

(2010) 8:1 *GenEdit*, 1-9

## RESEARCH AND DECEASED PERSONS: THE SECONDARY USE OF MEDICAL DATA AND BIOLOGICAL MATERIALS

Anne Marie Tassé<sup>1</sup>, Martin Letendre<sup>2</sup>, Bartha Maria Knoppers<sup>3</sup>

**The proliferation of data and the banking of biological materials collected during medical care leaves the impression that an impressive amount of resources are available for research. Moreover, the longevity of these resources often exceeds the lifetime of the persons involved. In this context, the secondary use of data and biological materials from deceased individuals raises important legal and ethical questions.**

---

<sup>1</sup> Anne Marie Tassé, LL.M., M.A., LL.D.(c) is a lawyer and Professional Associate, Centre of Genomics and Policy, McGill University.

<sup>2</sup> Martin Letendre, LL.B., LL.M. is a lawyer and Director of ethical and legal affairs, ethica Clinical Research inc.

<sup>3</sup> Bartha Maria Knoppers, PhD, Professor, Department of Human Genetics, Faculty of Medicine, McGill University; Director, Centre of Genomics and Policy, McGill University.

Since the emergence of modern medicine, health professionals have contributed to medical record keeping and the preservation of various biological materials. To date, millions of data and biological materials have been stored in different biobanks<sup>1</sup>, which were initially created for healthcare purposes. For many researchers, the use and combination of these resources (medical records, tissue banks, tumours, organs, blood, etc.) represent an inexpensive opportunity to “virtually” create mega-cohorts of subjects.

When data and biological materials are collected as part of healthcare, their use in biomedical research constitutes a secondary use<sup>2</sup>, if the patient has not previously consented to such a use. Such a retrospective secondary use<sup>3</sup> is governed by a comprehensive legal and ethical framework that requires obtaining, *a priori*, a free and informed consent of those who contributed samples to the biobank.

However, the requirement of obtaining free and informed individual consent can be problematic when the sustainability of these resources exceeds the life of the individuals involved. What happens to data and samples when the patient's death prevents any individual re-consent? Can a third party provide substitute consent? Is it possible to use these data and samples as part of research projects?

To answer these questions, we conducted a review of normative international, European, Canadian and Quebecois documents governing the secondary use of data and biological materials of deceased individuals. To identify the relevant normative documents<sup>4</sup>, we used the HumGen International database<sup>5</sup>. We also searched the websites of the Council of Europe<sup>6</sup>, Statutes and Regulations of Canada<sup>7</sup>, Publications du Québec<sup>8</sup> and various international, national and provincial organizations governing the ethical conduct of research. This review includes the available French or English documents, or those translated into one of these languages, updated on January 25, 2010.

This article's objective is not to study the residual nature of personal human rights after death, or to determine if a deceased person remains a subject of the law. In addition, its goal is not to study the legal framework for *post-mortem* tissue samples or to determine the legal status of biological samples that have already been collected.

## I. INTERNATIONAL

There are some international documents, which recognize the impact of death on the secondary use of data and biological material in research. While the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the International Bioethics Committee (IBC) recognize that access to genetic information of a deceased person raises special issues<sup>9</sup>, the guidelines of the Organisation for Economic Cooperation and Development (OECD) recommend that biobanks establish a clear policy on the effects of participants' deaths<sup>10</sup>. Despite its great relevance, this recommendation is not feasible in retrospective cohorts, when data and patient samples have already been collected.

Despite the consensus that access to data or identifiable biological material by a third party should be prohibited without prior consent from the individual<sup>11</sup>, several international normative documents recognize that, under certain circumstances, obtaining individual consent may raise significant concerns that may prevent or affect the validity of research. It can then be ethically justified to waive, in whole or in part, the requirements for obtaining individual consent (or substituted consent for minors and incompetent adults) for the granted authorization by a Research Ethics Board (REB) or other appropriate committee<sup>12</sup>.

It is then up to the REB to evaluate the ethical and legal acceptability of each project and to authorize, or not, such an exemption. These documents offer many criteria that could justify the exemption: respect for the rights and interests of the individual<sup>13</sup>, respect for privacy and

confidentiality<sup>14</sup>, minimal risk<sup>15</sup>, the importance of research and public interest<sup>16</sup>, epidemiological research<sup>17</sup> and the impossibility<sup>18</sup>.

The impossibility to obtain a new consent occurs when obtaining consent becomes unrealistic, especially when patients have died after the initial collection of data and biological material<sup>19</sup>. According to these documents, death can be used as evidence to justify the impossibility to re-contact the subject and justify the waiver of the requirement to obtain a free and informed individual consent.

## II. EUROPE

European law also lacks comprehensiveness when it comes to the secondary use of data and biological samples collected as part of health-care, when the individual is deceased.

On the one hand, the Council of Europe restates the founding rules in research ethics, particularly with regard to free and informed consent. While the *Recommendation R(90)3 concerning Medical Research on Human Beings*<sup>20</sup> mentions that no medical research can take place without the consent of the person undergoing it<sup>21</sup>, the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*<sup>22</sup> mentions that no research can be conducted without the informed, free, express, specific and documented consent of the individual<sup>23</sup>. However, this *Protocol* only applies to research involving an intervention on a human being, especially a physical intervention or other, to the extent that it involves a risk to the psychological health of the individual concerned<sup>24</sup>. Since the intervention must carry a risk to the individual concerned, it seems that this *Protocol* does not apply in the context of research on data and biological material of deceased individuals.

With respect to secondary use of biological material, the *Convention on Human Rights and Biomedicine*<sup>25</sup> anticipates that a body part removed during an intervention cannot be stored

or used for purposes other than those for which it was initially removed for<sup>26</sup>.

On the other hand, the *Recommendation on the Protection of Medical Data*<sup>27</sup> opens the door to some secondary use of medical and health information. This *Recommendation* first states that the use of medical information for research purposes should be anonymous<sup>28</sup>. However, it allows the secondary use of information that provides the identification of the patients when: 1) anonymization is impossible, 2) the research project includes substantial public interest and 3) this secondary use is authorized by the appropriate committee, designated by national legislation<sup>29</sup>. In all cases, the patient's consent must be impossible, the patient must not have previously expressed his/her opposition and the value of research must justify this waiver<sup>30</sup>.

## III. CANADA (FEDERAL)

Canadian federal legislation and the standards in research ethics deal with the outcome of data regardless of the biological samples.

### PERSONAL INFORMATION

Although intimately related, no judgment allows attributing to biological samples the protection given to information by the *Personal Information Protection and Electronic Documents Act*<sup>31</sup> and the *Privacy Act*<sup>32</sup>.

Under these two laws, the disclosure of personal and health information is not permitted without the consent of the individual concerned. Personal information is defined as any information concerning an identifiable individual. An a *contrario* interpretation of these provisions suggests that companies and agencies covered by these laws may provide information, to the extent that this information does not allow for the identification of the individual concerned.

In addition, the law specifies that the term "personal health information" refers to either living or deceased individuals. Therefore, the

confidentiality of health information of deceased individuals, who are still identifiable, is protected by this legislation. This legislation allows, however, under certain conditions, the use and disclosure of personal information without the subject's consent, for study or research purposes.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*<sup>33</sup> (TCPS) and the *CIHR Best Practices for Protecting Privacy in Health Research*<sup>34</sup> have also noted that research can begin only if the subject (or authorized third party) has consented, in a free and informed way. However, REBs may approve a consent procedure which waives or modifies, in whole or in part, the consent requirement<sup>35</sup>. In the particular case of data already collected, the TCPS states that REBs may approve a secondary use of identifiable data, when 1) they are essential to research, 2) measures are taken to protect the confidentiality of subjects and to reduce the risks of research and 3) the individuals to whom the data refer are not opposed to having it reused<sup>36</sup>. These criteria appear to apply mutatis mutandis to secondary use of identifiable data of deceased individuals, in the case where they have not, prior to their death, showed their opposition to such use.

## BIOLOGICAL MATERIAL

The secondary use of biological material from deceased individuals is not governed by federal law, but rather by a set of comprehensive norms and guidelines governing the practices of health professionals and researchers. In this regard, the Canadian College of Medical Geneticists and the Canadian Association of Genetic Counsellors issued the *Joint Statement on the Process of Informed Consent for Genetic Research*<sup>37</sup>. This statement mentions that following the approval of a local REB, the collections of existing biological material can be used in research if consent from the individuals concerned is obtained, or if the samples are anonymous or rendered anonymous.

The TCPS also specifies the procedures for the implementation of the secondary use of biological material already collected. In this regard, researchers should seek the free and informed consent of donors or authorized third parties before using previously collected, identifiable tissues<sup>38</sup>. If the donor dies without leaving any prior directives, the researcher must demonstrate that the free and informed consent can be granted by an authorized third party<sup>39</sup>. The TCPS, however, does not specify the identity of the third party authorized to consent to the secondary use of biological material from a deceased individual. Again, this requirement does not apply to anonymous or anonymized tissues<sup>40</sup>. With respect to biological samples collected as part of care, the TCPS remains cautious and states that the REB should study the importance of various factors on a case-by-case basis<sup>41</sup>.

In 2009, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada proposed a revised version of the TCPS<sup>42</sup>. Unlike before, this document proposes to allow some secondary use of biological material for research purposes. According to this draft *Policy Statement*, a research ethics committee may approve the research without seeking consent from the person from whom the biological material was collected, if the researcher demonstrates that: 1) the identifiable biological material is essential to research, 2) the waiver is unlikely to have negative consequences for the well-being of the individual, 3) researchers will take the appropriate steps to protect the privacy of individuals and the biological material, 4) researchers will respect any known preferences previously expressed by the individuals concerning the use of their biological material, 5) it is impossible or impracticable to seek consent from the person from whom the material was collected and 6) researchers have obtained all other necessary (e.g. legal) permissions for the use of secondary biological material for research purposes<sup>43</sup>. However, this docu-

ment was not in effect at the time of publication of this article<sup>44</sup>.

## IV. QUEBEC

In Quebec, the secondary use of data and biological material is governed by a comprehensive framework. In this regard, the *Civil Code of Québec* (CCQ)<sup>45</sup>, the *Act respecting health services and social services* (AHSSS)<sup>46</sup>, the *Act respecting access to documents held by public bodies and the protection of personal information*<sup>47</sup> and the *Act respecting the protection of personal information in the private sector*<sup>48</sup> require obtaining, *a priori*, a free and informed consent from the individuals concerned<sup>49</sup>.

### PERSONAL INFORMATION

The *Act respecting health services and social services*<sup>50</sup> protects the confidentiality of personal information available in the user's file. According to this law, access to the user's file may be obtained in two ways: with the user's consent or with the authorization of the Director of Professional Services (DPS)<sup>51</sup>. The DPS can allow a professional to examine a user's file for study, teaching or research purposes without the user's consent if: 1) the projected use is not frivolous; 2) the sought goals cannot be achieved unless the information is communicated in a nominative way and 3) the personal information will be used in a manner to ensure the confidentiality criteria.

Moreover, according to the *Act respecting access to documents held by public bodies and the protection of personal information*<sup>52</sup> and the *Act respecting the protection of personal information in the private sector*<sup>53</sup>, a public agency or a private enterprise cannot disclose personal information without the consent of the individual concerned. Personal information is defined as that concerning a physical individual and allowing for his/her identification. An *a contrario* interpretation of these provisions allow for the conclusion that companies and Quebec public organizations can share information, as long as

they do not allow for the identification of the individual concerned.

It is also possible to access this nominative data if the Commission d'accès à l'information du Québec is convinced that the use is not frivolous, that the sought goals cannot be achieved unless the information is disclosed in a form that enables the identification of individuals and that information will be used in a manner that ensures the confidentiality criteria.

### BIOLOGICAL MATERIAL

The *Civil Code of Quebec*<sup>54</sup> states that a body part, organ, tissue or other substance removed from an individual 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 research purposes<sup>55</sup>. This article does not differentiate between body parts made anonymous or not, or coming from a living or deceased individual.

Unfortunately, the legislator did not specify the identity of the person authorized to consent for another person under this provision. This omission is particularly problematic when the patient is deceased. In this respect, a review of the literature shows three dominant interpretations.

A first interpretation can be made by reading the Commission de l'Éthique de la Science et de la Technologie's (CEST) opinion on *Les enjeux éthiques des banques d'information génétique*<sup>56</sup> which confirms, by analogy, that the individuals able to consent for others in the context of Article 22 CCQ are those allowed to consent for others in the context of care; that is to say, the legal representative of the deceased patient, or failing that, his/her spouse, whether married, through a civil or common law union, or, if no spouse exists or if the latter is unable to act, a close relative or a person who shows, for the most part, a special interest in the patient concerned<sup>57</sup>.

A second interpretation comes to similar conclusions, but for different reasons. According to these authors, the secondary use of body parts is considered an extension of the act of care for which the tissues were initially taken. Therefore, the person who is normally in charge of care, as noted above, may give permission for the individual<sup>58</sup>.

According to the last interpretation, the right to consent for others for the secondary use of body parts collected in the context of care cannot be exercised following death, because death means the end of extra-patrimonial rights<sup>59</sup>.

However, the FRSQ *Guide d'éthique de la recherche scientifique* specifies that the protection of subjects does not require a restrictive interpretation of this article<sup>60</sup>.

## V. PRESENTATION OF DIFFERENT NORMATIVE APPROACHES

A comparative study of norms governing the secondary use of data and biological samples, collected in the context of care, of deceased individuals identifies three main normative approaches (**Table 1**).

### INITIAL CONSENT

All the studied jurisdictions impose, *a priori*, the requirement to obtain the consent of the individual concerned or, failing that, from an authorized third party. However, the identity of that third party varies across jurisdictions and remains debated in Quebec law regarding consent for the secondary use of biological material collected in the context of healthcare. Respect for the opposition of the individual concerned is also a common element of all studied jurisdictions.

### WAIVER OF CONSENT FOR REASONS OF IMPOSSIBILITY

Several jurisdictions waive the requirement to obtain individual or substituted consent prior to research. The justifications for such an exemption vary, but the most frequently stated are the respect of the individual's rights and interests, the respect for privacy and confidentiality, minimal risk, the importance of research and public interest, epidemiological research and impossibility. The death of the individual can then justify the impossibility of obtaining a new consent and, therefore, justify the full or partial waiver of this obligation by an REB.

### WAIVER OF CONSENT FOR REASONS OF ANONYMITY

Most jurisdictions allow the use, without consent, of anonymous or anonymized data and biological material of deceased individuals. Quebec law, however, departs from this approach, since the rules for secondary use of biological material collected in the context of care appear to create a single legal system, applicable to both identifiable body parts and anonymous or anonymized parts.

## VI. CONCLUSION – OUR POSITION

This review of international, European, national and provincial norms shows that, despite the consensus about free and informed consent, there is no clear consensus on the procedure of authorizing research using data and biological material collected initially for medical purposes, when the individual concerned is deceased<sup>61</sup>. Moreover, few documents make essential distinctions in this area, particularly with regard to:

1. The secondary use of data *versus* that of biological materials, or;
2. The secondary use of data or biological material initially collected for research purposes *versus* for care purposes, or;

3. The use of information and biological material from living individuals *versus* deceased individuals since the collection. Consequently, few papers directly address the issues related to the secondary use of data and genetic material of deceased individuals.

sent for impossibility or anonymity reasons, the solutions proposed by the Quebec legislator do not really reflect the dominant approaches at the national and international levels, namely on the secondary use of body parts collected in the context of care.

Moreover, despite the existence of different converging paradigms, such as waiver of con-

**TABLE 1**  
**Comparative table of consent requirements and waivers**

|  | International |                     | Europe |                     | Canada |                     | Quebec |                     |
|--|---------------|---------------------|--------|---------------------|--------|---------------------|--------|---------------------|
|  | Data          | Biological material | Data   | Biological material | Data   | Biological material | Data   | Biological material |
| Consent (individual or authorized third party) | Yes           | Yes                 | Yes    | Yes                 | Yes    | Yes                 | Yes    | Yes                 |
| Waiver of consent (impossibility)              | Yes           | Yes                 | Yes    | No                  | Yes    | Yes                 | Yes    | No                  |
| Waiver of consent (anonymity)                  | Yes           | Yes                 | Yes    | No                  | Yes    | Yes                 | Yes    | No                  |

## REFERENCES

<sup>1</sup> In this document, the terms “genetic databank”, “biological material bank” and “biobank” are used interchangeably and denote any organized and structured collection of human biological material and any associated personal information stored in order to comprise an accessible resource for research and clinical analyses.

<sup>2</sup> In this document, the expression “secondary use” denotes all uses carried out for purposes other than those anticipated at the time of the initial data and/or biological sample collection.

<sup>3</sup> In this document, the expression “retrospective use” of biological material and/or personal information denotes a use that was determined after the collection.

<sup>4</sup> This editorial limits itself to a review of the normative documents governing the secondary use of data and clinical, biological materials of deceased individuals. The relevant jurisprudence is therefore not considered in this study.

<sup>5</sup> HumGen International, online:

<<http://www.humgen.org/int/>>.

<sup>6</sup> Council of Europe, online:

<<http://www.coe.int/DefaultEN.asp>>.

<sup>7</sup> Statutes and Regulations of Canada (federal), online:

<<http://www.canlii.org/en/ca/laws/index.html>>.

<sup>8</sup> Publications du Québec, online:

<<http://www.publicationsduquebec.gouv.qc.ca/store.cfm?&ckey=CA&lang=eng>>.

<sup>9</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO) and the International Bioethics Committee (IBC), *Human Genetic Data: Preliminary Study by the IBC on its Collection, Processing, Storage and Use* (2002), paragraph 31.

<sup>10</sup> Organisation for Economic Co-operation and Development (OECD), *Recommendation on Human Biobanks and Genetic Research Databases* (2009), art. 44.

<sup>11</sup> Please see United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on the Human Genome and Human Rights* (1997), art. 5; World Health Organization (WHO), *Cloning in human health – Report by the Secretariat (A52/12)* (1999), paragraph 8; World Health Organization (WHO), *Statement of WHO Expert Advisory Group on Ethical Issues in Medical Genetics* (1998), p. 4; Human Genome Organization (HUGO) Ethics Committee, *Statement on DNA Sampling: Control and Access* (1998), recommendation 7; Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2003), guidelines 4 and 18.

<sup>12</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO) and the International Bioethics Committee (IBC), *supra* note 9, art. 18; World Medical Association (WMA), *Declaration of Helsinki* (1964, amended in 1975, 1983, 1989, 1996, 2000, 2002, 2004 and 2008), art. 25; Organisation for Economic Co-operation and Development (OECD), *supra* note 10, art. 3.1, 4.5 and 5.1; Council for International Organizations of Medical Sciences (CIOMS), *ibid.*, guidelines 4 and 18; World Medical Association (WMA), *WMA Declaration on Ethical Considerations regarding Health Databases* (2002), art. 18; Human Genome Organization (HUGO) Ethics Committee, *ibid.*, recommendation 2.

<sup>13</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO), *International Declaration on Human Genetic Data* (2003), art. 16; Organisation for Economic Co-operation and Development (OECD), *supra* note 10, art. 5.1; United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on Bioethics and Human Rights* (2005), art. 6 and 9; Council for International

Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 4.

<sup>14</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO) and the International Bioethics Committee (IBC), *supra* note 9, art. 18; Human Genome Organization (HUGO) Ethics Committee, *supra* note 11; Council for International Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 4; World Medical Association (WMA), *WMA Declaration on Ethical Considerations regarding Health Databases*, *supra* note 12, art. 24.

<sup>15</sup> Council for International Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 4.

<sup>16</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO), *International Declaration on Human Genetic Data*, *supra* note 13, art. 16; Council for International Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 4.

<sup>17</sup> Human Genome Organization (HUGO), *Statement on The Principled Conduct Of Genetics Research* (1995), par. 4; Council for International Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 18; United Nations Educational, Scientific and Cultural Organization (UNESCO), *International Declaration on Human Genetic Data*, *supra* note 13, art. 17.

<sup>18</sup> World Medical Association (WMA), *Declaration of Helsinki*, *supra* note 12, art. 25; World Medical Association (WMA), *WMA Declaration on Ethical Considerations regarding Health Databases*, *supra* note 12, art. 17; United Nations Educational, Scientific and Cultural Organization (UNESCO), *International Declarations on Human Genetic Data*, *supra* note 13, art. 16; Council for International Organizations of Medical Sciences (CIOMS), *supra* note 11, guideline 4.

<sup>19</sup> For more details on the implementation of the waiver of consent according to international normative documents, please see Emmanuelle Lévesque, William Fraser and Bartha Maria Knoppers, “Consent to Research: Exceptional Situations” (2009) 7 :3 *GenEdit* 1.

<sup>20</sup> Council of Europe (COE), *Committee of Ministers, Recommendation 90(3) concerning Medical Research on Human Beings* (1990).

<sup>21</sup> *Ibid.*, principle 3.

<sup>22</sup> Council of Europe (COE), *CETS n° 195 – Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, 25.I.2005.

<sup>23</sup> *Ibid.*, art. 14.

<sup>24</sup> *Ibid.*, art. 2.

<sup>25</sup> Council of Europe (COE), *ETS n° 164 – Convention on Human Rights and Biomedicine*, 4.IV.1997.

<sup>26</sup> *Ibid.*, art. 22.

<sup>27</sup> Council of Europe (COE), *Committee of Ministers, Recommendation No R(97)5 on the Protection of Medical Data* (1997), art. 12.

<sup>28</sup> *Ibid.*, art. 12.1.

<sup>29</sup> *Ibid.*, art. 12.2.

<sup>30</sup> *Ibid.*, art. 12.2.

<sup>31</sup> *Personal Information Protection and Electronic Documents Act*, L.C. 2000, c. 5.

<sup>32</sup> *Privacy Act*, L.R.C. 1985, c. P-21.

<sup>33</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998, with modifications from 2000, 2002 and 2005).

<sup>34</sup> Canadian Institutes of Health Research (CIHR), *Best Practices for Protecting Privacy in Health Research*, (2005), art. 2.3.

<sup>35</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada

(NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 2.1; Canadian Institutes of Health Research (CIHR), *ibid.*, art. 2.3.

<sup>36</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 3.3.

<sup>37</sup> Canadian College of Medical Geneticists (CCMG) et Canadian Association of Genetic Counsellors (CAGC), *Joint Statement on the Process of Informed Consent for Genetic Research*, online:

<[http://www.ccmg-cgm.org/pdf/policy/CCMG%20CAGC%20Joint%20Statement%20Informed%20Consent%20\\_final\\_080623.pdf](http://www.ccmg-cgm.org/pdf/policy/CCMG%20CAGC%20Joint%20Statement%20Informed%20Consent%20_final_080623.pdf)>.

<sup>38</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 10.3.

<sup>39</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 10.1.

<sup>40</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 10.3.

<sup>41</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *supra* note 33, rule 8.6.

<sup>42</sup> Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC), *Revised Draft 2<sup>nd</sup> Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2009), online: <<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revisee-reviser/Default/>>.

<sup>43</sup> *Ibid.*, art. 12.3.

<sup>44</sup> *Ibid.*

<sup>45</sup> *Civil Code of Quebec*, L.Q. 1991, c. 64, art. 22.

<sup>46</sup> *Act Respecting Health Services and Social Services*, L.R.Q. c. S-4.2.

<sup>47</sup> *Act Respecting Access to Documents held by Public Bodies and the Protection of Personal Information*, L.R.Q. c. A-2.1.

<sup>48</sup> *Act Respecting the Protection of Personal Information in the Private Sector*, L.R.Q. c. P-39.1.

<sup>49</sup> This article presents a review of the international, European, Canadian and Quebec normative documents governing the secondary use of data and clinical, biological materials of deceased individuals. By choice of the editor, this text does not look at legislation from other countries or Canadian provinces.

<sup>50</sup> *Act Respecting Health Services and Social Services*, *supra* note 46.

<sup>51</sup> *Ibid.*, art. 19, 19.1 et 19.2.

<sup>52</sup> *Act Respecting Access to Documents held by Public Bodies and the Protection of Personal Information*, *supra* note 47.

<sup>53</sup> *Act Respecting the Protection of Personal Information in the Private Sector*, *supra* note 48.

<sup>54</sup> *Civil Code of Quebec*, *supra* note 45, art. 22.

<sup>55</sup> *Ibid.*, art. 22.

<sup>56</sup> *Ibid.*, art. 22.

<sup>57</sup> Clémentine Sallée & Bartha Maria Knoppers, "Secondary Research Use of Biological Samples and Data in Quebec", 85 R. from B. 137.

<sup>58</sup> Robert P. Kouri & Suzanne Philips-Nootens, "L'utilisation des parties du corps humain pour fins de recherche : l'article 22 du Code civil du Québec" (1994-95) 25 *Revue de droit de l'Université de Sherbrooke* 368.

<sup>59</sup> Édith Deleury & Dominique Goubau, *Le droit des personnes physiques*, 3<sup>rd</sup> ed., Cowansville, Éditions Yvon Blais, 2002, p. 75.

<sup>60</sup> Fonds de la recherche en santé du Québec (FRSQ), *Guide d'éthique de la recherche scientifique* (2008), art. 28.

<sup>61</sup> Karen J. Maschke, "Navigating an Ethical Patchwork-Human Gene Banks" (2005) *Nature Biotechnology* 23:5, 539.