules applicable to biobanks.

Discussion is ongoing, especially among legal scholars, about the application of legislation⁶¹ on personal information protection to biological material. Some argue that such legislation is inapplicable to biobanks since biological material is altogether different from the “documents” mentioned in the legislation. Others draw an analogy between biological material and encrypted information⁶². They say that biological material contains information that is accessible to persons having the skill and technical resources to search for it, as with encrypted information. Considering the need to harmonize the administrative standards germane to data and biological material, the legislation on personal information protection should be amended so that its applicability to biological material becomes inarguable⁶³.

57. *Supra*, footnote 8.

58. *Supra*, footnotes 6 and 7.

59. *Supra*, footnote 10.

60. *Supra*, footnote 25.

61. This refers to two pieces of legislation: the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, R.S.Q. c. A-2.1, and the *Act Respecting the Protection of Personal Information in the Private Sector*, R.S.Q. c. P-39.1.

62. Encrypt: “*To convert (data) into code, esp. to prevent unauthorized access*” and thus to ensure its confidentiality. *Canadian Oxford Dictionary*.

63. The Conseil de la santé et du bien-être du Québec proposed a similar statutory amendment concerning genetic material in its brief titled “*L’information génétique et l’accès à l’information des chercheurs: Il est urgent de protéger la population*” (genetic information and researchers’ access to information: an imperative for public protection), p. 23.

Recommendation 5

The legislator should pass a law establishing a single framework applying to both data banks and biobanks.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

10.1 Rights to Privacy and Reputation

Privacy is a fundamental right set out in section 5 of Québec’s *Charter of Human Rights and Freedoms*⁶⁴:

“Every person has a right to respect for his private life.”

Section 4 of the *Charter* states the right to one’s reputation:

“Every person has a right to the safeguard of his dignity, honour and reputation.”

Section 3 of the *Civil Code of Québec* enshrines the right to respect for privacy as a personality right:

“Every person is the holder of personality rights, such as the right to life, the right to the inviolability and integrity of his person, and the right to the respect of his name, reputation and privacy. These rights are inalienable.”

One legal scholar states that the information protection guarantees the right to respect of one’s reputation, as well as the secrecy of personal health information:

“The protection of information encompasses all the rights pertaining specifically to the protection of personal information. It guarantees, inter alia, the protection of correspondence and the protection of telephone conversations, as well as shadowing and surveillance, including the right to one’s image and reputation, and personal data, including personal health information. The protection of personal information must, however, be moderated to account for the particular circumstances under study. The public interest is probably the chief moderating factor⁶⁵.” [translated from the French]

Legal protection for personal information stored in data banks and biobanks exists under the heading of the fundamental rights to reputation and privacy. Still, the public interest may qualify the absoluteness of fundamental protection. In the opinion of the Advisory Group, health research pursues a public interest.

It is possible to access confidential information, either with the consent of the person concerned or through authorization by law. These possibilities are mentioned in two

64. R.S.Q. c-12

65. Nadeau, A.-R., *Vie privée et droits fondamentaux*, Cowansville, Éditions Yvon Blais, 2000, p. 43-44.

provisions of the *Civil Code of Québec*. Section 35 sets out the right to privacy, then mentions two exceptions to this right (consent and authorization by law):

“Every person has a right to the respect of his reputation and privacy. No one may invade the privacy of a person without the consent of the person unless authorized by law.”

Section 37 of the *Code* is intended for everyone who opens a file on another person. It states that the person cannot disclose filed information to third parties without the consent of the person concerned or else authorization by law. Section 37 extends the provision of section 35 to the establishment of files. It reads as follows:

“Every person who establishes a file on another person shall have a serious and legitimate reason for doing so. He may gather only information which is relevant to the stated objective of the file, and may not, without the consent of the person concerned or authorization by law, communicate such information to third persons or use it for purposes that are inconsistent with the purposes for which the file was established. In addition, he may not, when establishing or using the file, otherwise invade the privacy or damage the reputation of the person concerned.”

Clearly, disclosure to third parties requires the consent of the person concerned or else legal authorization. This rule is not limited to medical information, but is universally applicable in our society.

Information entrusted to a health care professional in connection with the delivery of therapeutic care is confidential. It cannot be used for other than therapeutic purposes without the consent of the person concerned or else authorization by proxy.

10.2 Access to Personal Information

This section looks at some legal mechanisms for accessing personal information. Data banks can be established in one of three ways reflecting the type of consent and authorization required. The first entails authorization from the Commission d'accès à l'information (CAI). The second requires authorization by the director of professional services of a health and social services institution. The third calls for the consent of the person concerned. A combination of these approaches may be required. For each approach, we cite here the relevant provisions of the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, the *Act Respecting the Protection of Personal Information in the Private Sector* and the *Act Respecting Health Services and Social Services*.

10.2.1 With authorization from the Commission d'accès à l'information

Section 59.2 (5) of the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*⁶⁶ mentions a number of exceptions whereby a public entity is allowed to release nominative information without the consent of the person concerned:

66. *Supra*, footnote 6.

“59. A public body shall not release personal information without the consent of the person concerned.

“Notwithstanding the foregoing, a public body may release nominative information without the consent of the person concerned in the following cases and strictly on the following conditions:

(. . .)

5° to a person authorized by the Commission d'accès à l'information, in accordance with section 125, to use the information for study, research or statistics purposes;”

Authorization for access to personal information for study, research or statistical purposes shall be consistent with section 125 of this same statute:

“125. The Commission may, on a written request, grant a person or an agency the authorization to receive communication of personal information contained in a personal information file, for study, research or statistics purposes, without the consent of the persons concerned, if it is of the opinion:

“1° that the intended use is not frivolous and the ends contemplated cannot be achieved unless the information is communicated in nominative form;

“2° that the personal information will be used in a manner that will ensure its confidentiality.

“The authorization is granted for such period and on such conditions as may be fixed by the Commission. It may be revoked before the expiry of the period granted if the Commission has reason to believe that the authorized person or body does not respect the confidentiality of the information disclosed or the other conditions.”

It would be good to make a list of the foregoing conditions in order to grasp the full import of this section 125:

- The personal information is released for study, research or statistical purposes.
- The intended use of the personal information is not frivolous.
- Release of the information in nominative form is necessary to achieve the purposes contemplated.
- The intended use of the personal information provides for its confidentiality.
- Authorization is granted for a period of time set by the CAI.
- Authorization is granted on the conditions set by the CAI.
- Authorization may be revoked if the confidentiality of the information is not respected or the other conditions are not honoured.

Section 21 of the *Act Respecting the Protection of Personal Information in the Private Sector*⁶⁷ reiterates the provision of section 125.

10.2.2 With authorization from a director of professional services

The director of professional services of a health and social services institution is empowered to authorize access to user records. The relevant legislative provision is section 19.2 of the *Act Respecting Health Services and Social Services*:

67. *Supra*, footnote 7.

“19.2. The director of professional services of an institution or, if there is no such director, the executive director may authorize a professional to examine the record of a user for study, teaching or research purposes.

“Before granting such authorization, the director must, however, ascertain that the criteria determined under section 125 of the Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information (chapter A-2.1) are satisfied. If the director is of the opinion that the professional's project is not in compliance with generally accepted standards of ethics or scientific integrity, the director must refuse to grant the authorization.

“The authorization must be granted for a limited period and may be subject to conditions. It may be revoked at any time if the director has reason to believe that the authorized professional is violating the confidentiality of the information obtained or is not complying with the conditions imposed or with generally accepted standards of ethics and scientific integrity⁶⁸.”

Here is a summary of the conditions set out in this section 19.2:

- Professionals can access user records for study, teaching or research purposes.
- The criteria of section 125 apply.
- The intended use of the personal information is not frivolous.
- Release of the information in nominative form is necessary to achieve the purposes contemplated.
- The intended use of the personal information provides for its confidentiality.
- Authorization must be for a limited time.
- Authorization is granted on the conditions set by the director of professional services.
- Authorization may be revoked if the confidentiality of the information is not respected or the other conditions are not honoured.
- The professional adheres to the generally accepted standards of ethics or scientific integrity, failing which authorization may be revoked.

10.2.3 With consent from the person concerned

Section 19.1 of the *Act Respecting Health Services and Social Services*⁶⁹ governs access to a user record if the user so consents. We see from section 19.1 that the legislator chose not to give full rein to the freedom to contract in this area:

“Consent to a request for access to a user's record for study, teaching or research purposes must be in writing; in addition, it must be free and enlightened and given for specific purposes. Otherwise, it is without effect.

“The consent is valid only for the time required for the attainment of the purposes for which it was granted or, in the case of a research project approved by an ethics committee, for the period determined, where that is the case, by the ethics committee.”

68. *Supra*, footnote 8.

69. *Supra*, footnote 8.

Here is a summary of the conditions set out in this section 19.2:

- The user's consent must be in writing.
- The user's consent is given for a specific purpose.
- Consent is valid only for the time required to achieve that purpose.
- If an REB has approved the research project, consent is valid for the period of time set by that board.

The time required to carry out the intended activity may be short (e.g. one year) or much longer (e.g. 20 years).

Authorization from the CAI or a director of professional services and consent by the user of health and social services fall within a legal framework designed for research in the context of a specific project taking place within a definite or definable period of time. **This legal framework is ill suited to the reality and objective of data banks and biobanks, the use of which can be maximized if they are accessible for new research projects that could be carried out at a time unknown when the data and biological material were banked.**

Recommendation 6

That laws making provision for personal information protection be adapted to the emerging trends in health research so that such laws recognize the legal validity of data banks and biobanks and of research exploring themes rather than specific hypotheses.

10.3 Secondary Use of Data

The TCPS regards the secondary use of data as an issue arising only when those data can be linked to the subjects. It sets three conditions for researchers requesting access to data whose use will allow for identifying the subjects. Compliance with these conditions must be demonstrated to an REB:

“If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:

- a) Identifying information is essential to the research;*
- b) They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects;*
- c) Individuals to whom the data refer have not objected to secondary use⁷⁰.”*

According to the TCPS, researchers should have access to data that do not involve identifying information. However, where use of data does allow for identifying the subject, the persons concerned must not have objected to their secondary use.

70. *Supra*, footnote 25, art. 3.3, p 3.5-3.6.

Pursuant to article 3.4 of the TCPS, REBs are permitted to adopt certain additional requirements:

“The REB may also require that a researcher’s access to secondary use of data involving identifying information be dependent on:

- a) the informed consent of those who contributed data or of authorized third parties; or*
- b) an appropriate strategy for informing the subjects; or*
- c) consultation with representatives of those who contributed data⁷¹.”*

Justification for the additional requirements proposed in article 3.4 lies in the method of proportionate ethics review. When the magnitude of the burdens and the probability of their materializing so warrant, the REBs may require researchers to obtain the subjects’ consent to the re-use of data that allow for their identification.

The Advisory Group endorses the TCPS position authorizing the secondary use of data that does not identify the subject because those data are anonymous or have been anonymized. In such cases, the risks to privacy are virtually nil. Nonetheless, prior REB approval is still required because an independent, objective risk assessment is needed.

Recommendation 7

That the legislation authorize the secondary use of data that do not allow for identifying the subject, without the need for re-consent by the subject. However, the prior approval of a competent REB would be required.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

The situation is different when the secondary use of data will allow for identifying the subjects. In these cases, respect for privacy is definitely at risk. The Advisory Group is of the opinion that loyalty to the subjects requires researchers to honour their word or the agreement signified by expressed consent. If the consent or authorization mentions that data involving identifying information will be used for a specific research project, that word must be honoured and the REB cannot authorize use of the data outside those bounds. However, if the consent or authorization foresees that the data could be used for other research, REB approval is still required, but the subject’s re-consent should not be needed.

71. *Idem*, art. 3.4, p. 3.6.

Recommendation 8

The legislation should authorize the secondary use of data involving identifying information when the consent or authorization foresees that such data could be used for other research. Nonetheless, prior approval by a competent REB would still be required.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

11. IMPROVEMENTS IN CONSENT

The issue of free and informed consent is widely discussed, for many research stakeholders are interested in improving the process. In fact, there are a number of proposed improvements involving widely varying aspects of the issue, such as the procedure for soliciting potential subjects, the length of the consent form and the consequences of exercising the right to withdraw.

It is the Advisory Group's intention to make proposals for improving consent. We base these recommendations on two premises:

- The applicable rules should allow the subjects as much room as possible for exercising personal autonomy.
- Health research should be conducted with full respect for fair play vis-à-vis the subjects.

The practice of fair play goes far beyond literal compliance with legal or administrative rules. Fair play is a mindset, the attitude of individuals of loyal and candid conduct. Accordingly, it is inconsistent with fair play for researchers or sponsors to seek to diminish their legitimate liability in the event of harm. Nor should consent forms be so long that prospective subjects leaf through them or else sign without reading from beginning to end.

11.1 Specific Consent and General Consent

As has been said, several provisions of the “Care” division of the *Civil Code of Québec* indicate that consent must be obtained from persons who are approached to participate in an experiment or provide tissues for research purposes. In the matter of research ethics, the general requirements for valid consent are the competence of the subject or his legal representative, the subject's freedom and the communication of all necessary information to the subject⁷².

Québec civil law stipulates that consent must be free and informed, or enlightened. Our focus here is on the need for informed consent. For, we are dealing with data banks and biobanks, and so the idea of banking naturally brings to mind matters of duration and multiple uses.

For purposes of argument, we will explore the concepts of “specific consent” and “general consent.” Specific consent is confined to one particular research purpose and time period. The precise wording of this type of consent restricts research possibilities to the stated purpose and time. General consent, on the other hand, covers indefinite purposes and time periods. **This type of consent would permit the researcher to use the data bank and the biobank for purposes other than those pursued by the initial**

72. “It is widely recognized that in order to consent to participate in a research protocol, three conditions must be met – patient capacity (the ability of the patient to understand the nature of the research, as well as its risks and benefits, in order to make an informed decision), voluntariness (freedom from undue coercion, be it deliberate or unintended) and disclosure (the provision of all information necessary for the potential subject to assist them in the decision-making process).” Blackmer, J., *The unique ethical challenges of conducting research in the rehabilitation medicine population*, BMC Medical Ethics, n°. 4, Vol. 2, June 2003.

See at: <http://www.biomedcentral.com/1472-6939/4/2>

research initiative described on the consent form. General consent could also pertain to a bank or research infrastructure whose possible uses are not all known at the start. We believe that consent is valid if the person concerned knows the main themes of the potential research initiatives, as well as the general objectives of the research infrastructure. Accountability and a transparency obligation are necessary to ensure that the subjects know how their data and biological material are being used.

The qualifiers “specific” and “general” do not cover all possible situations, for certain forms of consent may fall in a grey area between the two. General consent does not rule out the possibility that a research project could also include specific content; nor does it rule out consent giving the subject the option of agreeing to initiatives that include a large number of unknowns. For instance, a project could propose using the specimens for the purposes of a) specific investigation of the AB marker in breast cancer, (b) breast cancer research, (c) cancer research or (d) health research.

It must be established whether or not general consent can be regarded as informed and valid, as is specific consent. Should the willingness expressed through general consent be sufficient for the banking of data or biological material? In other words, can general consent be informed consent?

The retention of data and biological material for research other than the stated original research honours the value of the act of giving from the dual standpoint of its worth for the person concerned and for the advancement of knowledge. Indeed, it seems more expedient to retain, and maximize the use of, biological material and data for the improvement of knowledge rather than destroy them once the stated specific objective has been achieved. Moreover, general consent allows widely varying commitment by the persons concerned. The possibility of calling for general consent is a step towards recognizing the personal autonomy of potential subjects wishing to provide this type of consent.

We should underline the difference between general consent and “blanket consent” that would permit any and all use of data or material. General consent can be informed consent on three conditions. First, the subjects must be informed that they are being asked to give general consent, and they must be told how this consent differs from specific consent. Potential subjects must know that in giving general consent, they forego the possibility of expressing their wishes with respect to specific uses of their data or biological material. Where general consent is concerned, the exercise of personal autonomy is possible only if the subjects are fully aware of what they are doing. Second, the subjects must be informed of the main themes of the possible research initiatives, as well as the general objectives of the research infrastructure. Third, they must be informed of the main properties of the governance framework for managing banks and the data and material they contain. The management framework explained to the subject includes a description of the process for deciding on future uses – unknown at the time of consent – and on a monitoring mechanism.

The applicable legislation and administrative standards provide no framework providing the flexibility required for the recognition of general consent.

In its opinion on the ethical issues raised by genetic databases, the Commission de l'éthique de la science et de la technologie (commission on ethics in science and technology) states that consent must be specific in order to be informed:

“For consent to be informed, the person preparing to participate in research must know the nature, purpose, advantages and risks of that research, as well as the extent of his consent. As is mentioned by the Conseil de la santé et du bien-être, consent must therefore be given for specific ends and a set duration.

Consent is deemed to be explicit when the subject signs a consent form that outlines the project and states the use that will be made of the information⁷³.” [translated from the French]

Here are our arguments in response to this opinion of the Commission:

- The recognition of general consent reinforces respect for the autonomy of the potential subject who prefers this means of demonstrating his willingness, especially in order to facilitate implementation of the research.
- If the potential subject is well informed about the nature of general consent by comparison with specific consent, his general consent is just as enlightened and informed as specific consent.

The collecting of a specimen from the body requires the free and informed specific consent of the person concerned. This principle comes fully into play when the specimen is collected for use in health research. Still, the research subject should be able to give general consent that would allow for the banking and use of material collected for health research uses.

Recommendation 9

The legislation should authorize the secondary use of biological material when consent foresees that the material could be used for other research. Nonetheless, prior REB approval would still be required.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

Basically, the risks posed by banks relate to the confidentiality of personal information. If the authoritative bodies and the procedures proposed here are operational, meaning that the confidentiality of information is well protected, general consent can be considered with confidence.

In this context, the bank governance framework will be outlined for the persons concerned, who will be assured that their data and biological material will be used only for health research purposes and that an REB will oversee protection of their dignity and rights.

73. *Supra*, footnote 42, p. 42-43.

Recommendation 10

The legislation should require banks to give subjects the following information and assurances:

- an outline of the bank governance framework;
- the assurance that the data and biological material will be used only for health research purposes;
- the assurance that an REB will oversee protection of their dignity and rights.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

11.2 Formality and Authenticity of Demonstrated Willingness

Written consent is the customary evidence that a person agrees to participate in the proposed research project. Section 24 of the *Civil Code of Québec*⁷⁴ clearly states that “consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to an experiment shall be given in writing.” Additionally, the *Code* provides no standard requiring a particular form for free and informed consent to what section 21 broadly terms a “research project.” We conclude that pursuant to the *Code*, written consent is not necessary for research that does not include care not required by a person's state of health, alienation of a part of the subject's body or experimentation.

However, the requirement to obtain consent stands even if that consent need not be in writing. Section 10 of the *Code* applies to what is broadly termed a “research initiative”:

“Every person is inviolable and is entitled to the integrity of his person. Except in cases provided for by law, no one may interfere with his person without his free and enlightened consent.”

Section 35 of the *Code* is applicable to a research initiative entailing a violation of privacy rather than personal integrity:

“Every person has a right to the respect of his reputation and privacy. No one may invade the privacy of a person without the consent of the person unless authorized by law.”

The potential subject may wish to participate in a project, but is unable to give consent in written form. At other times, the potential participant wishes to take part in the project but is afraid of being identified, especially because participation could reveal certain behaviours that are not altogether acceptable, if not downright criminal: drug possession or trafficking, vagrancy, conjugal violence, prostitution or risky sexual activities. How should this situation be handled? Could consent be designed to secure the potential

74. To recall the content of s. 24 C.c.Q.:

“Consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to an experiment shall be given in writing. It may be withdrawn at any time, even verbally.”

subjects' willingness to participate, while at the same time shielding them from the possibility of being identified? In this case, consent would be anonymous.

At other times, persons wishing to participate in a research initiative are able to sign a consent form, but refuse to do so because they consider a signature too binding. For example, persons agree to participate in a research project dealing with certain intimate aspects of their life. Over the next month, they will be required to complete four questionnaires. They would rather not sign a form so that it will be easier to withdraw if, as they fear, the questions begin making them uncomfortable.

The key consideration here is safeguarding the authenticity of expressed consent. In our opinion, less than formal consent is open for discussion and accommodation. **We believe it possible to relax the formality of expressed consent without diminishing the authenticity of demonstrated willingness.** The written form must remain the customary or “default” form of expressed consent.

11.3 Technological Document

Traditionally, documentary evidence was recorded on paper. Thanks to the development of new information technologies, a variety of media are now available for this purpose. Use of these new technological options is legally recognized in the *Act to Establish a Legal Framework for Information Technology*⁷⁵. The written consent prescribed in section 24 of the *Civil Code of Québec* can be recorded on paper or other information media. Information technologies convey information in a way that is “intelligible in the form of words, sounds or images”⁷⁶.

The legal value of these many kinds of documents is grounded in what section 5 of the *Act*⁷⁷ terms the “integrity” of the document. A document of guaranteed integrity has standard legal value, whether it is on paper or an information medium. Provided the integrity of the document is assured, a person’s consent to an experiment may be recorded on an audio or audiovisual document.

75. R.S.Q. c. C-1.1.

76. *Idem*, s. 3:

“3. Information inscribed on a medium constitutes a document. The information is delimited and structured, according to the medium used, by tangible or logical features and is intelligible in the form of words, sounds or images. The information may be rendered using any type of writing, including a system of symbols that may be transcribed into words, sounds or images or another system of symbols.

“For the purposes of this Act, a data bank whose structuring elements allow the creation of documents by delimiting and structuring the information contained in the data bank is considered to be a document.

“A record may comprise one or more documents.

In this Act, a technology-based document is a document in any medium based on any information technology referred to in paragraph 2 of section 1.”

77. *Ibidem*, s. 5:

“5. The legal value of a document, particularly its capacity to produce legal effects and its admissibility as evidence, is neither increased nor diminished solely because of the medium or technology chosen. A document whose integrity is ensured has the same legal value whether it is a paper document or a document in any other medium, insofar as, in the case of a technology-based document, it otherwise complies with the legal rules applicable to paper documents. A document in a medium or based on technology that does not allow its integrity to be confirmed or denied may, depending on the circumstances, be admissible as testimonial evidence or real evidence and serve as commencement of proof, as provided for in article 2865 of the Civil Code. Where the law requires the use of a document, the requirement may be met by a technology-based document whose integrity is ensured.” “The distinctive name of a natural person may be a pseudonym, but the certificate must indicate if that is the case. Certification service providers are required to communicate the name of the person using the pseudonym to any person legally authorized to obtain that information.”

Section 48 of the *Act*⁷⁸ provides a window for potential subjects who wish to remain anonymous. Their consent could be recorded on an audio document that would then be attached to a certificate using a pseudonym to identify the subject. However, the researcher would have to disclose the subject's name to anyone authorized to have that information. This detail will not escape the notice of persons who wish to avoid – or fear, rightly or wrongly – being investigated by a government agent. Consequently, the use of technological documents does not resolve the concerns we mentioned at the start of this section.

11.4 Documented Consent

The concept of “documented consent” comes into play when the written form of consent is impossible, objectionable or simply not wanted by the subject. Our conception of documented consent obviously excludes statements read and signed by the persons concerned themselves.

Documented consent is supported by, or based on, a variety of documents that can constitute proof or evidence. A partial list of such documents includes a witness's written or verbal statement, an audio or video recording, an electronic process or some other technological means. One encyclopaedic dictionary provides a very current description of what can constitute a document: “There are graphic, iconographic, micrographic, audiovisual and even multimedia and telematic documents⁷⁹.” [translated from the French]. The Advisory Group is particularly interested in the possibility that a witness could “document” the consent of a research subject⁸⁰. This makes anonymous consent possible.

The *Declaration of Helsinki* recognizes the validity of documented consent and favours the use of a witness whose attestation establishes the authenticity of the expressed consent:

“If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed⁸¹.”

The competent REB is the proper body for determining whether documented consent is sufficient and for approving its terms and conditions.

In some cases, the use of documented consent does not conceal the identity of the participant. In others, it does.

Let us look at the situations in which the use of documented consent does not conceal the subject's identity. *Good Clinical Practice: Consolidated Guidelines (Good Practice)*

78. *Ibidem*, footnote, s. 48:

“48. A certificate may be attached directly to another document used in a communication or be made accessible through a directory that is itself accessible to the public.

(. . .)

The distinctive name of a natural person may be a pseudonym, but the certificate must indicate if that is the case. Certification service providers are required to communicate the name of the person using the pseudonym to any person legally authorized to obtain that information.”

79. This definition is translated from the *Grand Usuel Larousse; dictionnaire encyclopédique*, Vol. 2, Larousse-Bordas, Paris, 1997, p. 2328.

80. In s. 24 C.c.Q. as it now stands, consent in a form other than writing would be possible for research projects that do not include care not required by the state of health, alienation of a part of the body or experimentation.

81. *Supra*, footnote 30, s. 22.

is a normative document applicable to clinical trials. It mentions that a potential research subject might be unable to read and therefore incapable of personally executing written consent. Obviously, the reasons why someone cannot read may be physiological or that person could be illiterate. In such cases, *Good Clinical Practice* recommends the presence of an impartial witness throughout the time the content of the consent form is being discussed. Once the subject has orally consented to participate and has signed the form if able to do so, the witness signs and thereby “attests that the information in the consent form and any other written document was accurately explained to, and apparently understood by, the subject or the subject’s legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative⁸².”

The TCPS broaches the matter of the more or less formal nature that expressed consent should have. It states that evidence of consent should ordinarily be in writing. Immediately after stating this general rule, it makes provision for two types of exceptions:

“Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented⁸³.”

Cultural exemption and the impossibility exception are the two types of exception mentioned here. In explaining cultural exception, the TCPS states that “for some groups or individuals, a verbal agreement, perhaps with a handshake, is evidence of trust, and a request for a signature may imply distrust⁸⁴.” The impossibility exception exists because “in some types of research, oral consent may be preferable⁸⁵.” The TCPS requires that written consent be replaced by documented consent in those cases.

We now turn to the cases in which the use of documented consent does conceal the identity of the participant. In these cases, the subject may voice verbal consent that someone else writes down. The subject is identifiable solely by a code or an alias, e.g. a number or pseudonym. It is vital that no information in the reference document allow for identifying the subject. This approach could reassure the potential subjects, especially for certain epidemiological research or for behavioural studies.

By way of example, imagine a social-research project including observation of subjects who use narcotics. Predictably, the persons concerned would all refuse to sign a form and perhaps even to be designated in the project documentation in a way making them identifiable to outside parties. By “outside parties,” we are referring mainly to the police⁸⁶.

Documented consent that conceals the subject’s identity should be ruled out for research projects that entail a health risk. The reality of a health risk must prompt caution so that the subject can immediately be helped should the risk materialize. Section 26 of the

82. International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use, *Good Clinical Practice: Consolidated Guidelines*, Health Canada, 1997, s. 4.8.9.

83. *Supra*, footnote 25, art. 2.1, par. b), p. 2.1.

84. *Idem*, art. 2.1, Comment, p. 2.2.

85. *Ibidem*, footnote 20, art. 2.1, comment, p. 2.2.

86. Possession of narcotics is prohibited under section 4(1) of the *Controlled Drugs and Substances Act* (S.C. 1996, c. 19).

FRSQ *Standards* requires including certain information in the subjects' file when their participation in the research poses a risk:

“If participation in the research project entails a risk, a copy of the research summary and a copy of the consent form are entered in the medical record of the subject, who must have consented to the procedure⁸⁷.” [translated from the French]

This standard is especially relevant in the case of clinical trials. Its practical application requires knowledge of the subject's identity.

The REBs must ensure that the exception does not become the rule, meaning that written consent must remain the customary form in which subjects express their willingness to participate in research.

Many different means of communication are currently used to inform the person involved, whether in a therapeutic or research context. Recognition of these types of communication should be maintained.

Recommendation 11

Section 24 of the *Civil Code of Québec* should be amended to set out the legislator's expectations in terms not of means but of outcomes achieved. In amending section 24, the legislator should bear these five concerns in mind:

- **continue to encourage the free quality of consent;**
- **continue to encourage the informed quality of consent;**
- **retain written consent as the general rule;**
- **allow researchers access to alternatives if they can show the REB that obtaining written consent would be highly problematic, that the suggested alternatives ensure that participants can express consent for themselves and that their consent can be documented;**
- **allow the broadest possible documentary evidence permitted by safe, easy and efficient management of evidence of consent.**

11.5 Donation for Scientific Purposes

Subjects who consent to having their biological material collected and stored are donating to research. The same is true of subjects who consent to access to their personal information. However, subjects retain the right to withdraw the biological material and information which they have entrusted to a bank, unless those items have been anonymized. The person to whom data and biological material are entrusted is not their owner, but the trustee, or custodian. The “donation” of biological material for research or banking purposes is therefore not a donation in the usual meaning of the word, for it does not mean total relinquishment of the things entrusted. Banked personal information and biological material are what the Advisory Group terms a “donation for scientific purposes.”

87. *Supra*, footnote 16, article 26, p. 32.

Recommendation 12

The legislation should include the concept of donation for scientific purposes as characterized below.

- A donation for scientific uses consists of personal information or biological material entrusted to persons for health research purposes.
- Subject retains the right to withdraw their donation.
- It becomes impossible to exercise this right to withdraw when the donations are anonymous or have been anonymized.
- The person to whom data and biological material are entrusted does not own them, but is the trustee.

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

11.6 Length of Consent Form and Civil Liability

Regardless of how complex some areas of research may be, the information disclosed and the language used must ensure that consenting subjects can fully subscribe to the research proposal. For, the subjects cannot exercise personal autonomy unless they understand the nature of the project.

We favour keeping the consent form fairly short. This orientation supposes using a separate document for the detailed description of the bank. That full presentation could include the following details: the nature, objectives and operation of the bank; the steps taken to guarantee confidentiality; and the researchers' obligations. Furthermore, interested subjects must be informed of all the bank management rules. The consent form itself could, however, describe the nature and objectives of the bank.

There is a difference between all the information the REB needs and the information the subjects need to give their consent. The consent form is intended to inform the subjects. The person who draws up the form should produce a short, understandable text which reminds participants that their consent in no way means renunciation of their rights.

Regarding the amount of information to provide, the form writer needs to avoid two erroneous extremes: too much information or too little. The obligation to disclose is greater for research or experimentation than for therapeutic intervention. However, huge quantities of information could obfuscate important matters and detract attention from the important factors needed for decision making.

Researchers and REBs should endeavour to restore balance between consent form information and type of research involved. Accordingly, long descriptions of the project mechanics are to be avoided. In our opinion, a potential research subject could have a difficult time staying focused on explanations more than five pages long. Furthermore, there is no standard that prevents limiting a consent form to one or two pages when the project can be briefly described and involves no particular risk.

Some consent forms contain clauses intended to limit or altogether exclude the liability of researchers, institutions and project promoters. This is totally unacceptable. The FRSQ *Standards* include a section on the limitation and exclusion of liability. It merits being reproduced here in full, especially for the liability provision it suggests:

“Under section 1474 of the Civil Code of Québec, ‘a person may not in any way exclude or limit his liability for bodily or moral injury caused to another.’

“No clause that limits or excludes the liability of a researcher, promoter, institution or any other person is legally valid or ethically acceptable. This type of clause should be prohibited because it is misleading, and it should never appear in a consent form.

“An acceptable statement for a consent form would read as follows: ‘If you were to suffer any harm whatever subsequent to administration of a medication or any other procedure relating to the study, you will receive all necessary medical care without cost to you. In agreeing to participate in this study, you do not waive any of your rights; nor do you release the researchers (or the organizations or companies, as the case may be) or institutions involved from their legal and professional responsibility⁸⁸.’” [translated from the French]

Recommendation 13

The legislation should prescribe that consent forms can include no clause that in any way limits or excludes liability. Moreover, consent forms should include the following paragraph:

“If you were to suffer any harm whatever subsequent to administration of a medication or any other procedure relating to the study, you will receive all necessary medical care without cost to you. In agreeing to participate in this study, you do not waive any of your rights; nor do you release the researchers (or the organizations or companies, as the case may be) or institutions involved from their legal and professional responsibility.”

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

88. *Supra*, footnote 16, art. 17, p. 27.

12. MANDATORY RECOGNITION OF RESEARCH ETHICS BOARDS

In earlier chapters, the Advisory Group recommends amending the legislation so that all research projects involving human subjects are approved by an REB before they begin. We also propose measures that increase the responsibilities assigned to REBs in two highly sensitive areas: review of the consent form preferred by researchers and authorization to access data and biological material. Our proposals assign REBs broader, more complex responsibilities, especially regarding the consent form and access to data and biological material. REBs will have to sharpen their competencies even more to discharge their additional responsibilities, for it is a matter of protecting the dignity and privacy of research subjects. This dual imperative – to protect research subjects and provide assurances of the competency of the REBs – prompts the Advisory Group to propose mandatory recognition of these boards. Our concern here is for research undertaken in the institutions contemplated by the *Act Respecting Health Services and Social Services*, as well as private research⁸⁹.

12.1 A Source of Inspiration: Notice Regarding the Application of Section 21

Section 21 of the *Civil Code of Québec* sets out special provisions pertaining solely to minors and incompetent persons. Experimentation involving such subjects must be carried out within research projects approved and monitored by an REB. The competent REBs are established or appointed by the Minister of Health and Social Services. The competent ethics body for institutions or establishments lacking a designated REB is the Central Research Ethics Committee, which is hosted by the FRSQ⁹⁰. An institution may also arrange with another institution to use the services of its REB. Researchers doing experimentation in private practice deal with the Central Research Ethics Committee.

A notice published in the *Gazette officielle du Québec*⁹¹ names the qualifications needed by an REB seeking ministerial appointment. It has two parts, one dealing with performance standards and the other with accountability.

89. By "private practice," we mean facilities not subject to the *Act Respecting Health Services and Social Services*. Examples include a medical clinic or a commercial enterprise whose sole purpose is to conduct clinical trials.

90. *Conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil* (1998) 35 G.O. I, 1039. Section 11 of this notice respecting practice conditions for REBs appointed or established by the health and social services minister under s. 21 C.c.Q. reads as follows:

"For all researchers whose institution has no research ethics board appointed by the Minister of Health and Social Services pursuant to section 21 of the *Civil Code of Québec*, the Minister maintains the Central Research Ethics Board already hosted by the FRSQ and establishes certain practice conditions for that central body:

- The board members are appointed by the Minister of Health and Social Services.
- The same standards governing the local REBs apply to the Central Research Ethics Board.
- The FRSQ provides the Central Research Ethics Board with support for operating its infrastructure."

91. *Idem*, p. 1039-1040.

The part on performance standards addresses the following:

- the mandate of an REB;
- the composition of an REB;
- the duration of the board members' mandate, and staggered renewal of the membership;
- administrative affiliation;
- the appointment of members;
- the REB appointment procedure;
- the responsibilities of board of directors with respect to ethics boards;
- ethics review: the aspects of research projects that REBs must review or consider;
- monitoring the implementation of research projects;
- dealing with conflicts of interest.

The part of the notice dealing with accountability addresses the following:

- the required content of the annual report to the Minister;
- monitoring visits;
- dismissal of an REB.

12.2 Mandatory Recognition

In discussions among themselves and with stakeholders, the Advisory Group members considered whether REB recognition should be voluntary or mandatory. A voluntary recognition mechanism would have several advantages: 1) predictably, REBs would willingly comply given the resulting boost to their credibility and 2) it is safe to assume that voluntary compliance is more productive than coercion.

On the other hand, mandatory recognition might be better suited to the primary purpose of REBs, which is to protect research subjects. REB approval of a research project has many possible implications for the integrity and privacy of the subjects. This is especially true because those subjects commit to a project in trust, knowing that an REB is keeping watch over them. The binding character of REB decisions is another factor in favour of mandatory recognition of these boards.

The MSSS should introduce a mandatory recognition system for all REBs, public and private alike. This would broaden the scope of the notice published in the *Gazette officielle du Québec*, making it applicable to all REBs. The proposed system would look like this:

- All health research projects carried out wholly or in part within Québec should be approved by an REB recognized by the Minister. This would require amending the *Civil Code of Québec* or passing legislation on health research governance.
- The competent REB in each institution is the one recognized by the institutional board of directors.
- Ministerial recognition could fall into one of two categories. In the first category, comprised of public- and private-sector REBs, the boards would be authorized to approve all research projects involving competent human subjects of full age. The second category, for the REBs of public institutions, covers everything in the first category, as well as experimentation involving minors and incompetent persons.

- The Central Research Ethics Committee would be maintained and continue in its present functions⁹².

Recommendation 14

Legislation on health research governance should establish a mandatory recognition system for REBs based in Québec or making decisions about research initiatives that will be carried out in Québec. Mandatory recognition would cover the following:

- **The competent REB within any institution is the REB recognized by the institutional board of directors.**
- **Ministerial recognition could fall into one of two categories. In the first category, comprised of public- and private-sector REBs, the boards would be authorized to approve all research projects involving competent human subjects of full age. The second category, for the REBs of public institutions, covers everything in the first category, as well as experimentation involving minors and incompetent persons.**
- **The Central Research Ethics Committee would be maintained and continue in its present functions.**

92. The formulation of section 12.2 draws on Giroux, M. T., *Document de réflexion pour une politique ministérielle globale en éthique*, an unpublished document submitted to the Evaluation, Research and Innovation Branch of the Québec department of health and social services, August 2003, p. 31.

13. COMPONENTS OF A BANK GOVERNANCE FRAMEWORK

Our focus is on all data banks and biobanks created or used for health research purposes, whether those banks are public or private, large or small. This includes banks created or used in the field of genetics. The Advisory Group proposes implementing a governance framework for guiding research stakeholders in the matter of data banks and biobanks for health research purposes. That framework shall provide credible, relevant guidelines for a wide variety of individuals and institutions interested in creating and operating data banks and biobanks.

Current legislation and administrative standards prove obsolete when we look at the new reality of data banks and biobanks. Research ethics has been concerned thus far with the conduct of researchers who ordinarily work on specific research projects of limited duration. Given the new health research landscape, people concerned with ethics feel strongly that organizational conduct should be looked at:

“Biobank research inherits the privacy concerns that apply to research in the health context in general, particularly as biobank information is linked with information data banks from the health system. Accordingly, the norms of research ethics, to the extent that those norms have been developed to apply more narrowly to researchers and research projects, do not adequately capture privacy-related issues concerning research and biobanking. It becomes less the ethics of the researcher per se that are at issue than the ethics of the organization or institution or, indeed, the overall research infrastructure itself⁹³.”

The new reality of banks as research infrastructures calls for contemplating a new governance framework. The Advisory Group suggests that this framework be written into law in Québec. Our reasons are as follows:

- Current laws on personal information protection do not provide an adequate or appropriate framework for the emerging reality of data banks and biobanks.
- Considering the large volume of existing administrative standards, health research stakeholders need to organize the directives for creating and managing the banks.
- If the obligations of the banks are solely contractual and grounded in the consent form, that instrument becomes so technical and voluminous that informed consent is merely an abstraction.
- A law has validity and authority that administrative standards lack.
- A law has longevity that administrative standards lack, and the various stakeholders can therefore trust in the stability of the applicable rules.
- The authority of law would encourage adequate protection of research subjects in the sensitive matter of access to personal information.
- Having the same legislation throughout the land would foster the exchange of data and biological material in a context that respects the subjects and sustains their trust.
- The legislation would disencumber consent forms, which are now repositories for all unwritten rules.

93. Yeo, M., *Biobank Research: The Conflict Between Privacy and Access Made Explicit*, study commissioned by the Canadian Biotechnology Advisory Committee, 2004, ch.3.
See at: <http://cbac-cccba.ca/epic/internet/incbac-cccba.nsf/fr/ah00514f.html#3>

13.1 Desirable Qualities of a Governance Framework

The governance framework needs certain qualities in order to accommodate the wide range of individuals and institutions concerned.

- The governance framework should be universal, meaning applicable to all situations in which a bank is created or used for health research purposes.
- It should be cohesive and fairly comprehensive.
- The principles set out in the governance framework must be compatible with what Québec legislative provisions for personal information protection.

13.2 Points to Consider for a Governance Framework

This section looks into the points that should be considered for the governance framework given the sensitivity of personal information and biological material, as well as the need to protect the rights of research subjects.

Here are the twelve points⁹⁴ which the Advisory Group suggests for structuring the governance framework:

- The role of bank trustee

The bank is trustee of the data and biological material stored in it. It does not own that information or material. The relationship between research subject and bank is built on the subject's trust. The bank and its administrators are readily identified and easy to reach. The arrangement between the bank and the organization to which it answers must anticipate the possibility of transferring the bank assets to another organization. On the other hand, the transfer of assets could be prohibited.

- Accountability

The bank guarantees that data and biological material entrusted to it will be handled properly. The accountable individuals within its ranks are clearly identified.

- Continuing staff training

Bank staff receive rigorous continuing training that covers confidentiality, free and informed consent, secure storage methods, relevant technological innovations, legitimate access to data and biological material, governing laws, existing administrative standards, internal bank policies, and so on. That training is intended chiefly to produce and sustain a vibrant ethics culture among bank staff. Continuing staff training is of paramount importance both for conducting quality research and protecting the subjects' rights.

- Mandatory approval by a competent REB

The competent REB works within its designated jurisdiction to approve and monitor the creation of all new banks. An REB's terms of reference embrace both research projects and the creation of banks as research infrastructures. The following initiatives also require the approval of a competent REB:

94. The reader will note that the Advisory Group consulted various documents in preparing these themes. Two of those documents are: Canadian Institutes of Health Research, *CIHR Best Practices for Protecting Privacy in Health Research*, September 2005, and Canadian Standards Association, *Model Code for the Protection of Personal Information*, CAN/CSA-Q830-96.

- access to personal information or biological material with the intention of creating a bank;
- access to banked data or biological material.

- Determining the research objectives

The persons tasked with collecting personal information or biological material are able to identify the necessary degree of access once they have determined the objectives of their research initiative. This may involve conducting a research project, examining a theme or building a research infrastructure.

The objectives may be specific, as well as general. The project officers must justify the desired access based on the expressed objectives. It then becomes a matter of authorizing access as needed to pursue those objectives. The same approach is used to specify the use, communication and storage of data and biological material.

Where long-term initiatives are concerned, the officers must periodically apply to the competent REB for renewal of their certificate of ethical approval.

- Determining the need for free and informed consent

Free and informed consent is a basic instrument for the protection of research subjects. It should be considered of paramount importance where data banks and biobanks are concerned.

However, the legislation does not always require the consent of the persons from whom information is collected. Not only may information be collected without consent; it may even be collected without the knowledge of the persons concerned.

- Obtaining free and informed consent, as needed

Consent must be obtained in a way that respects the freedom and enlightened decision of the potential subject. The practical conditions for expressing consent determine whether the potential subject espouses the proposed objective.

Consent is a continuing process and includes the right to withdraw. However, the potential subject must be informed that it is impossible in practice to withdraw data or biological material that are anonymous or have been anonymized.

Consent must be renewed in the event of significant changes in the research initiative, banking agreement or bank governance framework.

- Storage of data and biological material, and confidentiality protection

The storage of data and biological material requires appropriate human skills and technology.

Organizational, technological and physical security measures are used to safeguard the confidentiality of data and biological material. The bank establishes clear policies to manage collection, storage and access.

- Access to personal information

All individuals have the right to access the information concerning them. They can challenge the accuracy of those data and make any changes they deem appropriate. At their request, the bank is bound to inform them of the use being made of their data, e.g. the fact that their information has been communicated to other persons.

- Transparent management of data and biological material

The general public, and research subjects in particular, must have easy access to information concerning the principles, policies and practices of the bank.

- Grievances

The bank appoints a person to enforce the laws, as well as bank principles and policies. Grievance management is straightforward and readily available. Anyone connected with the bank is entitled to lodge a grievance alleging non-compliance with those laws, principles or policies.

- Sharing and confidentiality protection

Banks that entrust data or biological material to organizations outside Québec must ensure that those organizations can match the confidentiality protection provided in Québec. The bank shall also see that data and biological material are used in keeping with the conditions indicated in the consent form.

Establishing a governance framework should disencumber the consent form, for the rules would apply across the board instead of case by case as now.

Recommendation 15

Legislation providing data bank and biobank governance should include a normative framework that addresses these twelve points:

- **The role of bank trustee**
- **Accountability**
- **Continuing staff training**
- **Mandatory approval by a competent REB**
- **Determining the research objectives**
- **Determining the need for free and informed consent**
- **Obtaining free and informed consent, as needed**
- **Storage of data and biological material, and confidentiality protection**
- **Access to personal information**
- **Transparent management of data and biological material**
- **Grievances**
- **Sharing and confidentiality protection**

Paralleling the work of the legislator, the FRSQ should also amend its *Standards* accordingly.

14. FINAL COMMENT

Most of the recommendations made in this final report cannot be applied immediately or in isolation. Adopting this entire set of recommendations will provide for establishing an acceptable, balanced normative framework.

APPENDIX 1

Membership of the Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research

Dr. Marie-France Raynault, M.D., M.Sc., director of the Department of Social and Preventive Medicine, Université de Montréal; Advisory Group Co-chair.

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Ms. Michèle S. Jean, M.A, M. Ed., Vice-chair of the FRSQ Board of Directors; Chair of UNESCO's International Bioethics Committee (2002-2005)

Ms. Anne-Marie Mes-Masson, Ph.D., Director of the FRSQ Cancer Research Network; researcher at the Centre de recherche du CHUM; full professor, Faculty of Medicine, Université de Montréal.

Mr. Jack Siemiatycki, Ph.D., full professor, Faculty of Social and Preventive Medicine, Université de Montréal.

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APPENDIX 2

Four CIHR Research Themes

Basic/Biomedical Research⁹⁵

Research with the goal of understanding normal and abnormal human functioning at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Studies involving human subjects that do not have a diagnostic or therapeutic orientation.

Clinical Research

Research with the goal of improving the diagnosis and treatment (including rehabilitation and palliation) of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Research on, or for the treatment of, patients.

Health Services Research

Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being.

Social, Cultural, Environmental and Population Health Research

Research with the goal of improving the health of the Canadian population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status⁹⁶.

95. The Advisory Group adds the word “basic” to the expression “medical research” since this is a term frequently used by Québec researchers.

96. *CIHR Grants and Awards Guide (2005-2006)*, Section 1-A3, *Definition of the Four CIHR Themes*, See at: <http://www.cihr-irsc.gc.ca/e/22630.html#1-A3>

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