

SECONDARY RESEARCH USE OF BIOLOGICAL SAMPLES AND DATA IN QUEBEC

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Biological materials are routinely collected during medical care, and information collected with these materials may also be retained. The value of biological samples and related data in research raises a number of questions about how to define conditions for access to materials or information that will protect the dignity and privacy of patients. The authors provide a critical analysis of the current legal and institutional framework in Quebec with respect to the secondary use of biological samples in research, and access to data gathered in the course of medical care.

Les matières biologiques sont cueillies de façon routinière dans des établissements médicaux, et l'information amassée avec ces matières peut aussi être conservée. La valeur des échantillons biologiques et données connexes pour la recherche soulève un certain nombre de questions au sujet de la définition des conditions d'accès à ces matières ou à cette information tout en protégeant la dignité et la confidentialité des patients et patientes. Les auteures présentent une analyse critique du cadre juridique et institutionnel québécois qui régit l'utilisation secondaire des échantillons biologiques en recherche et l'accès aux données recueillies durant les soins médicaux.

1. Secondary Use for Research of Samples Removed during Medical Care

In 1994, the *Civil Code of Quebec* was amended to include a provision aiming to protect the dignity, autonomy and privacy of patients with regard to the secondary research use of biological material collected during medical care.¹ It is interesting to note that in the first draft version of article 22, a requirement of consent to the secondary use for research of samples collected during the patient's care was presumed, and the individual could choose to opt out of the research. However, the underlying philosophy of the amended *Civil Code* being one of individual autonomy and dignity, article 22 was modified to emphasise this

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¹ S.Q. 1991, c.64 (C.c.Q.).

consideration. Article 22 states: “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.” Though this seems explicit, the scope of this article and the nature of the consent it mandates continue to be debated.

A. *The Explicit Consent Requirement*

Article 22 explicitly requires individual consent to be obtained for the secondary use of samples for research when these samples were collected in the course of medical care. It does not distinguish anonymised from identifiable biological material, nor does it define “research.” It seems that the notion of “research” encompasses not only experimentation requiring physical intervention on the subject, but also any other kind of studies, including social studies.²

Consent must be free and informed, though the nature of the information provided to the patient may vary according to the research contemplated. The Fonds de la Recherche en Santé du Québec (FRSQ), a not-for-profit research funding agency under the auspices of the Ministère du Développement Économique et Régional et de la Recherche (MDERR), has published the *Guide d'éthique de la recherche et d'intégrité scientifique*, which applies to all public research that receives financial support from the FRSQ.³ The Guide suggests that the information offered to patients should include the nature and purpose of the research, the period during which such consent remains valid, and the confidentiality protection mechanisms contemplated.⁴ Though private research activities remain unregulated, with the exception of research involving minors and incompetent adults mentioned in article 21 of the *Civil Code*, most private research groups submit their proposals to ethical review and follow the rules enunciated in the FRSQ Guide.

² See E. Lévesque, B. Knoppers and D. Avard, “La génétique et le cadre juridique applicable au secteur de la santé: examens génétiques, recherche en génétique et soins innovateurs” (2004) 64 R. du B. 59 at 77. See also R. Kouri and S. Philips-Nootens, “L’“expérimentation” et les “soins innovateurs”: l’article 21 C.c.Q. et les affres de l’imprécision” (1996-1997) 27 R.D.U.S. 89 at 105.

³ Fonds de la Recherche en Santé du Québec, *Guide d'éthique de la recherche et d'intégrité scientifique*, 2nd ed. (Québec: Gouvernement du Québec, 2003), online: Fonds de la Recherche en Santé du Québec <http://www.frsq.gouv.qc.ca/fr/ethique/pdfs_ethique/GUIDE2003.pdf> [FRSQ Guide].

⁴ *Ibid.* at 101. See also R. Kouri and S. Philips-Nootens, “L’utilisation des parties du corps humain pour fins de recherche: l’article 22 du Code civil du Québec” (1994-1995) 25 R.D.U.S. 359 at 368-70.

B. Scope and Nature of the Consent Required

The debate surrounding article 22 has centered on its application to biological material collected prior to the entry into force of the article, on consent requirements concerning deceased individuals, and on the requirement that consent be in written form.

(a) Application to Biological Material Collected Before 1994

Though it was introduced in 1994, the question of the application of article 22 to tissues collected prior to its entry into force is still the subject of discussion.⁵ In principle, in accordance with the traditional rules of statutory interpretation⁶ and as provided for under section 2 of *An Act Respecting the Implementation of the Reform of the Civil Code*, “[t]he new legislation has no retroactive effect; it applies only to the future. It does not, therefore, change the conditions for creation of a previously created legal situation, nor the conditions for extinction of a previously extinguished legal situation, and it does not alter the effects already produced by a legal situation.”⁷ Some discussion has focused on the scope of the notion of “a previously extinguished legal situation.” It has been argued that in the case of non-anonymised biological material, that is, material that is identified or coded, the legal situation is not extinguished, and so an obligation to protect the confidentiality and the express wishes of the patient regarding the sample and the information it holds remains. According to this interpretation, the situation of non-anonymised biological samples should be governed by section 3 of the *Implementation Act* which establishes when the new provisions of the *Civil Code* apply.⁸ Under the terms of this section “[t]he new legislation is applicable to legal situations which exist when it comes into force. Any hitherto unfulfilled conditions for the creation or extinction of situations in the course of being created or extinguished are therefore governed by the new legislation; it

⁵ The origin of this article is unclear, as are the Minister’s comments given that no source is cited. Robert Kouri and Suzanne Philips-Nootens suggest that the Quebec legislators might have been inspired by the American case of *Moore v. Regents of the University of California*, 271 Cal. Rptr. 146 (Sup. Ct. 1990). On article 22, see Kouri and Philips-Nootens, *supra* note 4 at 361-365.

⁶ See generally P.-A. Côté, *Interprétation des Lois*, 3ème ed. (Montréal: Les éditions Thémis, 1999).

⁷ R.S.Q. c. 57, s. 2 [*Implementation Act*].

⁸ See generally Kouri and Philips-Nootens, *supra* note 4 at 392-95; M. Letendre, *Research with Stored Tissue Samples of Deceased Persons: A North-American Perspective* (M.A. Thesis, McGill University Law Faculty & Biomedical Ethics Unit, 2004) at 38-39 [unpublished].

also governs the future effects of existing legal situations.”⁹

Though it does not have legislative force, the FRSQ Guide indirectly supports this interpretation by not distinguishing between biological material collected before and after 1994.¹⁰ Nor does the Guide advocate a distinction between anonymised and identifiable or coded samples, holding that “[a]s far as we are concerned, the protection of the dignity, well-being and rights of the subjects must prevail over the advancement of knowledge.”¹¹ This latter statement is surprising in that other statements of ethical principles such as the *Helsinki Declaration* and legal enactments such as privacy legislation only apply to identifiable individuals and thereby permit broader access to anonymised samples and data.¹²

(b) Consent Requirements for Deceased Individuals

Absent any specific indication of a personal decision with respect to consent, where the patient has died before secondary uses were foreseen, one could conclude that any personal interests or control over these samples have ceased to exist upon death. Biological material from deceased individuals could thus be used for research without further qualification unless the deceased specifically expressed opposition at an earlier time. The question remains as to whether this position is contradictory to the underlying philosophy of the *Civil Code* in general and of article 22 in particular.

The first point to note is that articles 42 to 49 of the *Civil Code* mandate respect of the body after death. Except in limited circumstances, the deceased’s presumed or known wishes regarding his funeral, the disposal of his body,¹³ the authorisation for organ or tissue removal or the gift of his body to science,¹⁴ or authorisation for the performance of an autopsy¹⁵ must be deferred to. In the absence of such known or presumed intention, consent for such acts must be obtained from a person specified in article 15 of the *Civil Code* who could have authorised care during the life of the deceased.¹⁶ Under the terms of this article, should a person

⁹ *Implementation Act*, *supra* note 7, s. 3

¹⁰ *Supra* note 3 at 101.

¹¹ *Ibid.* [translated by author].

¹² *World Medical Association Declaration of Helsinki*, World Medical Association General Assembly, June 1964 (adopted in 1964 and amended in 1975, 1983, 1989, 1996, 2000, 2002), online: World Medical Association <<http://www.wma.net/e/policy/b3.htm>>.

¹³ Art. 42 C.c.Q.

¹⁴ Art. 43 C.c.Q.

¹⁵ Art. 46 C.c.Q.

¹⁶ See e.g. Arts. 42, 44, and 46 C.c.Q.

become incompetent and not be legally represented, consent to medical care is to be obtained from a spouse, a close relative, or a person who has shown interest in the individual.¹⁷ Read together, these provisions confer on the deceased or a representative of the deceased a personal right in the body and its parts after death that amounts to a limited right to dignity, autonomy and privacy.

Secondly, article 22 was implemented to prevent the use without consent of samples originally removed in the course of medical care, so as to provide the individual with control over the use of bodily tissues. It was designed to avoid situations where samples would be used for research to which the individual, if properly informed, would have objected and so should arguably extend beyond the life of the individual on the basis that the samples were collected for purposes other than research. This leaves the question of whether there may be circumstances where, in the absence of any known or presumed wishes of the deceased, someone else may consent to the use of the samples.

In accordance with the philosophy of the *Civil Code*, an analogy could be drawn from article 44, the specific provision of the *Code* regarding the removal of body parts or the gift of the body for therapeutic or scientific purposes after death. This article could be interpreted as mandating that consent may be obtained for the secondary use of samples removed during care from the spouse of the deceased, a close relative, or a person who has shown a particular interest in the individual while alive.¹⁸ The opinion statement on genetic databases of Quebec's Commission de l'Éthique et de la Science et de la Technologie (CEST) seems to lend support to this interpretation. The Commission recommends that "the spouse or closest relative of the deceased person who provided a biological sample complete another consent form in cases where the nature of the research was not yet determined when consent was given or the information obtained was not held in total anonymity."¹⁹ Though this recommendation applies to samples collected in the first instance for a specific research purpose that are to be further used for scientific purposes not contemplated at the time of the collection, it could *a fortiori* hold for samples collected during care that are to be secondarily used for research. Furthermore, it should be

¹⁷ According to article 15, consent may be given by a "married, civil union, or *de facto* spouse."

¹⁸ See e.g. Letendre, *supra* note 8 at 39.

¹⁹ Commission de l'Éthique de la Science et de la Technologie, *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation: Position Statement- Summary and Recommendations* (Sainte-Foy: Gouvernement du Québec, 2003), online: Commission de l'Éthique de la Science et de la Technologie <<http://www.ethique.gouv.qc.ca/eng/ftp/Avis10-02-03.pdf>>.

noted that if the samples are held in total anonymity, consent would not seem to be required. This position may be contrasted with the FRSQ Guide, which, as we have seen earlier, does not distinguish between anonymised and non-anonymised samples.²⁰

Some scholars challenge the application of article 44, even by analogy, to the interpretation of article 22, as its scope is specifically limited to the removal of body parts and gift of the body after death. However they come ultimately to a similar conclusion. According to these authors, the secondary use of samples from a deceased individual is considered an extension of the original act of care performed before death and from which the biological material was obtained.²¹ According to this view, a proper application of article 22 would require that, in the absence of the known wishes of the deceased, consent to secondary use of biological samples for research should be sought from one of the persons listed in article 15.

Both these positions could, however, be criticised as running afoul of the civil law tenet that absent an explicit provision of the law, extra-patrimonial rights terminate with the death of the person and so cannot be exercised by another.²²

(c) Writing as a Condition for a Valid Consent

Even if everyone agrees that the validity of the consent contemplated under the terms of article 22 depends upon its free and informed nature, the form that consent should take is also called into question. At first glance, it would seem that only written consent would be valid under Quebec's civil law. Indeed, article 24 of the *Civil Code* states: "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."²³ On the face of it, research seems to fall within the ambit of this article. However, it has been argued that the primary purpose of article 24 was to impose additional formalities in situations where the individual is a voluntary participant or donor and the act to be performed is non-therapeutic. In such situations, the written form urges voluntary research participants to carefully consider the non-beneficial nature of the medical act. It is argued that such precautions are not necessary in the situations encompassed by article 22 and that imposing a written consent form is

²⁰ *Supra* note 3.

²¹ Kouri and Philips-Nootens, *supra* note 4 at 368.

²² E. Deleury and D. Goubau, *Le droit des personnes physiques*, 3d ed., (Cowansville: Éditions Yvon Blais, 2002) at 75.

²³ Art. 24 C.c.Q.

unduly cumbersome for researchers.²⁴ Though the debate on the requirement of a written form as a condition to the validity of consent under article 22 is not over, Research Ethics Boards (REBs) and researchers have since 1994 requested consent in writing, perhaps due in part to legal uncertainty. This seems to have resulted in a decrease in the participation rate in research, especially of individuals who want to remain anonymous, such as prisoners, individuals affected by sexually transmitted diseases or those suffering from addictions.

This is borne out by a 2002 publication of the Canadian Institutes of Health Research (CIHR) that included a compendium of case studies that analysed and reported on research involving the secondary use of health information in Canada.²⁵ One such study undertaken in Quebec was on HIV seroprevalence among women undergoing abortion in Montreal that aimed to monitor the incidence of HIV infection in the general population.²⁶ Undertaken by the Université de Montréal and several teaching hospitals from 1993 to 2000, it collected information and leftover blood from samples taken from women before the performance of therapeutic abortions. The women were asked to give verbal consent to the secondary use of their blood (which was tested for HIV infection) and to provide information on questionnaires. Once the samples were tested and the results were associated with the questionnaires, all identifying information was removed. In 1994, after the introduction of article 22 and its interpretation in light of article 24, the REB required that written consent be obtained from all women. The participation rate dropped dramatically, women apparently fearing the association of their name with HIV research. As noted by the CIHR working group, “Ironically, a legal rule that was designed to better protect research subjects (i.e. the requirement for written consent), in this case afforded research subjects with less protection (anonymity) and actually put them at greater risk of being personally identified. In the specific circumstances of this case, verbal consent might have been more desirable for all concerned, but after 1994 this was not permitted under Quebec law.”²⁷

The strict provisions in force in Quebec with regard to the secondary use for research of biological material collected as part of medical care stand in contrast to the current international, regional and national

²⁴ Kouri and Philips-Nootens, *supra* note 4 at 372.

²⁵ Canadian Institutes of Health Research, *Secondary Use of Personal Information in Health Research: Case Studies* (Ottawa: Public works and Government Services Canada, 2002), online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/pdf_15568.htm>.

²⁶ *Ibid.* at 61-63.

²⁷ *Ibid.* at 62-63.

propensity towards the simplification, if not waiver, of consent requirements provided that other additional safeguards are present. Aiming to protect the fundamental personal rights to dignity, autonomy and privacy, article 22 of the *Civil Code* serves laudable purposes. We suggest, however, that a more nuanced interpretation should be given to article 22 depending on the type of research, the degree of identifiability of samples and the correlative risks to autonomy and privacy. Above all, consideration should be given to a patient's wishes with respect to these fundamental principles where expressed or known. To this end, where possible, researchers should secure the consent of the patient to future uses at the time of the original collection.

2. Access to Data for Research Purposes

Quebec has implemented comprehensive legislation to protect the right to privacy. With regard to data derived from medical samples, questions remain about the degree of identifiability required for information to be considered personal, about whether tissues are information whose use requires consent at all, and about the type of ethical review required.

A. Principle: The Need for Explicit Consent

The right to privacy is protected under both the *Quebec Charter of Human Rights and Freedoms*²⁸ and the *Civil Code*.²⁹ They mandate that personal information be confidential and protected from unwarranted access by third parties, notably when collected by a health professional bound by professional secrecy. Consequently, third party access to personal information held in a file by a private entity such as a private medical practice,³⁰ to personal data contained in documents maintained by public bodies³¹ or to medical records,³² is subject to the consent of the living individual from whom the data originates with certain limited legal exceptions.

B. Personal Information and Nominative Data Defined

The application of the abovementioned legislation is incumbent upon the information being "nominative", that is, personal. Transfer to a third party without consent would breach confidentiality and violate an individual's

²⁸ *Quebec Charter of Human Rights and Freedoms*, R.S.C. c. C-12, s.5. See also ss. 4, 9.

²⁹ Arts. 3, 35, C.c.Q.

³⁰ See art. 37 C.c.Q. See also the *Private Sector Act*, *infra* note 33, s. 18.

³¹ *Personal Information and Public Bodies Act*, *infra* note 34, ss. 53, 59.

³² *Health and Social Services Act*, *infra* note 38, ss.19, 19.1.

right to privacy. In the *Private Sector Act*³³ and the *Personal Information and Public Bodies Act*³⁴, both nominative data and personal information are defined as information about a physical person allowing for his or her identification. For purposes of consistency, *Bill 86*, introduced in the National Assembly on December 16, 2004, proposes to substitute the term “personal information” for “nominative data” in the latter statute.³⁵

The Commission d'accès à l'information du Québec (CAI), an administrative tribunal, reviews decisions made by private companies or public bodies pursuant to the *Private Sector Act* and the *Personal Information and Public Bodies Act* as concerns access to data. In this context, it has had occasion to further interpret the concept of personal information or nominative data in its decisions. The CAI maintains that these two concepts are interchangeable and answer to a common sense definition: personal information is any data that enables the identification of an individual. In a 1998 decision, it held that:

With the assistance of these dictionary definitions, we can state that nominative data, within the context of section 54, must not only enable an individual to acquire some knowledge of and refer to a natural person but also this information must likely (enable) distinguishing that person from another.³⁶

The CAI further added: “In short, according to the law, only data that defines an individual’s characteristics - characteristics he/she is uniquely defined by - is personal. This is objective information whose existence is grounded in an individual in the flesh.”³⁷

Therefore data that is anonymous, anonymised, or double-coded when sent to a researcher who has no key to link back would fall outside the

³³ *An Act Respecting the Protection of Personal Information in the Private Sector*, R.S.Q., c. P-39.1, s. 2 [*Private Sector Act*].

³⁴ *An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, R.S.Q. c. A-2.1, s.54 [*Personal Information and Public Bodies Act*].

³⁵ *Bill 86, An Act to Amend the Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information and other Legislative Provisions*, 1st Sess., 37th Leg., Quebec, 2004, online: National Assembly of Quebec <<http://www.assnat.qc.ca/eng/37legislature1/Projets-loi/Publics/04-a086.htm>>.

³⁶ *Myriam Segal c. Centre de Services Sociaux de Québec*, [1988] C.A.I. 315 [translated by author].

³⁷ *Claude Stébenne c. Assurance-vie Desjardins*, [1995] C.A.I. 14, leave to appeal received (C.Q.M. 500-05-000595-954), 1995-03-13 [1995] C.A.I. 416 ; appeal allowed; file returned to the Commission (C.Q.M. 500-05-036851-978), 1998-01-30 [1998] C.A.I. 562 ; appeal refused (C.A.M. 500-09-006257-984) 2001-11-08 (94 03 66) [translated by author].

scope of the two abovementioned statutes. Furthermore, if the data to be accessed by researchers, though not coded, is so unconnected to the individual that it could not lead to identification, it would similarly not be covered by Quebec's legislation. Thus, in these two situations access to the data would not require the consent of the individual. Nevertheless, information that is part of the individual's medical record and held by an institution encompassed by section 19 of the *Health and Social Services Act* requires consent to access the record.³⁸ Indeed, sections 17 to 27 of the *Health and Social Services Act* apply notwithstanding the provisions of the *Personal Information and Public Bodies Act*.³⁹

Finally, it is interesting to note that the CEST in its position statement on genetic databases argued that the CAI should be competent to oversee all research involving the use of genetic data, including anonymised and coded data, and to authorize access to such data; their concern was that discrimination could be a by-product of such research.⁴⁰

C. *Are Tissues Personal Information?*

If the information resulting from the analysis of tissue or other biological material is part of a medical record and is therefore confidential personal information, what of the tissue or biological material itself? Though the information it holds is not readily readable, it potentially contains genetic material (DNA) that if analysed could lead to the identification of the individual. Some authors seem reluctant to consider tissues themselves as elements of medical records.⁴¹

In a 1999 decision, the Superior Court of Quebec held that the difference between the results of a sample analysis and the sample itself was difficult to ascertain: "[I]t is somewhat difficult to outline a fundamental difference between the results of a sample analysis and the sample itself."⁴² While the court refused to take a position in the debate

³⁸ *An Act Respecting Health Services and Social Services*, R.S.Q. c. S-4.2, s.19 [*Health and Social Services Act*].

³⁹ *Ibid.*, s. 28. Exceptions are discussed below; see text accompanying footnotes 48-54.

⁴⁰ Commission de l'Éthique de la Science et de la Technologie, *Les enjeux éthiques des banques d'information génétique: pour un encadrement démocratique et responsable* (Sainte-Foy: Gouvernement du Québec, 2003), online: Commission de l'Éthique de la Science et de la Technologie <<http://www.ethique.gouv.qc.ca/fr/ftp/AvisBanquesGen.pdf>> at 39 [*Les enjeux éthiques*].

⁴¹ M. Hirtle, "Civil Law and the Status of Human Genetic Material" c. 6 in B. Knoppers, T. Caulfield and T. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Edmond Montgomery Publications Limited, 1996) at 95.

⁴² *Léveillé c. St.-Pierre, succession*, [1999] J.Q. no 4999, (C.S.) at para. 31 [translated by author].

concerning the inclusion of samples as part of medical records, it concluded that the principles applicable to medical records should, at least by analogy, be applicable to samples as well. In this case, the plaintiff was seeking access to samples for paternity testing in a situation where the heir of the deceased person had refused consent. Referring to sections 19 to 23 of the *Health and Social Services Act* and to article 22 of the *Civil Code*, the Superior Court refused access to the DNA sample collected during care on the grounds that there was no convincing justification for such access.

It is also interesting that in the 1989 decision of *Bouchard c. Ministère de la Sécurité Publique du Québec*, the CAI held that microscopic tissue slides were nominative confidential information within the scope of the *Personal Information and Public Bodies Act*.⁴³ However, this case was decided prior to the inclusion of article 22 in the *Civil Code*, and did not concern an authorization to obtain data for research purposes without the consent of the individual of the kind discussed earlier. It would therefore be hazardous to draw any analogies when interpreting a specific section of the *Civil Code* that seemingly does not allow for any exceptions.

Furthermore, recent recommendations for the inclusion of genetic material in the definition of nominative data or personal information by the Conseil de la santé et du bien-être (CSBE),⁴⁴ the CAI⁴⁵ and the CEST⁴⁶ should *a fortiori* be interpreted as implying that to date, under current Quebec law, such material and anonymised data are *not* considered personal information. The CSBE and the CEST both suggest that the mandate of the CAI should be extended to cover data derived from biological or genetic material. The CEST states: “The definition of these data [personal data] covers neither biological material from which personal

⁴³ [1989] C.A.I. 416.

⁴⁴ Conseil de la santé et du bien-être, *La santé et le bien-être à l'ère de l'information génétique: enjeux individuels et sociaux à gérer* by A. Marcoux (Québec: Gouvernement du Québec, 2000), online: Conseil de la santé et du bien-être <<http://www.csbe.gouv.qc.ca/site/download.php?id=546871,137,1>> [CSBE 2000] ; Conseil de la santé et du bien-être, *L'Information génétique et l'accès à l'information des chercheurs: Il est urgent de protéger la population* (Québec: Gouvernement du Québec, 2003), online: Conseil de la santé et du bien-être <<http://www.csbe.gouv.qc.ca/site/download.php?id=397705,123,1>> [CSBE 2003].

⁴⁵ Commission d'accès à l'information du Québec, *Une réforme de l'accès à l'information: le choix de la transparence – Rapport sur la mise en œuvre de la loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels et de la loi sur la protection des renseignements personnels dans le secteur privé* (Québec: Gouvernement du Québec, 2002) online: Commission d'accès à l'information du Québec <http://www.cai.gouv.qc.ca/06_documentation/01_pdf/quin.pdf>.

⁴⁶ *Supra* note 19.

information can be derived nor denormalised data (or anonymised data in the context of genetic databases)...In the Commission's opinion, the mandate of the CAI could be extended and its budget adjusted accordingly."⁴⁷ Similarly, the CSBE recommends that the government amend the *Personal Information and Public Bodies Act*⁴⁸ and the *Private Sector Act*⁴⁹ in order to ensure that they apply to genetic material.⁵⁰ Subscribing to the CSBE recommendations, the CAI expressed its willingness to assume the extended role that the modifications to existing legislative provisions would entail.⁵¹

D. Access to Data Without Consent

Exceptions to consent requirements are envisioned by the *Personal Information and Public Bodies Act*, the *Private Sector Act* and the *Health and Social Services Act*. Indeed, the CAI is empowered to waive consent requirements and enable the communication of protected personal information to a third party. The conditions for such communication are the same under both the *Personal Information and Public Bodies Act*⁵² and the *Private Sector Act*⁵³:

- a) the CAI receives a written request,
- b) the data is intended to be used for study, research or statistical purposes, and
- c) the CAI is of the opinion that:
 - the use intended is not trivial
 - the objectives of the study, research or statistical analysis could not be achieved using data that is not nominative
 - confidentiality mechanisms are adequate to protect the individual's privacy and confidentiality.

Furthermore, such authorisation is of limited length, is conditional and can be revoked should the confidentiality of the data communicated, or the

⁴⁷ Commission de l'Éthique de la Science et de la Technologie, *Les enjeux éthiques*, *supra* note 40.

⁴⁸ *Supra* note 34.

⁴⁹ *Supra* note 33.

⁵⁰ CSBE 2000, *supra* note 44 at 7.4 [translated by author]; CSBE 2003, *supra* note 44 at 23 [translated by author].

⁵¹ *Supra* note 45 at 128-29. For a discussion on the inclusion of samples in the definition of personal data, see E. Lévesque, B.M. Knoppers, and D. Avaré, "La protection de l'information génétique dans le domaine médical au Québec: principe général de confidentialité et questions soulevées par les dispositions d'exception" at 109-111.

⁵² Ss. 59(5), 125.

⁵³ Ss. 18(8), 21.

conditions of the authorisation be breached.

However, for data contained in medical records held in health establishments, researchers need not obtain the prior authorisation of the CAI. Section 19.2 of the *Health and Social Services Act* enables the Director of Professional Services (DPS), or the Director General of the establishment (in the absence of a DPS) to grant “professionals” access to medical records kept by the establishment for teaching or research purposes, without the consent of the patient. Professionals are understood as health or social services professionals in accordance with the purpose of the *Health and Social Services Act*, and thus include researchers undertaking health research.⁵⁴ This authorisation is subject to the conditions set forth above under section 125 of the *Personal Information and Public Bodies Act*, and can be denied should the DPS be of the opinion that the project contemplated does not meet standards of ethical propriety or scientific integrity. This authorisation is conditional, limited in time, and can be revoked in the event of a breach of confidentiality, a breach of the conditions set forth by the DPS, or a violation of ethical or scientific norms. Finally, as previously mentioned, this section applies notwithstanding the provisions of the *Personal Information and Public Bodies Act*.⁵⁵

This exception to the confidentiality of medical records empowers the DSP in a health facility to authorise access without the intervention of the CAI. The CSBE has recommended to the government that section 19.2 of the *Health and Social Services Act* be repealed and that the CAI be responsible for all requests from researchers to access protected personal information.⁵⁶ Such an amendment would ensure that all requests would be centrally processed by the CAI and uniform standards applied. In light of its existing role and expertise with regard to data protection, the CAI endorses this recommendation.⁵⁷ Additional resources and qualified personnel would, of course, be required. The CAI and the CSBE further propose that researchers, prior to their application to the CAI for release of data without the consent of an individual, receive ethical and scientific approval for their research by an REB charged with monitoring compliance with the ethical guidelines applicable to biomedical research.⁵⁸ The REB would thus perform a review of all aspects of the projects, scientific and ethical, and consider the use of data in the form and manner

⁵⁴ X. c. *Centre Hospitalier Universitaire de Québec*, [2001] C.A.I. 86.

⁵⁵ *Health and Social Services Act*, *supra* note 38, s. 28.

⁵⁶ CSBE 2000, *supra* note 44 at 74-75; CSBE 2003, *supra* note 44 at 28-29.

⁵⁷ *Supra* note 45 at 129.

⁵⁸ Canadian universities and other research institutions are required to put REBs in place to review proposals for biomedical and behavioural research projects involving

explained in relation to the project in its entirety.

Whether the recommendations are adopted or not, the shortcomings of the current procedures for data access without consent and ethical approval are manifold. The choice of authorizing body that examines access requests from researchers depends on whether the information is held in a health establishment or in a private clinic or office. In the case of the former, the decision would be made by the DPS, in the case of the latter, the CAI. Centralizing these requests would enable the CAI not only to standardize its norms but also to build on its expertise and experience in the field of data protection. Currently, REBs may intervene after the fact, once the authorization of the CAI with regard to data access has been granted. Thus, the CAI examines only one aspect of the project without having all the information a REB has at its disposal, and the REB when reviewing the protocol is influenced by the authorization provided by the CAI, which they do not question. Requiring that ethics review be undertaken before a written request is sent to the CAI would ensure that only ethically and scientifically sound projects are presented to the CAI, thereby promoting the quality of REB review.

E. Ethical Review of Research Projects

According to article 21 of the *Civil Code*, only research protocols that involve “experimentation” on minors or adults lacking the capacity to consent must be reviewed and approved by an Ethics Committee designated or instituted by the Health and Social Services Minister. No other legal requirement for ethical review can be found in Quebec law. However, according to an action plan issued by this department in 1998, all health research involving human subjects, human embryos, or medical genetics performed in a health establishment or an organization conducting research and encompassed by the *Health and Social Services Act* must undergo an ethical and scientific review.⁵⁹ Similarly, the FRSQ Guide requires that all research projects involving human subjects must be approved by an Ethics Committee. Research involving human subjects is described as (a) research involving the participation of human subjects; (b) research involving the use of cadavers, human remains, tissues, organic

human subjects, in order to have access to research grants from a range of public granting agencies, such as the Canadian Institutes for Health Research, the Natural Science and Engineering Research Council and the Social Sciences and Humanities Research Council. The REBs use national and international guidelines as the basis for their review.

⁵⁹ Ministère de la Santé et des Services Sociaux, *Plan d'Action Ministériel en Éthique de la Recherche et en Intégrité Scientifique* (Québec: Gouvernement du Québec, 1998), online: Ministère de la Santé et des Services sociaux <<http://ethique.msss.gouv.qc.ca/site/download.php?id=1081608,5,1>> at 11.

liquids, gametes, embryos and foetuses; and (c) research using personal information held in records.⁶⁰

Finally, it should be noted that REBs often lack the necessary training or financial means to conduct the reviews they are responsible for. Efforts should be made to ensure that such issues are addressed. We maintain that research performed in both the public and private sectors should be approved and supervised by an ethics committee, and that the standards applied by such committees be consistent and uniform.⁶¹

Conclusion

In light of the shortcomings of the current legal and institutional framework with regard to the secondary use for research purposes of biological material and data collected during care, we suggest the adoption of a more nuanced approach. This approach would be more sensitive to the different levels of data sensitivity and identifiability, different types of research, and different levels of actual and potential risks that exist. Furthermore, the retrospective use of data and tissues from deceased individuals should be clarified in light of the ambiguities we have alluded to in article 22 of the *Civil Code*. Finally, a better understanding of the protection of biological samples and data by REBs and the CAI should be fostered. Finally, steps should be taken to ensure that REBs and the CAI have a more comprehensive understanding of the rationale underlying the legal protection of biological samples and data, and that their roles are more effectively coordinated.

⁶⁰ *Supra* note 3 at 20.

⁶¹ CSBE 2003, *supra* note 44 at 18-20.