

AMENDMENTS TO THE *CIVIL CODE OF QUÉBEC'S* RESEARCH PROVISIONS: A LEGISLATIVE COMMENT

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On 14 June 2013, Québec's National Assembly passed Bill 30, *An Act to amend the Civil Code and other legislative provisions with respect to research*, which entered into force the same day. Bill 30 amended research provisions in the *Civil Code of Québec* (CCQ) pertaining to research, specifically articles 20-22, 24, and 25, as well as a section of the *Act respecting health services and social services*, modifying a complaint mechanism for research participants and their heirs or legal representatives. The goal of Bill 30 was to eliminate confusion surrounding the provisions and remove a number of barriers to research activities in

Le 14 juin 2013, l'Assemblée nationale du Québec a adopté le projet de loi 30, *Loi modifiant le Code civil et d'autres dispositions législatives en matière de recherche*, entré en vigueur le jour même. Le projet de loi 30 a modifié les dispositions du *Code civil du Québec* (CcQ) en matière de recherche, en particulier les articles 20 à 22, 24 et 25, ainsi qu'une partie de la *Loi sur les services de santé et les services sociaux*. Cela a eu pour effet de modifier le mécanisme de plainte pour les participants à la recherche et leurs tuteurs ou héritiers. L'objectif de ce projet de loi était d'éliminer la confusion dans les dispositions et de supprimer un

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Québec – particularly where the research presented minimal risk to participants – so that the scientific community could investigate important research questions. The CCQ amendments are welcome in many respects, foremost because they bring much-needed revision to an anachronistic section of the *Code* that reflected a twentieth-century research environment. Replacing the term “experiment” with “research,” for example, is to be applauded. The amendments also warrant criticism, however, and in this legislative comment we critically discuss both the improvements and missed opportunities that Bill 30 presents, particularly in the context of biomedical research.

certain nombre d’obstacles liés aux activités de recherche au Québec, en particulier lorsque la recherche présentait un risque minimal pour les participants – de sorte que la communauté scientifique puisse examiner des questions de recherche importantes. Les modifications au CcQ sont bienvenues à bien des égards. Avant tout, elles apportent une révision nécessaire à une section du *Code* qui reflétait un contexte de recherche anachronique datant du vingtième siècle. À titre d’exemple, le remplacement du terme « expérimentation » par « recherche » est une initiative à saluer. Cependant, ce projet de loi amène aussi son lot de critiques, qui feront l’objet du présent commentaire de texte législatif, tant au niveau des modifications apportées que des occasions manquées de proposer de meilleures solutions, surtout dans le contexte de la recherche biomédicale.

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INTRODUCTION

On 14 June 2013, Québec's National Assembly passed Bill 30, *An Act to amend the Civil Code and other legislative provisions with respect to research*,¹ which entered into force the same day. Bill 30 amends provisions in the *Civil Code of Québec* (CCQ) pertaining to research, specifically articles 20-22, 24, and 25, as well as a section of the *Act respecting health services and social services* that modifies a complaint mechanism for research participants and their heirs or legal representatives.² The National Assembly enacted these changes to the legislative regime on research ethics after its Standing Committee on Health and Social Services heard testimony that the former research ethics regime was so difficult to interpret – for example, in regard to research involving people with a compromised ability to consent – that approval of projects by research ethics committees (RECs) amounted to a “lottery.”³

In this legislative comment, we focus on Bill 30's amendments to the CCQ and seek to address two key questions from a medical law perspective. First, does the new CCQ regime properly balance the protection of research participants with the promotion of socially beneficial health discoveries in genomic research, biobanking, personalized medicine, and other areas that now dominate the biomedical research funding landscape? Second, does the new CCQ regime for research provide clear guidance on the correlative rights and duties of researchers, research participants, and RECs?

These questions are increasingly critical as Québec takes a leading role in biomedical research, which is burgeoning in both the public and private

¹ 1st Sess, 40th Leg, Québec, 2013.

² CQLR c S-4.2, s 34. The amendment introduced a requirement that the complaint examination procedure of an institution that carries on research activities must enable any person, whether or not they are a user of that institution, who participates in research that the institution approved, as well as the heirs or the legal representatives of such a person, to address a complaint to the local service quality and complaints commissioner concerning the research.

³ Québec, National Assembly, *Journal des débats de la Commission permanente de la santé et des services sociaux* [*Journal of Debates of the Standing Committee on Health and Social Services*], 40th Parl, 1st Sess, Vol 43, No 16 (24 April 2013) at 9 (Philippe Voyer) [CSSS Debates (24 April 2013)]. According to Philippe Voyer, “there is really a serious problem of interpretation” so “researchers cross their fingers” when submitting their projects for approval (*ibid* [translated by authors]).

sectors,⁴ buoyed in part by the reorientation of government priorities toward monetizable research.⁵ For example, the CARTaGENE biobank project, which began in 2007,⁶ has already started to release discoveries with a significant potential impact on public health, including a finding that nearly all Québécois with end-stage kidney disease were unaware of their condition.⁷ Many newer projects – notably in cancer research, personalized medicine, and genomics – are underway in Quebec City⁸ as well as in the greater

⁴ Despite a brief slump in the Montréal biotech sector between 2010 and 2012. See e.g. Guy Paquin, “Biotechs québécoises sorties du désert”, *La Presse* (14 March 2012), online: LP <<http://affaires.lapresse.ca/portfolio/industrie-pharmaceutique/201203/14/01-4505360-biotechs-quebecoises-sorties-du-desert.php>>; Guy Paquin, “Pour une pépinière d’entreprises”, *La Presse* (14 March 2012), online: LP <<http://affaires.lapresse.ca/portfolio/industrie-pharmaceutique/201203/14/01-4505351-pour-une-pepiniere-dentreprises.php>>.

⁵ See e.g. Ulysse Bergeron, “Économie du savoir – Les politiques qui encadrent les subventions « ont un impact désastreux »”, *Le Devoir* (13 May 2006), online: LD <www.ledevoir.com/societe/science-et-technologie/108936/economie-du-savoir-les-politiques-qui-encadrent-les-subventions-ont-un-impact-desastreux>.

⁶ See Pauline Gravel, “Ottawa et Québec financent la biobanque CARTaGENE”, *Le Devoir* (23 May 2007), online: LD <www.ledevoir.com/societe/science-et-technologie/144482/ottawa-et-quebec-finacent-la-biobanque-cartagene>; Philippe Mercure, “L’ADN de 2000 Québécois à Chicoutimi”, *La Presse* (22 August 2007), online: LP <<http://affaires.lapresse.ca/economie/200901/06/01-682655-ladn-de-20000-quebecois-a-chicoutimi.php>>.

⁷ See Charlie Fidelman, “Researcher turns to new biobank to explain spike in kidney disease: More than 90 per cent of Quebecers afflicted with end-stage illness didn’t know they had it, CARTaGENE project data show”, *The [Montreal] Gazette* (22 April 2014), online: NewsLookup.com (archived copy) <http://cached.newslookup.com/cached.php?ref_id=125&siteid=2117&id=5759568&t=1398210163>. For prior discoveries about other ailments, see also Pauline Gravel, “Cartagène commence à porter ses fruits”, *Le Devoir* (15 January 2013), online: LD <www.ledevoir.com/societe/science-et-technologie/368384/cartagene-commence-a-porter-ses-fruits>.

⁸ See e.g. Caroline Rodgers, “Génomique: 22 millions pour la recherche”, *La Presse* (13 May 2013), online: LP <<http://affaires.lapresse.ca/cv/201305/13/01-4650345-genomique-22-millions-pour-la-recherche.php>>.

Montréal area, initiated not only at universities⁹ and in the private sector,¹⁰ but also in partnerships between the two.¹¹ These newer projects have already generated discoveries of their own.¹²

⁹ See e.g. Jacinthe Tremblay, “McGill inaugure son nouveau Complexe des sciences de la vie”, *Le Devoir* (17 September 2008), online: LD <www.ledevoir.com/societe/sante/205968/mcgill-inaugure-son-nouveau-complexe-des-sciences-de-la-vie>; Pascale Breton, “Vers une médecine personnalisée”, *La Presse* (7 April 2009), online: LP <www.lapresse.ca/sciences/genetique/200904/07/01-844221-vers-une-medecine-personnalisee.php>; Claude Lafleur, “La relève est à l’IRCM : L’institut montréalais abrite 36 équipes de recherche en science biomédicale”, *Le Devoir* (10 October 2009), online: LD <www.ledevoir.com/societe/education/271053/la-releve-est-a-l-ircm-l-institut-montrealais-abrite-36-equipes-de-recherche-en-science-biomedicale>. Regarding university-linked hospitals, see e.g. “Une Biobanque pour comprendre la cancer de la prostate”, *La Presse* (28 October 2008), online: LP <www.lapresse.ca/sciences/medecine/200810/28/01-33574-une-biobanque-pour-comprendre-la-cancer-de-la-prostate.php>.

¹⁰ See e.g. Canadian Press, “Cancer: Québec injecte 10 millions pour développer la médecine spécialisée”, *Le Devoir* (15 February 2013), online: LD <www.lapresse.ca/la-tribune/actualites/201302/15/01-4622096-quebec-injecte-10-m-pour-developper-la-medecine-specialisee.php>; Guy Paquin, “Viser la bonne cible!”, *La Presse* (23 April 2013), online: LP <<http://affaires.lapresse.ca/portfolio/industrie-pharmaceutique/201304/23/01-4643653-viser-la-bonne-cible.php>>; Martin Primeau, “Prognomix: prévenir par la lecture du génome”, *La Presse* (14 November 2011), online: LP <<http://affaires.lapresse.ca/economie/sante/201111/14/01-4467582-prognomix-prevenir-par-la-lecture-du-genome.php>>; Guy Paquin, “Davantage d’alliances avec les chercheurs québécois”, *La Presse* (6 December 2013), online: LP <<http://affaires.lapresse.ca/portfolio/industrie-pharmaceutique/201312/06/01-4718336-davantage-dalliances-avec-les-chercheurs-quebecois.php>>.

¹¹ See e.g. Guy Paquin, “Impartir la recherche”, *La Presse* (14 March 2012), online: LP <<http://affaires.lapresse.ca/portfolio/industrie-pharmaceutique/201203/14/01-4505364-impairtir-la-recherche.php>>; Pauline Gravel, “CRCHUM en PPP : le délai et le budget ont été respectés”, *Le Devoir* (9 October 2013), online: LD <www.ledevoir.com/societe/science-et-technologie/389513/crchum-en-ppp-le-delai-et-le-budget-ont-ete-respectes>.

¹² See e.g. Sarah Champagne, “Maladies infantiles : percée majeure au CHU Sainte-Justine”, *La Presse* (31 January 2013), online: LP <www.lapresse.ca/actualites/sante/201301/30/01-4616797-maladies-infantiles-percee-majeure-au-chu-sainte-justine.php>.

For reasons explained below, these CCQ amendments are welcome in many respects, mainly because they bring much-needed modernization to an anachronistic section of the CCQ that reflected a twentieth-century research environment. Replacing the term “experiment” with “research,” for example, is welcome. The CCQ amendments also warrant criticism, however, and so we will discuss both the improvements and missed opportunities that Bill 30 presents, particularly in the context of genomic research.

In Part I, we explain the changes to the CCQ. In Part II, we evaluate the improvements and missed opportunities in these amendments, focusing on four key aspects relevant to biomedical research (and genomic research in particular): research and care, the notion of “minimal risk,” residual use of tissues, and RECs. Finally, we conclude with an overall assessment of the CCQ amendments, how they now situate Québec within the global research ethics ecosystem, and what further paths may be taken to improve research governance in this province.

I. OVERVIEW OF THE CCQ AMENDMENTS

Bill 30 was formally introduced on 28 March 2013 in the National Assembly of Québec by the then-Minister of Health and Social Services, Réjean Hébert. As shown in Table 1, Bill 30’s amendments to the CCQ were the following:

- (1) It changed the term “experiment” to “research,”¹³ and made various changes related to the consent required to participate in research.¹⁴

¹³ Furthermore, people “participate in” research rather than “submit to” an experiment. See the amendments to arts 20-21, 24 CCQ.

¹⁴ These amendments are that:

- research ethics committees must now approve and monitor research on competent adults (art 20 CCQ);
- research on minors that poses a serious risk can now take place, so long as that risk is proportionate “to the benefit that may reasonably be anticipated” (art 21, para 1 CCQ);
- there is no longer an exception for “innovative care required by the state of health of the person” (previously in art 21, para 4 CCQ); and

- (2) It permitted minors 14 to 17 years old to consent to research on their own if, according to a REC, the risk posed by the research to the minor's health is "minimal ... and the circumstances justify it."¹⁵
- (3) It allowed consent to now be given to participate in research involving minimal risk (as determined by an REC) – for adults who lack the mental capacity to give consent and who have no legally authorized representative – by the same person who could provide consent for the adult's care.¹⁶
- (4) It allowed "consent to ... research [to] be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee [is to] determine ... the proper manner, for evidential purposes, of obtaining consent."¹⁷
- (5) It specified the rules governing consent to the use for research purposes of a body part removed as part of the care received by a person who has since died. In such cases, consent may be given by the person who could give or could have given consent to the care the deceased person required.¹⁸

Figure 1 provides a flowchart representing the norms in articles 20 and 21 CCQ.

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- the provisions are now restricted to apply only to "research that could interfere with the integrity of [the participant's] person" (arts 20-21, 25 CCQ).

For a detailed discussion on the issues that have shaped approaches to informed consent, see generally Margaret A Somerville, "Structuring the Issues of Informed Consent" (1981) 26:4 McGill LJ 740.

¹⁵ Art 21, para 5 CCQ.

¹⁶ Art 21, para 6 CCQ.

¹⁷ Art 24, para 2 CCQ.

¹⁸ Art 22 CCQ.

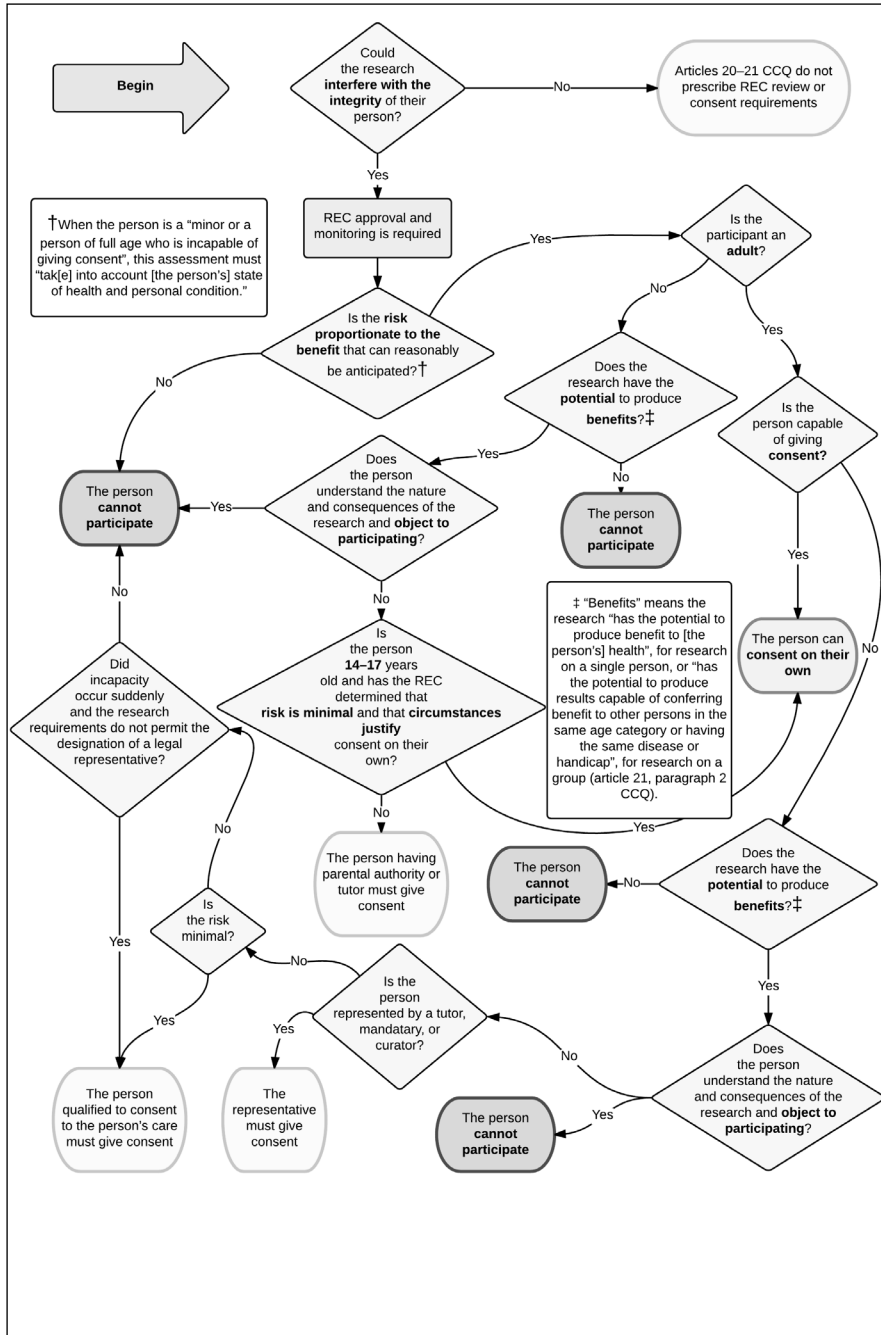
TABLE 1. TABLE OF CHANGES TO THE *CIVIL CODE OF QUÉBEC*.

Article	Amendments (bold text indicates additions; struck-out text indicates deletions)
20	<p>A person of full age who is capable of giving his consent may submit to an experiment participate in research that could interfere with the integrity of his person provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated. The research project must be approved and monitored by a research ethics committee.</p>
21	<p>A minor or a person of full age who is incapable of giving consent may not be submitted to an experiment if the experiment involves serious risk to his health or, where he understands the nature and consequences of the experiment, if he objects: participate in research that could interfere with the integrity of his person only if the risk incurred, taking into account his state of health and personal condition, is not disproportionate to the benefit that may reasonably be anticipated.</p> <p>Moreover, a minor or a person of full age who is incapable of giving consent may be submitted to an experiment participate in such research only if, where the person he he is the only subject of the experiment research, it has the potential to produce benefit to the person's his health or only if, in the case of an experiment research on a group, it has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap. Such an experiment must be part of a research project approved and monitored by an ethics committee. The competent ethics committees are formed by the Minister of Health and Social Services or designated by that Minister among existing research ethics committees; the composition and operating conditions of the committees are determined by the Minister and published in the <i>Gazette officielle du Québec</i>.</p> <p>Consent to experimentation may be given, in the case of a minor, by the person having parental authority or the tutor and, in the case of a person of full age incapable of giving consent, by the mandatary, tutor or curator. Where a person of full age suddenly becomes incapable of consent and the experiment, insofar as it must be undertaken promptly after the appearance of the condition giving rise to it, does not permit, for lack of time, the designation of a legal representative, consent may be given by the person authorized to consent to any care the person requires; it is incumbent upon the competent ethics committee to determine, when examining the research project, whether the experiment meets that condition.</p> <p>Care considered by the ethics committee to be innovative care required by the state of health of the person concerned does not constitute an experiment.</p> <p>In all cases, a minor or a person of full age incapable of giving consent may not participate in such research where he understands the nature and consequences of the research and objects to participating in it.</p> <p>The research project must be approved and monitored by a competent research ethics committee. Such a committee is formed by the Minister of</p>

Table 1, continued

Article	Amendments (bold text indicates additions; struck-out text indicates deletions)
21 (cont'd)	<p>Health and Social Services or designated by that Minister from among existing research ethics committees; the composition and operating conditions of such a committee are determined by the Minister and published in the <i>Gazette officielle du Québec</i>.</p> <p>Consent to research that could interfere with the integrity of a minor may be given by the person having parental authority or the tutor. A minor 14 years of age or over, however, may give consent alone if, in the opinion of the competent research ethics committee, the research involves only minimal risk and the circumstances justify it.</p> <p>Consent to research that could interfere with the integrity of a person of full age incapable of giving consent may be given by the mandatary, tutor or curator. However, where such a person of full age is not so represented and the research involves only minimal risk, consent may be given by the person qualified to consent to any care required by the state of health of the person of full age. Consent may also be given by such a qualified person where a person of full age suddenly becomes incapable of giving consent and the research, insofar as it must be undertaken promptly after the appearance of the condition giving rise to it, does not permit, for lack of time, the designation of a legal representative for the person of full age. In both cases, it is incumbent upon the competent research ethics committee to determine, when evaluating the research project, whether it meets the prescribed requirements.</p>
22	<p>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 or, if he has died, be so used with the consent of the person who could give or could have given consent to any care required by his state of health.</p>
24	<p>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 research that could interfere with the integrity of his person shall be given in writing.</p> <p>However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent.</p> <p>It may be withdrawn at any time, even verbally.</p>
25	<p>The alienation by a person of a part or product of his body shall be gratuitous; it may not be repeated if it involves a risk to his health.</p> <p>An experiment A person's participation in research that could interfere with the integrity of his person may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenience suffered.</p>

FIGURE 1. FLOWCHART REPRESENTING THE NORMS IN ARTICLES 20-21 CCQ.



II. IMPROVEMENTS AND MISSED OPPORTUNITIES

According to Minister Hébert, revising the CCQ provisions relating to research was necessary because, in the period since the last CCQ revisions in 1998, the research environment in the province had become much more structured.¹⁹ The CCQ's provisions were seen as overly restrictive particularly with respect to seniors and minors, which impeded important research from proceeding.²⁰ Consequently, it was the government's position that the CCQ needed to be modernized in several areas.²¹ The term "experiment" was outdated and should be replaced with "research." Writing should not constitute the only form of consent. Minors aged 14 and over should be able to consent to research if the research risk is minimal, just as they could consent to their own care from age 14 onwards. And research projects concerning adults incapable of giving consent (e.g., seniors with Alzheimer's disease) should not be prevented from proceeding simply because the prospective participants lack representation by a mandatary, tutor, or curator. In sum, the goal of Bill 30 was to eliminate "incoherence"²² in the CCQ provisions and to remove a number of barriers to research activities in Québec – particularly when the research presented minimal risk to participants. Indeed, Bill 30 focused on the notion of "minimal risk," which Minister Hébert stated was well defined in research policies and guidelines, including the influential pan-Canadian *Tri-Council Policy Statement (TCPS)*.²³

Members of the public, ethicists, health research experts, and researchers submitted written commentary and testified at the public hearings of the

¹⁹ *CSSS Debates* (24 April 2013), *supra* note 3 at 1 (Hon Réjean Hébert) ("in 1998 the research landscape was much less structured than at present. In Québec we now have well-established research centres and, in particular, ethics committees that have been rolled out in all health and social services establishments and which thus oversee the approval of research projects and also the implementation of research projects" [translated by authors]).

²⁰ *Ibid.*

²¹ *Ibid* at 1 (Hon Réjean Hébert), 16 (Pierre Blain).

²² *Ibid* at 1 (Hon Réjean Hébert) [translated by authors].

²³ *Ibid.* See 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 2014* (Ottawa: Secretariat on Responsible Conduct of Research, 2014) at 22, online: Government of Canada Panel on Re-

Standing Committee on Health and Social Services regarding how research was unduly limited by provisions such as article 21 CCQ, which – if not in letter, certainly in spirit – hindered specific communities in Québec from benefiting from research results, and caused Québec to lag behind other jurisdictions such as Australia and the United States, not to mention certain other Canadian provinces.²⁴ The Standing Committee heard testimony that some RECs interpreted article 21 CCQ as requiring a legal representative even for minimal-risk research on incapacitated adults.²⁵ Some experts opined that minors aged 14 years and over should be allowed to consent to certain research projects presenting minimal risk, albeit under the direction of RECs and only in situations where obtaining parental consent would be impossible or impracticable.²⁶ Introducing “minimal risk” into article 21 CCQ would give leeway to RECs to make a more proportionate and consistent decision regarding research on minors and incapacitated adults alike.

Researchers and ethicists also testified that the word “experiment” confused the research community as it was open to multiple interpretations.²⁷ Many researchers would tell RECs their project was not an “experiment” as there was no control group, while RECs would respond that because it was a study of people, it constituted an experiment.²⁸ Replacing “experiment” with “research” would provide clarity as to the scope of the CCQ provisions.

search Ethics <www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf> [TCPS].

²⁴ *CSSS Debates* (24 April 2013), *supra* note 3 at 3 (Philippe Voyer). See also Centre of Genomics and Policy, *Mémoire du Centre de génomique et politiques sur le projet de loi n° 30, Loi modifiant le Code civil et d’autres dispositions législatives en matière de recherche : Présenté à la Commission de la santé et des services sociaux* (2 May 2013) at 7, online: Assemblée nationale du Québec <www.assnat.qc.ca/Media/Process.aspx?MediaId=ANQ.Vigie.Bll.DocumentGenerique_71473> [CGP, *Mémoire*].

²⁵ *CSSS Debates* (24 April 2013), *supra* note 3 at 9 (Philippe Voyer).

²⁶ CGP, *Mémoire*, *supra* note 24 at 9.

²⁷ See National Assembly of Québec, *Journal des débats de la Commission permanente de la santé et des services sociaux* [*Journal of Debates of the Standing Committee on Health and Social Services*], 40th Parl, 1st Sess, Vol 43, No 17 (25 April 2013) at 15 (Mylène Deschênes) [*CSSS Debates* (25 April 2013)].

²⁸ See *CSSS Debates* (24 April 2013), *supra* note 3 at 12 (Philippe Voyer).

A third area highlighted by researchers and ethicists was the amendment to article 22 CCQ, which allowed research on a deceased person's biological material provided there was "consent of the person who could give or could have given consent to any care required by his state of health." Researchers noted that the amendment would advance personalized medicine in the province by allowing greater access to, and the creation of, DNA databanks²⁹ and tissue banks.³⁰

In the rest of this Part, we evaluate the improvements and missed opportunities in the CCQ amendments, focusing on four key elements particularly relevant to biomedical research: research and care, the notion of "minimal risk," residual use of tissues, and RECs.

A. On research and "care"

A welcome update to the CCQ is the removal of the term "innovative care." Previously, article 21 CCQ stated that "care considered by the ethics committee to be innovative care required by the state of health of the person concerned does not constitute an experiment." The concept of "innovative care" was not only restrictive in application, but also lacking in precision.³¹ The vagueness³² of the term "innovative care" provided RECs with a high degree of discretion with little-to-no guidance,³³ especially concerning the application of specific requirements for research projects to particular interventions. This ambiguity had the potential to reduce much-needed oversight, and to increase risks to participant health and safety.

²⁹ See *CSSS Debates* (25 April 2013), *supra* note 27 at 11, 17 (Rémi Quirion).

³⁰ *Ibid* at 24 (Serge Rivest).

³¹ Robert P Kouri & Suzanne Philips-Nootens, "L'« expérimentation » et les « soins innovateurs » : l'article 21 CCQ et les affres de l'imprécision" (1996-97) 27:1-2 RDUS 89.

³² Robert P Kouri, "Observations concernant certains changements apportés au Code civil par la Loi modifiant le Code civil et d'autres dispositions législatives en matière de recherche", Comment, (2012-13) 43:3 RDUS 867.

³³ Suzanne Philips-Nootens, Pauline Lesage-Jarjoura & Robert P Kouri, *Éléments de responsabilité civile médicale : Le droit dans le quotidien de la médecine*, 3rd ed (Cowansville, Que: Yvon Blais, 2007) at para 247.

Yet, given the recent changes to the CCQ, it is a wonder that “research” did not merit its own section, but rather was subsumed under a vaguely defined section for “care.” According to article 11 CCQ, “care” is subject to a number of interpretations, including “examination, specimen taking, removal of tissue, treatment or any other act.” While one could conceive of “clinical care” as being one example of “care,” it is clear that most of the procedures enumerated in article 11 CCQ relate to interventions usually undertaken in a clinical care setting.³⁴ That said, research would fall under the final sweeping category of “any other act.” This classification is inadequate, since research has often been defined as “a scientific activity directed to the advancement and systemization of knowledge”³⁵ that “offers no therapeutic benefit to the patient.”³⁶ While there is often a fine line between research and clinical care, equating these two concepts under the general umbrella of “care” can create problems both in fact and in law, especially if the researcher is also a clinician.³⁷

In point of fact, the duties of physicians and of researchers are theoretically and practically distinct. This distinction arises from fundamental differ-

³⁴ “Treatment” is an example of an intervention done in the clinical care setting that is fundamentally different from research. According to the Law Reform Commission of Canada,

[T]reatment or therapy is the opposite of research in the following three ways. First, its aim is to cure an individual’s illness or disease and it can only be measured in terms of the patient’s interests. Second, it is administered on the basis of individual needs not according to a predetermined protocol. Finally, and perhaps most important, the therapist’s role is quite different from the researcher’s; the objective being not to increase scientific knowledge but to cure the patient or relieve suffering. The therapist’s loyalty is to the patient and a fiduciary relationship is implicitly established as an integral part of the process.

(Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects*, Working Paper 61 (Ottawa: Law Reform Commission of Canada, 1989) at 4.)

³⁵ *Ibid.*

³⁶ Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Carswell, 2007) at 102.

³⁷ Ma’n H Zawati, “Liability and the Legal Duty to Inform in Research” in Yann Joly & Bartha Maria Knoppers, eds, *Routledge Handbook of Medical Law and Ethics* (London, UK: Routledge, 2015) 199 at 212-13.

ences between the overall aims of research and of clinical care.³⁸ While the former seeks to produce generalizable results, the latter seeks to benefit individual patients.³⁹ Obligations in medical research must reflect these differences and dispel any therapeutic misconception⁴⁰ whereby a “research subject ... inaccurately attributes therapeutic intent to research procedures.”⁴¹

Consider the context of genomic research, where the potential of discovering health-related findings of clinical significance to research participants is becoming ever more prevalent.⁴² Large-scale human genomic research has been made possible by powerful technologies such as genomic microarrays, scanning technologies, and other research instruments that generate massive amounts of information.⁴³ The issue of how to handle these findings is not only topical, but also increasingly challenging for researchers. Is there an obligation to return individual research findings to participants? If findings were discovered during the course of a research project, would their return increase the likelihood of therapeutic misconception? While the concept of “care” is generally associated with therapeutic benefit,⁴⁴ many biomedical research projects are non-therapeutic in nature. Biomedical research projects are becoming increasingly observational, such that no drugs

³⁸ Gail E Henderson et al, “Clinical Trials and Medical Care: Defining the Therapeutic Misconception” (2007) 4:11 PLoS Med 1735 at 1736.

³⁹ Franklin G Miller & Howard Brody, “A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials” (2003) 33:3 Hastings Cent Rep 19 at 21.

⁴⁰ Inmaculada de Melo-Martin & Anita Ho, “Beyond Informed Consent: The Therapeutic Misconception and Trust” (2008) 34:2 J Med Ethics 202.

⁴¹ Charles W Lidz & Paul S Appelbaum, “The Therapeutic Misconception: Problems and Solutions” (2002) 40:9 Med Care V-55 at V-55.

⁴² Mildred K Cho, “Understanding Incidental Findings in the Context of Genetics and Genomics” (2008) 36:2 JL Med & Ethics 280.

⁴³ Susan M Wolf et al, “Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations” (2008) 36:2 JL Med & Ethics 219.

⁴⁴ According to the Belmont Report, “[t]he term ‘benefit’ is used in the research context to refer to something of positive value related to health or welfare. Unlike ‘risk,’ ‘benefit’ is not a term that expresses probabilities.” US, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, DHEW Publication No (OS) 78-0012 (Washington, DC: Government Printing Office, 1978) at 15.

are administered and toxicity is not assessed.⁴⁵ Accordingly, the legal classification of these projects as “care” is not only misleading but in fact fundamentally inaccurate. In Bill 30, the legislator failed to disassociate research from care, and to dissipate this persistent confusion once and for all.

B. Minimal risk

Bill 30 introduces the notion of minimal risk to Québec’s legislative regime on research ethics. Where the research risks to participants are only minimal, there are now two situations in which the burden on researchers to obtain participants’ consent is reduced. First, if a “competent” REC has determined that “the circumstances justify it,”⁴⁶ a minor 14 years of age or over may consent alone, without the need to obtain additional consent from the minor’s guardian or tutor. Second, if a “competent” REC has determined that a research project “meets the prescribed requirements,” an adult who is incapable of giving consent may now have consent given on their behalf by the appropriate surrogate decision-maker (often a family member), but only when the adult does not already have a court-appointed guardian.⁴⁷

⁴⁵ Canadian courts have yet to adjudicate on cases relating to longitudinal observational research, such as biobanks for example. See Ma’n H Zawati, “There Will Be Sharing: Population Biobanks, the Duty to Inform and the Limitations of the Individualistic Conception of Autonomy” (2014) 21 Health LJ 97 at 118 [Zawati, “There Will Be Sharing”].

⁴⁶ Art 21, para 5 CCQ. The Minister’s comments specify that the circumstances in question are “situations where it would be difficult or undesirable to obtain the parent’s consent,” presumably such as where the effort in obtaining consent would be grossly disproportionate to the risks, or perhaps in consideration of the child’s privacy rights. See Ministère de la santé et des services sociaux (Ministry of Health and Social Services), “Modifications législatives – recherche”, online: MSSS <<http://ethique.msss.gouv.qc.ca/lethique-en-bref/modifications-legislatives.html>> [Ministère de la santé et des services sociaux, “Modifications législatives”].

⁴⁷ Bill 30 provides that “consent may be given by the person qualified to consent to any care required by the state of health of the person of full age” (art 21, para 6 CCQ). This provision still allows, as it did prior to Bill 30, this form of consent to be used even where there are more than minimal risks when an adult “suddenly becomes incapable of giving consent and the research, insofar as it must be undertaken promptly after the appearance of the condition giving rise to it, does not permit, for lack of time, the designation of a legal representative” (*ibid*).

How should “competent” RECs determine whether a proposed research project poses only minimal risk in order to decide whether these less onerous consent procedures are permissible? Looking to the intent of the National Assembly, Minister Hébert stated that minimal risk was “well defined, notably by the policy statement of the three Canadian funding councils” (i.e., the *TCPS*).⁴⁸ The *TCPS* defines minimal risk research as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of *their everyday life* that relate to the research.”⁴⁹

Yet the notion of minimal risk has made legal scholars uneasy.⁵⁰ Minimal risk in the *TCPS* has been criticized primarily for being overbroad.⁵¹ The *TCPS* uses minimal risk for three significantly different purposes – each of which has its own underlying rationale – and thus conflates determinations of:

⁴⁸ *CSSS Debates* (24 April 2013), *supra* note 3 at 1 [translated by authors]. Similarly, Professor Robert Kouri states that prior to Bill 30, “the notion of minimal risk was [already] well known” (Kouri, *supra* note 32 at 879 [translated by authors]).

⁴⁹ *TCPS*, *supra* note 23 at 22 [emphasis added]. The United States’ Common Rule’s definition of minimal risk extends beyond risks “ordinarily encountered in daily life,” and explicitly also includes those “ordinarily encountered ... during the performance of routine physical or psychological examinations or tests” (*Protection of Human Subjects*, 45 CFR §46.102(i) (2009)). Loretta Kopelman observes that clinicians regularly encounter “highly sensitive information in routine examinations and testing, including data about family assaults, substance abuse, or sexual preference,” which can result in significant consequences (in “Children as Research Subjects: A Dilemma” (2000) 25:6 *J Med Philos* 745 at 751).

⁵⁰ In particular, minimal risk’s “role in the regulation of large-scale biobank and cohort research is unsettled” (Timothy Caulfield & Charles Weijer, “Minimal Risk and Large-Scale Biobank and Cohort Research” (2009) 17:2-3 *Health L Rev* 53 at 53).

⁵¹ See e.g. Lynette Reid & Timothy Krahn, “Minimal Risk in the *Tri-Council Policy Statement*” (2007) 15 *Health LJ* 469; Caulfield & Weijer, *supra* note 50 at 54.

- (1) whether to allow an REC to undertake a simplified research review evaluation for a given project;⁵²
- (2) whether to allow the researcher to deviate from the usual approach to consent;⁵³ and
- (3) whether to allow a person to participate at all, in certain circumstances.⁵⁴

Bill 30 helpfully separates these three determinations, and uses minimal risk only to determine when less onerous requirements in the consent process are permissible (i.e., the second determination above), such as requiring solely the consent of a minor of at least 14 years of age, rather than consent from a guardian or tutor as well as assent from the minor, no matter their (adolescent) age.

For the other two tasks, Bill 30 relies instead on the potential of the research to “interfere with the [participant’s] integrity” to determine when formalized ethics review by a REC is required. Protection against interference with one’s integrity is a central concept in the CCQ, evidenced in part by the name and location of the chapter in which the relevant CCQ provisions are situated (Book One, Chapter 1: Integrity of the Person). Integrity, which denotes soundness, wholeness, and protection from any wrongful interference with one’s physical, psychological, and emotional well-being, is linked to personality rights, as seen in article 3 CCQ (“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 article 10 CCQ (“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.”).

As for barring research participation outright, the CCQ amendments eliminate the previous limiting criterion of “serious risk”⁵⁵ and instead intro-

⁵² See *TCPS*, *supra* note 23 (“[m]inimal risk research should normally receive delegated review and above-minimal risk research shall receive full RE[C] review” at 23).

⁵³ See *ibid* (“Alterations to Consent Requirements” at 35).

⁵⁴ See *ibid* (for “individuals who lack capacity to consent,” researchers must demonstrate that their “research does not expose the participants to more than minimal risk without the prospect of direct benefits for them” at 53).

⁵⁵ The former art 21, para 1 CCQ. See Table 1, above.

duce the notion of proportionality – namely that “the risk incurred is not disproportionate to the benefit that can reasonably be anticipated”⁵⁶ – so that it now applies to research participants of all ages and capacities.⁵⁷ The Bill retains the additional protection that research must have the potential to produce benefit for a minor or person of full age incapable of giving consent, yet this protection is itself problematic. The notion of “benefit” in article 21, paragraph 2 CCQ varies with the number of participants: in the case of research on a group, the research must have the potential to produce results capable of conferring benefit on other persons in the same age category or having the same disease or handicap. This gives rise to the strange result that in some circumstances simply adding more research participants allows participation that would otherwise be impermissible.⁵⁸ Moreover, a restriction that the benefit must be possible for the same age category, disease, or handicap is rapidly becoming obsolete with biomedical research discovery. Diagnostic boundaries are disappearing as researchers learn more about the genetic and biological sub-states of disease, and pleiotropic effects of genes often show that the same genes are involved in different health outcomes.⁵⁹

While introducing the notion of minimal risk beneficially lessens some of the otherwise onerous consent process requirements that arose from the previous CCQ provisions, particularly in article 21, the legislator failed to clarify important issues through Bill 30. Aside from the modifications to substitute decision making, Bill 30 is silent on when researchers may devi-

⁵⁶ Art 20 CCQ.

⁵⁷ When the participant is not a competent adult, however, this determination must be made “taking into account his state of health and personal condition” (art 21, para 1 CCQ).

⁵⁸ The *TCPS* adopts the clearer and more sensible rule that “[w]here the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong” (*supra* note 23 at 53). The apparent incoherence of the CCQ in this respect is significant enough to raise doubts about whether the legislative intent was not to adopt the same rule as the *TCPS*, although the legislative committee that drafted Bill 30 did hear at least one submission that raised this issue. See CGP, *Mémoire*, *supra* note 24 at 7.

⁵⁹ Pleiotropy describes the state when one gene influences multiple, seemingly unrelated phenotypic traits. See Shanya Sivakumaran et al, “Abundant Pleiotropy in Human Complex Diseases and Traits” (2011) 89:5 *Am J Hum Genet* 607 at 608. We thank Dr. Jennifer R Harris of the Norwegian Institute of Public Health for this observation about disappearing diagnostic boundaries.

ate from standard consent principles, for example, by allowing participants to waive fresh (i.e. new) consent for the purposes of secondary research. There is consensus in the research and medical legal community that contemporary biomedical research warrants (renewed) consent to be waived or made “broad” in certain circumstances where risks are minimal,⁶⁰ particularly in biobanking, data-driven genomic studies, and observational studies. Yet the CCQ gives no indication as to what is minimal, and therefore as to when such waiver of consent is possible.

This lack of clarification opens the door to several challenging questions. Can the risks involved in biobank and genomic research, which are largely psychosocial, be considered “minimal” so as to allow a researcher to deviate from the usual approach to consent? For research making use of personally identifiable biomedical data, can the risks ever be minimal in the absence of anonymity, and where they are not, what technical standards must the anonymizing techniques satisfy to achieve minimal risk? The legislator was undoubtedly wise to forgo answering these questions via detailed provisions in the *Civil Code*, which in keeping with the civil law tradition, is primarily rules- or principles-driven; however, it should not have failed to offer RECs guidance on the matter at all.

The result is that RECs are now left on their own to resolve the deep tension in the bioethics and legal scholarship on minimal risk – specifically, is risk to be determined according to an absolute or a relative standard? Exposing someone to a risk that is serious in absolute terms, such as brain surgery, might still be considered minimal if that person’s everyday life already involves serious risk, for example if a chronic health prob-

⁶⁰ See e.g. UNESCO, International Bioethics Committee (Sylvia Rumball & Alexander McCall Smith, Rapporteurs), “Human Genetic Data: Preliminary Study by the IBC on Its Collection, Processing, Storage and Use”, SHS-503/01/CIB-8/3 (Rev.2) (15 May 2002) at para 50 (“[a] system which required fresh consent would be extremely cumbersome and could seriously inhibit research”). See also Bernice S Elger & Arthur L Caplan, “Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework” (2006) 7:7 EMBO Rep 661; Kristin Solum Steinsbekk, Bjørn Kåre Myskja & Berge Solberg, “Broad Consent versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?” (2013) 21:9 Eur J Hum Genet 897; Gert Helgesson, “In Defense of Broad Consent” (2012) 21:1 Camb Q Healthc Ethics 40.

lem means that dangerous treatment is routine in their life.⁶¹ While courts and scholars tend to prefer the absolute standard,⁶² commentators usually view the *TCPS* definition as explicitly adopting the relative standard.⁶³

Bill 30's introduction of less onerous consent procedures for situations where risks are minimal in an absolute sense is welcome and was necessary to avoid creating "therapeutic orphans"⁶⁴ by inappropriately excluding potential participants. For example, this change should better ensure robust Alzheimer's disease research in Québec.⁶⁵ But the lack of clarity in article 21 CCQ on the *standard* for minimal risk is unfortunate. The *TCPS*, despite apparently adopting the relative standard in general, also explicitly provides that

[i]n their *assessment* of the acceptable threshold of *minimal risk*, RE[C]s have special ethical obligations to *individuals or groups whose situation or circumstances make them vulner-*

⁶¹ Provided, of course, that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.

⁶² See e.g. Reid & Krahn, *supra* note 51 ("[t]he absolute interpretation ... appears to be endorsed by the courts insofar as they have ruled on the question" at 472); Loretta M Kopelman, "Minimal Risk as an International Ethical Standard in Research" (2004) 29:3 *J Med & Philos* 351 ("the 'relative standard' sets the minimal risk standard as being relative to the everyday risks of a particular person or group.... There are many problems with this 'relativistic interpretation'" at 362).

⁶³ The *TCPS* defines minimal risk in terms of "harms ... encountered by participants in ... *their* everyday life" (*supra* note 23 at 22) [emphasis added]. See also Reid & Krahn, *supra* note 51 (the *TCPS* "persist[s] in asserting a relative standard" at 472).

⁶⁴ See e.g. Harry Shirkey, "Therapeutic Orphans", Editorial Comment (1968) 72:1 *J Pediatr* 119. This type of concern has led to the *TCPS*'s instruction to RECs not to "inappropriately exclude" people having compromised abilities to consent (*supra* note 23 at 53).

⁶⁵ See e.g. *CSSS Debates* (24 April 2013), *supra* note 3 ("all the research projects that include, for example, people with Alzheimer's can't be carried out in Québec because of this Civil Code provision" at 1 (Hon Réjean Hébert) [translated by authors]); Kouri, *supra* note 32 ("the amendments made to article 21 relative to consent are appropriate and respond to advocacy by researchers working in certain fields of specialization, notably geriatrics" at 878 [translated by authors]).

able in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability.⁶⁶

These are precisely the people (individuals or groups) with whom the concept of minimal risk in Bill 30 is concerned. The legitimacy of a fully relative standard for minimal risk in the consent context is thus questionable at best, given the perverse incentives it creates, namely encouraging researchers to seek out already risk-burdened populations to recruit for more risky research studies.⁶⁷ By comparison, the *TCPS* framework includes protections for research participants who lack capacity to consent for themselves that are absent, or at least not explicit, in article 21 CCQ, such as limiting participants' involvement to that which is "necessary and appropriate to address the research question."⁶⁸ Even if the *TCPS* prescribed a relative standard in this context, it is questionable whether the intention of the National Assembly was to adopt such a standard for Bill 30: when the legislative members heard the words "minimal risk," they likely did not have procedures such as invasive brain surgery in mind.⁶⁹

C. *Residual use of tissues*

Article 22 CCQ permits the use of body parts – whether organs, tissues or other substances – retrieved during care for research purposes, provided

⁶⁶ *TCPS*, *supra* note 23 at 22 [emphasis added].

⁶⁷ See Reid & Krahn, *supra* note 51 at 495. See also *ibid* at 491 ("the relative definition of minimal risk treats the same risks as less serious and less worthy of review and oversight for the ill or disadvantaged than for the healthy and advantaged").

⁶⁸ *TCPS*, *supra* note 23 at 53. Prior to Bill 30's amendments, Lynette Reid and Timothy Krahn, observed that this requirement "rules out research being done with such a group for regulatory convenience, as does (by a different mechanism) the Civil Code of Quebec requirement that such research benefit the patient and age group to which the participant belongs" (Reid & Krahn, *supra* note 51 at 495).

⁶⁹ Proponents of the relative standard often claim that it produces a win-win situation by allowing important research to continue while protecting the vulnerable. But because this is achieved "by mislabeling serious risks as minimal," the goal "clearly ... can be achieved in word only, and not in deed" (*ibid* at 512).

that the patient has consented to such use. Bill 30 now adds to the article: “or, if he has died, [his body parts may] be so used with the consent of the person who could give or could have given consent to any care required by his state of health.”⁷⁰ This addition will most likely increase the use of leftover samples in hospitals and from public health surveillance programs.⁷¹ This said, for two reasons, the amended article 22 CCQ falls short of what is needed to successfully steer Québec to twenty-first-century science and health. First, it remains unclear what “care” refers to in this provision. Second, the new addition does not take into consideration the fact that many of these leftover samples are anonymized or that the patients from whom the samples were retrieved are no longer reachable.

Regarding the first limitation, the words “care” and “research” are differentiated in this article. Although this is what we have called for in Part II.A above, the fact that article 11 CCQ largely interprets the term “care” as encompassing “research” creates confusion in the subsequent distinction made between the two terms in article 22 CCQ. While we support such delineation, doing so without a systematic change of the title to the overarching section in the CCQ, as well as the other provisions found therein, is insufficient. It remains unclear whether the residual samples provided from care can also include residual samples from previous research projects. Maximising the use of these samples is important and such puzzling language does not provide proper guidance to researchers or to RECs.

Regarding the second limitation, and perhaps more importantly, article 22 CCQ does not consider the challenges facing researchers in “re-consenting” patients for the secondary use of their samples. This is in no way a repudiation of the concept of free and informed consent, but rather is a call for more flexibility in case it is impossible or impracticable for the research team to recontact these patients. Also, if these samples are not identifiable, will the requirement in article 22 CCQ still apply? On that note, the legislator missed an opportunity to harmonize the CCQ provision with the *TCPS* article on secondary use of identifiable human biological samples, which provides the research community with a more pragmatic approach:

⁷⁰ Art 22 CCQ.

⁷¹ See generally Kouri, *supra* note 32 at 882.

Article 12.3A[:] Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if they have satisfied the REB [research ethics board] that:

- (a) identifiable human biological materials are essential to the research;
- (b) the use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;
- (c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;
- (d) the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;
- (e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and
- (f) the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.

If a researcher satisfies all the conditions in Article 12.3A(a) to (f), the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.⁷²

The approach taken by the *TCPS* offers researchers the needed flexibility to use these identifiable samples, provided ethics approval is given by a REC. Moreover, there is no requirement for researchers to seek consent from patients for the secondary use of non-identifiable biological samples (Article 12.3B).⁷³ By contrast, this specification is not made in article 22 CCQ. As for the term “impracticable,” the *TCPS* explains that it “refers to undue hardship or onerousness that jeopardizes the conduct of the research [and that]

⁷² *TCPS*, *supra* note 23 at 179.

⁷³ *Ibid* at 180.

it does not mean mere inconvenience.”⁷⁴ Indeed, there could be cases where the patient is difficult to locate or where the effort needed to find him or her is unduly onerous. Preventing the use of a patient’s samples because of that reality will continue to create barriers to biomedical research in the future. The legislator should have exercised more openness when revising article 22 CCQ by providing exceptions to the general principle reflected therein.

D. Research ethics committees

The CCQ amendments express a further leap towards legislative endorsement of RECs, tracking the broader parallel expansion of the *TCPS* and, generally, oversight of human subjects research over the past three decades.⁷⁵ First, RECs must now approve and monitor all research involving humans in Québec, irrespective of who is participating, their age, and their ability to consent. The trade-off is that the CCQ provisions on research are now qualified such that they apply only to “research that could interfere with the integrity of [the] person,” seemingly permitting research without REC review for research projects that do not so interfere. Second, RECs may now allow consent to “be given otherwise than in writing” in some situations where this was previously impermissible.⁷⁶ The provision implies that “evidential purposes”⁷⁷ are the primary concern, and leaves it to RECs to determine, in a particular case, whether video, a computer tablet, or any other communication medium will be sufficiently reliable in the particular circumstances.⁷⁸ This vote of confidence in RECs suggests an intent by the

⁷⁴ *Ibid.*

⁷⁵ See e.g. Carol A Heimer & JuLeigh Petty, “Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research” (2012) 6 Annual Review of Law and Social Science 601 (“[t]he regulation of human subject research is a growth industry” at 616; “[c]learly, however, the expansion of regulation also increases demand for the services of IRB professionals” at 617).

⁷⁶ Art 24, para 2 CCQ.

⁷⁷ *Ibid.*

⁷⁸ Consent must still always be given in writing for research involving medication, natural health products, or medical devices, all of which are governed by federal legislation. Written informed consent is required by several regulations adopted pursuant to the *Food and Drugs Act*, RSC 1985, c F-27, for example the *Food and Drug Regulations*, CRC, c 870, s C.05.010(h) (clinical drug trials), *Medical Devices Regulations*, SOR/98-282, s 81(k)(ii) (investi-

legislator to grant significant deference to REC determinations made within its members' fields of expertise.

The CCQ also now references two distinct types of RECs, although the text of Bill 30 is unhelpful in making this clear.⁷⁹ Those formed or approved by the Minister of Health and Social Services have exclusive competence in respect of research involving persons who cannot consent on their own,⁸⁰ while research that involves only competent adults may be overseen by RECs not so approved.⁸¹ On the one hand, the creation of non-ministerially approved RECs beneficially increases regulatory leniency. On the other hand, aside from the formal difference of ministerial approval, it is not yet clear whether these two types of RECs will be held to different standards, for example with respect to REC member expertise regarding research participants unable to consent on their own or to methodological rigour. As Bill 30 provides no guidance regarding the structure and functioning of RECs, regrettably it remains an open question whether it has created a two-tiered

gational testing using medical devices), and *Natural Health Products Regulations*, SOR/2003-196, s 74(h) (natural health product clinical trials). Further, consent still cannot be given before other determinations, such as the relationship between risks and benefits, have been made. See *Parent c Maziade*, [1998] RJQ 1444 at 1457, 80 ACWS (3d) 649 (CA):

Article 20 C.C.Q. provides that a person may submit themselves to an experiment 'provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.' In the context of experimentation, the patient's consent is thus insufficient. Consent can in fact neither be solicited nor obtained until after the risk/benefit relationship has been taken into consideration. It is not until after this evaluation that the researcher may contemplate proceeding with the experiment and obtaining consent from the research subjects [translated by authors].

⁷⁹ The position is clarified by the Ministry's comments on the amendments, which specify that in art 20 CCQ, "[t]he law does not require that this is an REC designated by the Minister of Health and Social Services, in contrast with what is required for research involving minors or incompetent majors" (Ministère de la santé et des services sociaux (Ministry of Health and Social Services), "Modifications législatives", *supra* note 46 [translated by authors]). It may be that the inconsistent presence of the adjective "competent" before "research ethics committee" in Bill 30 was intended to convey the distinction.

⁸⁰ See art 21, para 4 CCQ.

⁸¹ See art 20 CCQ. This same distinction is likely thus implied in the reference to RECs in art 24, para 2 CCQ.

system of RECs.⁸² Indeed, one is left wondering if ministerially approved RECs provide more protection than a “normal” REC, which would govern most biomedical research conducted in Québec.⁸³

Moreover, one wonders whether the legislator has now bestowed too much deference on RECs and faith in REC members. There is an open question as to whether RECs possess the breadth and depth of expertise necessary to adequately deliberate on the panoply of contemporary, complex biomedical research issues.⁸⁴ Indeed, an emerging trend in jurisdictions outside Canada has been to defer specific research ethics issues to specialized committees composed of individuals with expertise in a given domain, while RECs remain the locus for general review of research protocols and consent forms.⁸⁵ While this possibility remains in Québec, Bill 30's clear endorse-

⁸² Or, if there remains a role for RECs in research that does not interfere with participants' integrity, perhaps even a three-tiered system.

⁸³ The website of the Ministère de la santé et des services sociaux (Ministry of Health and Social Services) explains that “[t]he composition and function of the [non-ministerially approved] REC must comply with the rules set out in the *Tri-Council Policy Statement*, Health Canada or any other organization, if any” (Ministère de la santé et des services sociaux, “Modifications législatives”, *supra* note 46 [translated by authors]). The “if any” qualification to this statement suggests that not all non-ministerially approved RECs in Québec are obligated to follow formalized research ethics rules. This is understandable, given that research protocols must satisfy the criteria of the relevant regulatory or normative documents/bodies.

⁸⁴ Edward S Dove, Bartha M Knoppers & Ma'n H Zawati, “Towards an Ethics Safe Harbor for Global Biomedical Research” (2014) 1:1 *J Law Biosci* 3 (“[e]ven as [REC]s are becoming professionalized, a recurring complaint is that members lack knowledge of formal guidelines or regulations specific to the domain of the project they are charged with applying, thereby leading to haphazard outcomes” at 17). See also James A Anderson et al, “Research Ethics Broadly Writ: Beyond REB Review” (2011) 19:3 *Health L Rev* 12 (“REBs are also hampered by a chronic lack of resources, including significant informational shortfalls” at 19).

⁸⁵ See e.g. Ingrid A Holm et al, “Guidelines for Return of Research Results from Pediatric Genomic Studies: Deliberations of the Boston Children's Hospital Gene Partnership Informed Cohort Oversight Board” (2014) 16:7 *Genet Med* 547. Holm et al discuss the creation of the Gene Partnership Informed Cohort Oversight Board at Boston Children's Hospital (ICOB). ICOB is a body separate from, but endorsed by, the hospital's Institutional Review Board (IRB) focusing on providing accurate and comprehensible individual results that arise

ment of RECs alone will make this more difficult to achieve. Consequently, the expansion of REC powers is likely to be accompanied first by a heightening of the legal duties owed to researchers and research participants,⁸⁶ and second by more frequent judicial review of decisions, which in turn entails increased scrutiny according to the principles of administrative law such as the rights of independence and procedural fairness.⁸⁷

Lastly, it is important to note that Bill 30 retains in article 21 CCQ the previously existing right for minors and incapable adults to refuse participation in research, which is a right held by everyone who “understands the nature and consequences of the research and objects to participating in it.”⁸⁸ Professor Robert Kouri has noted that the *a contrario* interpretation of this formulation undermines the principle that the more vulnerable a person, the greater the protection they merit. The only people with no right to object to research participation are precisely those most in need of protection: those who are *unable* to understand the nature and consequences of the research.⁸⁹ Whether this provision amounts to a legislative oversight or an attempt to remain faithful to the fiction of substituted consent, it is ethically wrong that the current legislative approach allows a person, despite his or her objec-

in the course of genomic biobank research and other large genomics studies results in accordance with participant preferences in a manner that minimizes harm.

⁸⁶ This duty is suggested by art 21 CCQ, para 6 (“it is incumbent upon the competent research ethics committee to determine, when evaluating the research project, whether it meets the prescribed requirements”). See generally Michael Hadskis & Peter Carver, “The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards” (2005) 13:2-3 Health L Rev 19.

⁸⁷ See e.g. Hadskis & Carver, *ibid.*

⁸⁸ Art 21, para 3 CCQ, which previously appeared in slightly different wording in art 21, para 1 CCQ. Although this provision applies only to those unable to consent, for competent adults the right to refuse is simply another way of saying they can consent on their own, which is provided for in art 20 CCQ.

⁸⁹ The provision confers an exclusive “right of veto to incompetent participants (and minors) who are able to understand the nature and the consequences of the research. But if the person is unable to appreciate the elements of the investigation, logically that person can never exercise this veto. So the more ‘incompetent’ a person is, the less they are protected!” (Kouri, *supra* note 32 at 879 [translated by authors]).

tion, to be submitted to an experiment⁹⁰ when the research has no potential to result in benefits for that specific person.⁹¹ From an ethical standpoint, refusal by minors or incapable adults to participate in research that is not intended to specifically benefit them must be respected, regardless of their ability to understand the nature and consequences of the research. Unless there is clear justification for ignoring the individual's objection, the same principle should hold true for research that could still result in benefits for the individual. This ongoing gap in protection might be taken as support for Letendre and Lanctôt's provocative suggestion that the success of Québec RECs in avoiding controversy is attributable less to the regime itself – which they suggest is incoherent and full of gaps – than to the vigilance and good character of REC members.⁹²

CONCLUSION

Overall, Bill 30 improves Québec's research ethics environment and better situates the province within the global research ethics regulatory ecosystem. By replacing the concept of serious risk with proportionality, reducing requirements in consent procedures for minors over 14 years of age and adults incapable of giving consent through the concept of minimal risk, replacing "experiment" with "research," and specifying the rules governing consent for residual use of tissues for research, the legislator has placed Québec within a modern biomedical research environment. Beneficially, the province is now more suited for international biomedical research collaboration.

⁹⁰ It seems more appropriate here to use the language that was previously found in art 21 CCQ, rather than to say that the person would be "participating in research."

⁹¹ Although this concern may initially appear to be addressed by the law's requirement that research must have the potential to produce benefits when it involves people unable to consent on their own, note that the CCQ defines benefits to include those to third parties, namely "the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap" (art 21, para 2).

⁹² See Martin Letendre & Sébastien Lanctôt, "Le cadre juridique régissant la relation entre le chercheur et le sujet de recherche : la sécurité conférée par le droit canadien et le droit québécois est-elle illusoire ?" (2007) 48:4 C de D 579.

However, as we have noted in this legislative comment, several shortcomings emerge from Bill 30, and further work will be required to truly steer Québec towards twenty-first-century science and health. The conflation of “research” with vaguely defined “care” (combined with the subsequently unclear distinction of the two in article 22 CCQ), the lack of clarity as to when researchers may deviate from standard consent principles more broadly during the consent process, the failure to consider the limitations facing researchers in re-consenting patients for the secondary use of their samples, and the questionable amplified deference given to RECs – not to mention the possibility of a two-tiered system of RECs (both those that are ministerially approved and those not) – all lead to questions about research ethics governance in Québec that transcend Bill 30.

If a theme emerges from our criticisms, it is that biomedical research, and genomic research in particular, is no longer staying local, and that law is limited in its ability to regulate dynamic biomedical research practices. Increasingly, twenty-first-century biomedical research is global, collaborative, data-rich, and longitudinal. Consequently, it begs assessment of fundamental research ethics governance structures. Cosmetic changes alone do not suffice.

Consider the role of RECs for international, multi-site research projects. Should we continue to rely on a siloed research ethics review process for internationally collaborative data-driven research, leading to contradiction and duplication, or can we imagine a kind of ethics review equivalency model that harmonizes research ethics review governance, allowing for mutual recognition of such review across the globe?⁹³ Consider also the continuing fixation on the individualistic conception of autonomy. Should we

⁹³ Dove, Knoppers & Zawati, *supra* note 84. We note that the Ministère de la santé et des services sociaux (Ministry of Health and Social Services) has announced a new streamlined ethics review process for multi-centre research trials conducted in Québec, gradually taking effect from 1 December 2014. As of now, the new process will affect research conducted only within and between Québec’s four integrated university health networks (*réseaux universitaires intégrés de santé*): RUIS McGill, RUIS Montréal, RUIS Laval, and RUIS Sherbrooke. The purpose is to enable a research project that is conducted in more than one location in a network (or networks) to undergo a single research ethics assessment that will be recognized by the other institutions involved. See Ministère de la santé et des services sociaux, “Nouvelles modalités de reconnaissance”, online: MSSS <<http://ethique.msss.gouv.qc.ca/lethique-de-la-recherche/recherche-multicentrique/nouvelles-modalites-de-reconnaissance.html>>.

continue to apply a restrictive unilateral interpretation of autonomy where “rights” tend to be claimed “without any sense of reciprocal obligations”?⁹⁴ Such an approach puts health professionals in a position where they no longer rely on logical or rational persuasion characterized by the use of facts and rationality to make their case.⁹⁵ Increasingly, the focus is merely on perfunctorily providing the patient or participant with information.⁹⁶ Is it not time for a complementary principle premised on multilateral respect, trust, and transparency, which imposes fair and balanced duties on professionals by taking into account the type of services they are providing, the multilateral characteristics of their duties, and the nature of the research project?⁹⁷

Given these profound challenges, one may legitimately query whether legislation alone is the best governance tool. Can we envision an alternative avenue for addressing research ethics and for steering Québec to twenty-first-century science and health? While a full discussion is outside the scope of this legislative comment, we believe a paradigm shift is needed in policy-making mechanisms for research ethics governance. It is worth quoting Professor Graeme Laurie at length on this point:

The fact that responsible science is often being conducted against the backdrop of existing legal frameworks and without the need for further specific legal provision speaks volumes. Notwithstanding, it must be recognised that law has played its part in getting us to this stage and in helping to ensure that the science in question is, indeed, responsible. The role of ethical review mechanisms now helps to protect against the worst vagaries of poor science, albeit that this system has come in for much criticism over the years as unduly burdensome, a possible hindrance to research and not necessarily conducive to more ethically robust science.

⁹⁴ Gordon M Stirrat & Robin Gill, “Autonomy in Medical Ethics after O’Neill” (2005) 31:3 *J Med Ethics* 127 at 127.

⁹⁵ Gary Yukl & John W Michel, “Proactive Influence Tactics and Leader Member Exchange” in Chester A Schriesheim & Linda L Neider, eds, *Power and Influence in Organizations: New Empirical and Theoretical Perspectives* (Greenwich, Conn: Information Age Publishing, 2006) 87; Barbara JA Eiser, Arnold R Eiser & Michael A Parmer, “Power of Persuasion: Influence Tactics for Health Care Leaders” (2006) 26:1 *Leadership in Action* 3 at 3.

⁹⁶ Zawati, “There Will Be Sharing”, *supra* note 45.

⁹⁷ *Ibid.*

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This is made worse because ethics committees are put in a position of having to balance ethical reflection with acting as a gatekeeper to research; many of the associated legal architectures further compound the problem by establishing bureaucratic, inspectorate-driven oligarchies of science regulation. The cumulative effect is that we have lost sight of ethics as a means to assist reflection on genuine dilemmas, in favour of a tick-box mentality which – albeit driven by the best of motives – fosters unhealthy suspicion and favours procedure and caution at the expense of real engagement with the issues at hand. Something gets lost in the process, most notably, that the issues are not simply about the protection of research participants’ interests but also about the promotion of core interests and values that are in the public interest.⁹⁸

How can we answer the law’s challenge to both protect research participants and promote the public interests in scientifically sound and ethically robust research? Like Professor Laurie, we think enacting positive change for research ethics requires recognition that first, law “is ... often prescriptive, inflexible, and static (frozen in time and technological capability)” and second, that we “re-imagine[] or recast[] ... law as one of several tools in the governance ‘toolbox’, or one component of the larger governance framework.”⁹⁹ Policy mechanisms are myriad, but those which carry the most potential for success avoid top-down regulation and allow for a multi-disciplinary array of non-traditional publics in the policy-making process. Indeed, engaging more stakeholders in the biomedical research regulatory ecosystem, be they researchers, participants, regulators, funders, or the public *en masse*, to collectively anticipate challenges that might arise and to construct flexible and adaptive systems that respond to changing needs and interests, we posit, may go a long way towards not just steering Québec towards, but bridging it with, twenty-first-century science and health.

⁹⁸ Graeme Laurie, “Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law” (2011) 130:3 *Hum Genet* 347 at 351.

⁹⁹ Shawn HE Harmon, Graeme Laurie & Gill Haddow, “Governing Risk, Engaging Publics and Engendering Trust: New Horizons for Law and Social Science?” (2013) 40:1 *Sci Public Policy* 25 at 28-29.