

# **DATA COLLECTION FROM LEGALLY INCOMPETENT SUBJECTS: A PARADIGM LEGAL AND ETHICAL CHALLENGE FOR POPULATION DATABANKS**

***Tom Archibald\* & Trudo Lemmens\*\****

An earlier version was prepared for the Ethical-Legal-Social Issues Advisory Committee, Canadian Lifelong Health Initiative, Canadian Institutes for Health Research. We thank the Committee members for their comments on earlier drafts. We especially wish to thank Tracey Bailey for her most valuable review and very detailed comments on an earlier draft. Both authors remain responsible for any possible errors.

Background research was funded by Genome Canada through the Ontario Genomics Institute, by Génome Québec, the Ministère du Développement Économique et Régional et de la Recherche du Québec and the Ontario Cancer Research Network, as part of the ARCTIC project (Assessment of Risk for Colorectal Tumors in Canada).

## **Introduction**

This paper reviews the legal and ethical implications of a loss of decision-making capacity by research subjects in long-term studies in Canadian common law provinces.<sup>1</sup> Presently, the most prominent such study in Canada is the Canadian Lifelong Health Initiative (CLLHI), launched in 2001 by the Canadian Institutes for Health Research.<sup>2</sup> The CLLHI aims to conduct large multi-centered longitudinal cohort studies of Canadians. These studies will focus on “the role and interaction of different genetic and environmental exposures involved in the human development and aging processes over

---

\* Tom Archibald, Associate, Heenan Blaikie LLP, Vancouver, British Columbia.

\*\* Trudo Lemmens, Associate Professor, Faculty of Law, University of Toronto, Toronto, Ontario.

1 This article was based on a report submitted to the Canadian Institutes of Health Research. Our mandate was to focus exclusively on the common law provinces. A separate report was prepared focusing on Quebec civil law.

2 Specifically, the CIHR Institute of Human Development, Child and Youth Health.

the life course, the multi-factorial causes and evolution of common diseases, and the utilization of health care services.”<sup>3</sup> In short, the CLLHI will focus on both the beginning and end of life. It will contain a large birth cohort study and a large representative cohort of about 50,000 individuals of 40 years and older. The need for these large cohort studies is that, to truly understand the complex interaction of genetics, environment, and lifestyle on health, it is crucial to follow a large cohort of people for a prolonged period of time.

Canada’s development of the CLLHI is part of a world-wide trend to establish population-based cohort studies and biobanks. Well-known biobanks exist now in Iceland (DeCode Genetics), Estonia, Singapore, and the United Kingdom.<sup>4</sup> In Canada, Québec is the first province to host a large population-based biobank, under the original name CARTaGENE.<sup>5</sup> In 2008, a new biobank project was also launched by a pan-Canadian cancer research consortium, the Canadian Partnership Against Cancer. This new biobank project, the Canadian Partnership for Tomorrow Project, aims at recruiting 300,000 Canadians to study how genetics, environment, lifestyle and behaviour contribute to the development of cancer.<sup>6</sup>

By nature, these large cohort studies are complex and costly. This explains why, after seven years of planning and discussion, studies under the CLLHI are only now, in 2008, scheduled to officially start. One of the significant hurdles in the development of this large cohort study is the need for a long-term commitment of funding. It would not make sense to invest now significantly in the establishment of a cohort study if there is no guarantee that funding to maintain and follow-up the cohort will still be available in 15 years.

---

3 See the website of the initiative: Canadian Institutes of Health Research, “The Canadian Lifelong Health Initiative – A CIHR Cross Cutting Initiative,” online: CIHR <<http://www.cihr-irsc.gc.ca/e/18542.html>>.

4 See Anne Cambon-Thomsen, “Assessing the impact of biobanks” (2003) 34 *Nature Genetics* 25; Lori Luther & Trudo Lemmens, “Human Genetic Data Banks: From Consent to Commercialization, An Overview of Current Concerns and Conundrums” in Horst W. Doelle & Edgar J. DaSilva, eds., *Encyclopedia of Life Support Systems* (Oxford: EOLSS Publishers, 2007), online: EOLSS <<http://www.eolss.net>> [Luther & Lemmens].

5 See CARTaGENE, “Home,” online: CARTaGENE <[http://www.cartagene.qc.ca/index.php?option=com\\_content&task=view&id=2&Itemid=60](http://www.cartagene.qc.ca/index.php?option=com_content&task=view&id=2&Itemid=60)>.

6 See Canadian Partnership Against Cancer, “Home,” online: Canadian Partnership Against Cancer <<http://www.partnershipagainstanccancer.ca/inside.php?lang=EN&ID=127>>.

But financial support is not the only challenge. One of the main difficulties researchers are facing in the context of establishing biobanks is that, unlike research projects that focus on a specific research question and involve short-term involvement of research subjects, population-based long-term research endeavours like the CLLHI are open-ended and require on-going participation. The value of CLLHI research derives precisely from tracking the health conditions of a group of people over their entire lifespan.

These features of the CLLHI create significant challenges with respect to the need to obtain informed consent. Several authors have discussed these dilemmas, describing how truly meaningful consent is difficult to obtain in the context of biobanks.<sup>7</sup> Most articles focus on the difficulty of obtaining consent for future research projects that are not yet defined, and on some of the practical challenges created by strict application of consent procedures, requiring re-consent for any research project that does not fit well with a more general consent obtained. Less attention has been paid to the fact that many of the population-based studies will inevitably encounter the loss of decision making by some subjects. Indeed, the studies that aim at understanding the complex interaction between genes, environment, and disease in an older population will involve people who have lost or who will lose capacity at one point during the study.

Here, then, we explore the legal consequences and ethical challenges of this change in capacity in the Canadian common law provinces. Under what circumstances, we ask, is it legally appropriate and ethically acceptable for researchers to continue studying a person after she has lost capacity? Should researchers continue to intervene and observe the now-incapable subjects, relying on the original consent they signed before losing capacity, or are there legal and ethical problems that may interfere with the research?

After a general review of health care treatment law and health information privacy law, we consider the ethical and legal issues raised in a hypothetical study similar to the CLLHI. In this hypothetical study, researchers seek what we will call, for ease of reference, “physical access” and “infor-

---

7 See e.g. Timothy Caulfield, “Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales” (2007) 18 *King’s Law Journal* 209 [Caulfield]; M. Deschênes *et al.*, “Human genetic research, DNA banking and consent: a question of ‘form?’” (2001) 59 *Clinical Genetics* 221 [Deschênes *et al.*]; and Henry T. Greely, “Informed Consent and Other Ethical Issues in Human Population Genetics” (2001) 35 *Annual Review of Genetics* 785. See also the discussion in Luther & Lemmens, *supra* note 4.

mation access" to the subjects. By "physical access" we mean the physical touching of an individual necessary to assess their health condition. Physical access can involve verbal questioning pertaining to physical/medical indicators as well as low-risk procedures to take bodily fluids. By "information access" we mean accessing or otherwise collecting private health information about a research subject.

Like the CLLHI, our hypothetical study involves the recruitment of a large number of research subjects who are contributing to the establishment of a large-scale biobank, through the donation of samples and through permitting access to health information that relates to them. This biobank and the connection to existing records will be used to conduct a variety of future studies, many still undefined at this point in time. Research participants have signed written consents, while still capable, to both physical and health information access. The consent wording seems to authorize such access even after they have lost capacity. For the sake of clarity, "lose capacity," in our hypothetical, means the subject has lost capacity for decisions about whether to continue to participate in research.

Because of the fundamental open-ended nature of biobank research, it cannot be taken for granted that an initial consent can adequately capture all the different forms of research that will potentially take place in the context of a biobank project. While we acknowledge the arguments that have been made with respect to the possibility of obtaining open consent for future research, and while such open-ended consent may very well be sufficient for many forms of biobank research,<sup>8</sup> it seems fair to state that: 1) problems can arise with respect to the precise nature of the research people consented to when donating a sample; and 2) a solid legal argument can be made in the Canadian legal context that informed consent forms for such open-ended research clash with the common law of informed consent. With respect to the latter, we note the argument that to err on the safe side, a legislative basis for consent to biobank research seems required to avoid problems down the road.<sup>9</sup> Indeed, not only the common law imposes a detailed duty of informed consent in the context of research, which clashes with the nature of biobank research. The informed consent provisions of the influential Tri-Council Policy Statement (TCPS), the research ethics guidelines emanating from the three major Canadian funding agencies, which may also have an

---

8 For an interesting model of open-ended consent, see Deschênes *et al.*, *ibid.*

9 Caulfield, *supra* note 7.

indirect impact on the common law requirement, are clearly hard to reconcile with vague and open-ended consent.<sup>10</sup> The TCPS stresses that detailed information ought to be given to research subjects with respect to the nature of the research project, the risks and benefits, the procedures involved, the duration of the project and the identity of the researcher. In addition, it prescribes that meaningful opportunities ought to be given to research subjects to decide whether or not to continue to participate. For the purpose of this discussion, it is also worth pointing out that the TCPS' provisions related to research involving incompetent people also explicitly emphasize the need to obtain "continued free and informed consent from an appropriately authorized third party."<sup>11</sup> This short discussion suffices to indicate that it may be problematic to rely on one-time consent from a research subject for future research interventions and information access. Our discussion starts from this cautionary approach.

Because the presence or absence of either or both of an advance directive or substitute decision maker changes the particular legal and ethical questions facing researchers, we consider four broad alternative scenarios proceeding from our hypothetical situation. These are:

- I. No substitute decision maker or advance directive;
- II. No substitute decision maker, but advance directive exists;
- III. Substitute decision maker, but no advance directive; and
- IV. Substitute decision maker with advance directive.

Our main conclusion is that researchers may face potential legal challenges in continuing to physically access subjects after they have lost capacity. Depending on the province, researchers may be on a strong legal footing to do so, or they may not. Much of this uncertainty comes from the fact that in most provinces SDMs cannot make decisions regarding the incapable individual's participation in research. It also comes from doubt about the threshold applicability of health care treatment legislation to research-motivated physical access. Also important are legislative provisions in some provinces that preserve the common law in relation to research.

---

10 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* (Ottawa: Government of Canada, 1998) [TCPS] at art. 2.4.

11 *Ibid.* at art. 2.6.

## I. Overview of Ethical Problems with Research on Incapable Subjects

People who lose capacity are, in general, no longer able to exercise their autonomy. One approach to this problem is to fully acknowledge their lack of capacity and give others a wide discretion to act on behalf of the incapable person. This approach will generally also be connected to the idea that people who act on behalf of an incompetent person have to act exclusively for the benefit of that person. The emphasis, then, is on respecting the person's expressed instructions, wishes, or – if neither instructions nor wishes are known – their overall best interests.

When strictly applied, this norm clearly limits the type of research procedures an incapable person can be submitted to. Research ethics guidelines will, for example, emphasize that incompetent adults and children cannot be included in research that exposes them to more than minimal harm unless they can expect direct benefit from the study.<sup>12</sup> But even with this seemingly clear limitation, there is room for a strict or more lenient interpretation of what constitutes minimal harm. When we are dealing with information access, for example, harm will often be more of a “dignitary nature” or relate to the idea that there is some form of invasion of a person's private space. What constitutes minimal harm is also socially and culturally determined. There is, in other words, no clarity around the concept.

There is a clear tendency, both in law and in bioethics, not to rely exclusively on a concept of harm but on substitute decision making. The emphasis on the importance of making advance directives for a variety of situations is a clear expression of the idea that we value the idea that people should have some say over what happens after they have become incompetent. It suggests that we see autonomy as extending beyond the strict temporal borders of capacity. Under this approach, it becomes important to try to understand what the previously competent person would have wanted, had he been able to explicitly make a choice.

One of the important ethical dilemmas is that, regardless of what statements the subject made when signing on to the study, there remains the possibility that the subject would, if still capable, have revoked her consent. Related to this dilemma is the fact that it is rarely, if ever, possible to accurately capture in advanced directives the very concrete events and poten-

---

12 See *infra*.

tial medical complications that can happen when people are incompetent.<sup>13</sup> How, indeed, can we really know now what we would do under specific future circumstances that cannot accurately be predicted? Relatively easy research procedures, such as the testing of hair, saliva, or even blood levels, may not be controversial. But when future research consent is framed in more vague terms, and captures many possible forms of research, it can become a problem.

In addition, as Rebecca Dresser convincingly points out in the context of the debate over advanced directives of people who suffer from Alzheimer's disease: if one adheres to a more complex and fluid view of personhood, one can easily see how interests, desires, even the concept of a valuable life, change over time.<sup>14</sup> The now incompetent person may have different interests, and even different values, than the former competent person who signed the advance directive or consented to future research. This issue should not be seen as a trivial philosophical dilemma. People suffering from Alzheimer's, for example, may have been truly committed to research when still competent, but may suffer significantly from various forms of research which would raise few problems in a competent patient population. They may be extraordinarily stressed by being questioned by researchers, by having blood drawn, and by being submitted to tests such as CT scans— all research procedures the risks of which would have seemed trivial to them while competent.

A very strict approach would be to consider therefore any physical or information access after a subject loses capacity to be problematic or questionable. If a presumption about her wishes is to be made, it must, goes this view, err on the side of withholding or revoking consent. No further physical or perhaps even information access should occur, on this view, unless it is connected to a medical purpose that will directly benefit the subject. Only in those circumstances can we be reasonably confident that the subject would consent, and only in these circumstances can we claim that it is in the incompetent person's best interests. Those who embrace this more stringent approach would likely still make a distinction between physical access and

---

13 For a valuable model of a detailed consent form with many options that enhance individual decision making in the context of genetic data bases, see Deschênes *et al.*, *supra* note 7.

14 Rebecca Dresser, "Precommitment: A Misguided Strategy for Securing Death with Dignity" (2003) 81 Tex. L. Rev. 1823.

information access. The former is clearly more intrusive, as it requires the invasion of a person's physical space, while the latter can often be justified on the basis of the fact that the original gathering of data was based on full informed consent. This approach is also reflected in "consistent use" provisions in privacy statutes, which allow continued use of health information when the new use is in accordance with the original conditions under which information was collected.<sup>15</sup> This reflects a presumption that a person would have consented to such new, but similar use.

SDMs and advance directives create further ethical dilemmas. If personal autonomy is seen as strongly demanding that individuals make their own decisions, then it would seem important to interpret them in a very restrictive way, to limit their application to medically motivated physical and information access where there is no real choice other than to make some kind of decision on behalf of the now incompetent person. They should not be treated like open-ended powers of attorney that allow others to enroll incompetent people in research or other activities that are not immediately connected to their interests. On the other hand, those who strongly value individual autonomy and subscribe to a more stable view of personhood may argue that respecting the individual autonomy of these individuals requires precisely that we try to understand what the now incompetent person would have wanted, on the basis of her explicitly expressed wishes that were directed towards the future. As already mentioned, ethics guidelines take a more cautionary position, and research involving incompetent people is submitted to more serious restrictions than research involving competent people. Yet, they do leave some room for construction of earlier wishes, particularly related to research that may benefit a particular disease group to which a person belongs.

## II. Review of Applicable Law

At the provincial level, two broad legal regimes apply to the loss of capacity during research: (1) the law of health care treatment, and (2) the law of health information privacy. A detailed exhaustive review of these regimes is not the intent of this paper, but a general overview of them is important in understanding many of the legal concerns for researchers discussed below.

We preface the following survey by reiterating that not every rule or principle mentioned exists in legislation in every province. Some provinces,

---

<sup>15</sup> See *infra*.

such as Ontario and Alberta, have very comprehensive legislative regimes for both health care treatment and health information privacy, while others have very minimal regimes. Therefore, this is not an authoritative statement of the law in any particular province. Rather, our survey covers key provisions common to most provinces and particular rules specific to only one or several provinces that nevertheless may be of interest to researchers.

### (a) Health Care Treatment Law

As we use the phrase here, “health care treatment law” consists of a large and complex body of rules found mostly in one or more enactments at the provincial level. It consists of rules about (a) consent and capacity, (b) advance directives, and (c) substitute decision makers. In some provinces, all three types of rules are found in a single enactment. In others, they are divided between two or more enactments.<sup>16</sup>

#### *Law of Consent and Capacity*

The first type of rules in health care treatment law governs when and how health practitioners can administer treatment. In most provinces, these

---

16 ALBERTA: *Personal Directives Act*, R.S.A. 2000, c. P-6 [Alberta PDA], *Dependent Adults Act*, R.S.A. 2000, c. D-11 [Alberta DAA]; BRITISH COLUMBIA: *Adult Guardianship Act*, R.S.B.C. 1996, c. 6 [British Columbia AGA], *Health Care (Consent) and Care Facility (Admission) Act*, R.S.B.C. 1996, c. 181 [British Columbia HCCFA], *Representation Agreement Act*, R.S.B.C. 1996, c. 405 [British Columbia RAA]; MANITOBA: *Health Care Directives Act*, C.C.S.M. c. H27 [Manitoba HCDA], *Vulnerable Persons Living with a Mental Disability Act*, C.C.S.M. c. V90; NEW BRUNSWICK: *Infirm Persons Act*, S.N.B. 2000, c. I-8; NEWFOUNDLAND & LABRADOR: *Advance Health Care Directives Act*, S.N.L. 1995, c. A-4.1 [Newfoundland AHCA]; NOVA SCOTIA: *Hospitals Act*, R.S.N.S. 1989, c. 208 [Nova Scotia Hospitals Act], *Incompetent Persons Act*, R.S.N.S. 1989, c. 218, *Medical Consent Act*, R.S.N.S. 1989, c. 279; ONTARIO: *Health Care Consent Act*, 1996, S.O. 1996, c. 2, Sch. A. [Ontario HCCA], *Substitute Decisions Act*, 1992, S.O. 1992, c. 30 [Ontario SDA]; PRINCE EDWARD ISLAND: *Consent to Treatment and Health Care Directives Act*, R.S.P.E.I. 1988, c. C-17.2 [PEI CTHCDA]; Saskatchewan: *Health Care Directives and Substitute Health Care Decision Makers Act*, S.S. 1997, c. H-0.001 [Saskatchewan SHCDMA]; NORTHWEST TERRITORIES: *Guardianship and Trusteeship Act*, S.N.W.T. 1994, c. 29 [NWT GTA]; NUNAVUT: *Guardianship and Trusteeship Act*, S.N.W.T. 1994, c. 29 [Nunavut GTA]; YUKON: *Care Consent Act*, S.Y. 2003, c. 21, Sch. B. [Yukon CCA].

rules exist in legislation; in those without specific legislation on consent to treatment, the applicable principles derive from the common law. Provincial legislative provisions on capacity and consent protect patients and health practitioners by codifying the precise conditions under which medical treatment is to proceed.

Whether under statute or common law, the starting principle of consent and capacity law is that no treatment can proceed without the free and informed consent of the patient. Such consent, however, cannot be given when a person loses decision-making capacity, so legislation in most provinces sets out circumstances for treatment without the direct consent of the individual. Among these circumstances are the giving of consent by either or both of a substitute decision-maker and instructions in an advance directive.

In most provinces, legislation creates a presumption of capacity.<sup>17</sup> The basic legislative test for capacity requires an understanding of the nature and consequences of the proposed treatment.<sup>18</sup> Most consent legislation also prescribes procedures and criteria for determining capacity. In most provinces, physicians or other health care providers may determine capacity alone or in conjunction with a medical colleague.<sup>19</sup> In Alberta, legislation allows people to name a person (even a non health provider) to assess their capacity, although even in those cases the named person must still consult with a health provider before deciding.<sup>20</sup>

---

17 e.g. British Columbia HCCFA, s. 3(1)(a), Newfoundland AHCD, s. 7(b), Nova Scotia Hospitals Act, s. 56, Ontario HCCA, s. 4(2), Ontario SDA, s. 2(2), PEI CTHCDA, s. 3(1), Nunavut GTA, s. 1.1, NWT GTA, s. 1.1, *supra* note 16.

18 e.g. British Columbia HCCFA, s. 7, Newfoundland AHCD, s. 14, Nova Scotia Hospitals Act, s. 52(2), Ontario HCCA, s. 4(1), PEI CTHCDA, s. 7(1), Saskatchewan SHCDMA, s. 2(1)(b), Nunavut GTA, s. 7(1)(b), NWT GTA, s. 7(1)(b), Yukon CCA, s. 5(e), *supra* note 16.

19 e.g. British Columbia HCCFA, s. 7, Newfoundland AHCD, s. 15, Nova Scotia Hospitals Act, s. 52(1) (by psychiatrist), Ontario HCCA, ss. 17-19 (by provider), PEI CTHCDA, s. 7(1), Yukon CCA, s. 6(1) (by provider), *supra* note 16. In some provinces, legislation provides avenues of review of determinations of incapacity. These appeals are to the courts or to an administrative body such as the Consent and Capacity Board in Ontario, or the Capability and Consent Board in the Yukon Territory.

20 e.g. Alberta PDA, s. 9(2), *supra* note 16.

Most consent legislation affirms that a person may have no capacity in relation to one decision, yet have capacity in relation to another.<sup>21</sup> For instance, a research subject may not be capable regarding a complex and highly risky procedure, but may still be capable regarding a less complex decision about whether to consent to diagnosis and testing. If so, then the subject can give direct consent.

Where the individual regains capacity, and has this declared in accordance with the legislation, it extinguishes the legal powers of both substitute decision makers and the legal effect of any advance directive that had been made. Some individuals may experience fluctuating incapacity. Even if an initial declaration of incapacity is valid, health providers still have a duty to watch the subject closely for any signs that they may have regained capacity. Providers in some provinces also have obligations to reassess the subject if they have a reasonable basis to believe capacity has returned.<sup>22</sup>

### *Law of Advance Directives*

The second type of rules in health care treatment law consists of those on advance directives. In all provinces these rules are entirely legislative. Legislation normally sets out basic conditions for making advance directives, such as minimum age and decision-making capacity. Advance directives take effect upon loss of capacity, and lose effect where capacity is regained, where the directive itself specifies a termination date, or where the directive is destroyed or lost.

Advance directives can appoint a substitute decision maker, give instructions on treatment, or do both. Terms possible in an advance directive can range from specific instructions and directions to broad statements of principles, values and beliefs. Where the advance directive appoints a SDM, that person has full decision-making authority regarding treatment decisions, constrained only by legislation and any instructions contained in the directive. Alternately, where the directive only contains instructions, those instructions may, depending on the province, still bind any guardians or “near relatives” that may act as SDM.

---

21 Such provisions affirm the common law position: e.g. Manitoba HCDA, s. 6(2), Ontario HCCA, s. 15(1)-(2), PEI CTHCDA, s. 7(3)-(4), *supra* note 16.

22 e.g. Alberta PDA, s. 21(1), British Columbia HCCFA, s. 17(2.1), Nova Scotia Hospitals Act, s. 55, *supra* note 16.

Advance directives can be legally binding in different ways. In three provinces, instructions in advance directives are, by operation of law, deemed equivalent to consent by the individual herself.<sup>23</sup> In others, legislation requires SDMs to follow such instructions, if clear and relevant to the decision before them.<sup>24</sup> Where directions are not clear and relevant, however, they can still stand as statements of the individual's wishes, beliefs and values that can guide an SDM.<sup>25</sup>

### *Law of Substitute Decision Makers (SDMs)*

The third area of health care treatment law consists of rules about substitute decision makers: their appointment, powers and duties. As already mentioned, SDMs can acquire their status in different ways. The most common forms are:

- Court-appointed guardians: Usually called “guardians” appointed by courts (or, in Ontario, by an administrative tribunal) to manage all of the individual's affairs, including health care decisions. In some provinces, the legislation governing guardians is separate from (and typically older than) enactments governing SDMs specific to health care decisions. And in those provinces without guardianship legislation, courts still have a common law power to appoint guardians for infirm persons.
- Patient-appointed SDMs: Usually called “substitute decision makers,” “proxies,” or “attorneys for personal care,” these SDMs are appointed by the individual under an advance directive under applicable health care treatment legislation.
- Statutory SDMs: Sometimes called “near relatives” or “temporary SDMs,” these persons acquire their SDM status and rights under legislation, but only in the event that no SDM of the other two

---

23 e.g. Manitoba HCDA, s. 7(1), PEI CTHCDA, s. 24(1), Saskatchewan SHCDMA, s. 5(1), *supra* note 16.

24 e.g. Alberta PDA, s. 14(2), Manitoba HCDA, s. 13, para. 1, Newfoundland AHCDA, s. 12(1)(a), Ontario SDA, s. 47, PEI CTHCDA, s. 13(1)(a), Saskatchewan SHCDMA, s. 21(2), Yukon CCA, s. 20, *supra* note 16.

25 Indeed, legislation in Saskatchewan affirms that an advance directive without specific directions is still to be used as guidance on wishes, beliefs and values. See Saskatchewan SHCDMA, s. 5(2), *supra* note 16.

kinds can be located.<sup>26</sup> Typically, where no other SDM can be found, legislation sets out a list of people (spouse, child, sibling), and assigns SDM powers automatically to the highest-ranked person available who is eligible and willing to act.

Legislation governing SDMs generally prescribes how SDMs are appointed; legislation often prescribes baseline qualifications for SDMs. These include age (18 or older), capacity on the part of the person nominated as SDM, and no conflict of interest with the incapable individual.

In some provinces, health providers have a duty to make a “reasonable effort” to locate a SDM.<sup>27</sup> Should no SDM be found after such efforts, then in some provinces the immediate providers can act as SDM where the treatment is medically necessary. In Newfoundland and Labrador, for example, providers themselves are designated as SDMs if no other near relative can be located. The same applies in Saskatchewan, where providers may do so with a second opinion.<sup>28</sup>

When making decisions, SDMs in most provinces, however they are appointed, must usually follow what for the sake of brevity can be called the “instructions-wishes” analysis. Under this two-step approach, SDMs must first decide in accordance with any clear and relevant instructions in any advance directive that may exist.<sup>29</sup> If the directive contains no instructions, then the SDM must decide in accordance with any express wishes of the individual that are known to her.<sup>30</sup> If such wishes are unknown, the SDM must then decide on the basis of her assessment of the individual’s best

---

26 e.g. Newfoundland AHEDA, s. 10(1), Nova Scotia Hospitals Act, s. 54(2), Ontario HCCA, s. 20(1), PEI CTHEDA, s. 11(1), Saskatchewan SHEDA, s. 15(1), Yukon CCA, s. 12(1), *supra* note 16.

27 e.g. Alberta PDA, s. 19(2)(b)(ii), British Columbia HCCFA, s. 16(4), Newfoundland AHEDA, s. 9(1)(a), PEI CTHEDA, s. 11(2), *supra* note 16.

28 e.g. Newfoundland AHEDA, s. 10(1)(j), Saskatchewan SHEDA, s. 16(4), *supra* note 16.

29 e.g. Alberta PDA, s. 14(2), Manitoba HEDA, s. 13, para. 1, Newfoundland AHEDA, s. 12(1)(a), Ontario SDA, s. 47, PEI CTHEDA, s. 13(1)(a), Saskatchewan SHEDA, s. 21(2), *supra* note 16.

30 e.g. Alberta PDA, s. 14(2)-(3), Manitoba HEDA, s. 13, Newfoundland AHEDA, s. 12(1), PEI CTHEDA, s. 13(1), Saskatchewan SHEDA, s. 12 (“proxies”), 16(3) (“nearest relatives”), Nunavut GTA, s. 12(6), NWT GTA, s. 12(6), Yukon CCA, s. 20, *supra* note 16.

interests. Some provincial legislation defines or sets out mandatory factors for determining “best interests.”<sup>31</sup>

The powers and duties of guardians are defined differently than those of other SDMs. Because they are court-appointed, the court can, unless the provincial statute forbids it, confer upon them a very wide sweep of authority over personal affairs such as property management, housing and social arrangements and the conduct of litigation, in addition to authority over medical treatment decisions. In Alberta, for example, the court appointing the guardian must specify the precise powers of the guardian in its order.<sup>32</sup>

Importantly though, for the purpose of health care treatment decisions, guardians in most provinces are subject to the same duty as other SDMs – meaning the duty to apply the “instructions-wishes” analysis mentioned above. Further, in some provinces, a guardian cannot displace the authority of a patient-appointed SDM on matters contained in an advance directive unless the court specifically orders it. In Alberta, for instance, the court is prohibited from granting a guardian any decision-making powers over matters already held by a SDM under an advance directive unless the court first terminates the SDM’s authority on those matters.<sup>33</sup> However, the guardian is then bound, as was the SDM she supplanted, to follow any instructions in the directive.<sup>34</sup> Similarly, in British Columbia, the appointment of a guardian under the *Adult Guardianship Act* voids any representation agreement made under which the person appointed a SDM.<sup>35</sup>

Legislation in most provinces protects health care providers who rely upon consents given by SDMs, as it also does for providers who rely on instructions in advance directives. Thus, providers are entitled to take either consents or instructions at face value at the time of treatment without risk of liability even if they are subsequently found to be invalid.

Most applicable legislation provides mechanisms for review of SDM decisions.<sup>36</sup> Grounds for review include SDM non-compliance with an advance directive, with prior express wishes, and/or with restrictions in the legisla-

---

31 e.g. British Columbia HCCFA, s. 19(3), Ontario HCCA, s. 21(2)(c), PEI CTHC-DA, s. 13(2), Nunavut GTA, s. 12(7), NWT GTA, s. 12(7), *supra* note 16.

32 Alberta DAA, s. 10(3)(h), *supra* note 16.

33 Alberta DAA, s. 10(2), *supra* note 16.

34 Alberta DAA, s. 19(2), *supra* note 16.

35 British Columbia AGA, s. 14(2), *supra* note 16.

36 e.g. Alberta PDA, s. 25, British Columbia RAA, s. 30(1), Manitoba HCDA, s. 17, Newfoundland AHCD, s. 13, Ontario HCCA, s. 37(1), PEI CTHCDA, s.

tion itself. Depending on the province, complaints are brought to the courts, to administrative agencies like the Ontario Consent and Capacity Review Board, to the Public Guardian's Office, or to the Minister of Health. These bodies usually have wide remedial powers to set aside the SDM's decision, remove the SDM and appoint a new one, and to substitute their own decision for that of the SDM.<sup>37</sup>

## (b) Health Information Privacy Law

The second legal regime applicable to the loss of capacity during research is the law of health information privacy. All provinces protect health information privacy with either general privacy legislation or specialized health information legislation.<sup>38</sup> Most health information privacy legislation applies to "custodians" of health information. Custodians usually include any health care providers or institutions, but can also include a range of non-medical

---

27(1), Saskatchewan SHCDMA, s. 20(1), Nunavut GTA, s. 13(1), NWT GTA, s. 13(1), *supra* note 16.

37 e.g. Alberta PDA, s. 27, British Columbia HCCFA, s. 32, Manitoba HCDA, s. 17(1), Newfoundland AHCD, s. 13, Ontario HCCA, s. 37(4), PEI CTHCDA, s. 27(3), Saskatchewan SHCDMA, s. 20(2), Nunavut GTA, ss. 14(1), 18(4), NWT GTA, ss. 14(1) 18(4), *supra* note 16.

38 ALBERTA: *Health Information Act*, R.S.A. 2000, c. H-5 [Alberta HIA], *Personal Information Protection Act*, S.A. 2003, c. P-6.5, BRITISH COLUMBIA: *Freedom of Information and Protection of Privacy Act*, R.S.B.C. 1996, c. 165 [British Columbia FOIPPA], *Personal Information Protection Act*, S.B.C. 2003, c. 63., MANITOBA: *Personal Health Information Act*, C.C.S.M. c. P33.5 [Manitoba PHIA], NEW BRUNSWICK: *Protection of Personal Information Act*, S.N.B. 1998, c. P-19.1 [New Brunswick PPIA], NEWFOUNDLAND & LABRADOR: *Access to Information and Protection of Privacy Act*, S.N.L. 2002, c. A-1.1 [Newfoundland AIPPA], NOVA SCOTIA: *Freedom of Information and Protection of Privacy Act*, S.N.S. 1993, c. 5 [Nova Scotia FOIPPA], ONTARIO: *Personal Health Information Protection Act*, S.O. 2004, c. 3, Sch. A [Ontario PHIPA], PRINCE EDWARD ISLAND: *Freedom of Information and Protection of Privacy Act*, R.S.P.E.I. 1988, c. F-15.01 [PEI FOIPPA], SASKATCHEWAN: *Health Information Protection Act*, S.S. 1999, c. H-0.021 [Saskatchewan HIPA], NORTHWEST TERRITORIES: *Access to Information and Protection of Privacy Act*, S.N.W.T. 1994, c. 20 [NWT AIPPA], NUNAVUT: *Access to Information and Protection of Privacy Act*, S.N.W.T. 1994, c. 20 [Nunavut AIPPA], YUKON: *Access to Information and Protection of Privacy Act*, R. S. Y. 2002, c. 1 [Yukon AIPPA].

bodies.<sup>39</sup> In some provinces, non-medical personnel are not “custodians” per se, but the legislative rules applicable to disclosure from custodians to non-custodians still govern them. In Ontario, for example, custodians include any non-custodians to whom a custodian discloses health information.<sup>40</sup> Thus, even though not all parties to a research study may be “custodians” properly speaking, the same rules effectively apply to all information sharing within the group.

The most basic rule in health information privacy legislation is that no person may collect, use or disclose health information about an individual without the consent of that individual.<sup>41</sup> At the same time, most health information legislation permits such acts without consent in a range of circumstances. At the same time, though, privacy legislation authorizes the sharing of health information without consent in certain circumstances, such as emergencies, legal proceedings, police investigations, public health crises or on other public interest grounds. As we discuss in more detail below, some provinces’ health information legislation includes research among these circumstances.

Some provinces’ health information legislation prescribe requirements for the validity of consents to the collection, use or disclosure of health information.<sup>42</sup> Further, in some provinces, individuals are not to collect, use or disclose more information than is necessary for the stated purpose of collection, use or disclosure.<sup>43</sup>

---

39 e.g. Alberta HIA, s. 1(1)(f), British Columbia FOIPPA, s. 1, Manitoba PHIA, s. 1, New Brunswick PPIA, s. 1(1)(b), Newfoundland AIPPA, s. 2(g),(k), Nova Scotia FOIPPA, s. 1(ea), Ontario PHIPA, s. 3(1), PEI FOIPPA, s. 1(k), Saskatchewan HIPA, s. 2(t), Nunavut AIPPA, s. 2, NWT AIPPA, s. 2, Yukon AIPPA, s. 3, *supra* note 38.

40 e.g. Ontario PHIPA, s. 7(1)(b)(ii), *supra* note 38.

41 e.g. Alberta HIA, s. 34(1), British Columbia FOIPPA, s. 33.1(b), Manitoba PHIA, s. 22(1)(b), New Brunswick PPIA, Sch. A, 5, Newfoundland AIPPA, s. 39(1)(b), Nova Scotia FOIPPA, s. 27(b), Ontario PHIPA, s. 29(a), PEI FOIPPA, s. 37(1)(c), Saskatchewan HIPA, ss. 5(2)(a), 27(1), Nunavut AIPPA, s. 48(b), NWT AIPPA, s. 48(b), Yukon AIPPA, s. 36(b), *supra* note 38.

42 e.g. Ontario PHIPA, s. 18(1), Saskatchewan HIPA, s. 6(1),(2), *supra* note 38.

43 e.g. Manitoba PHIA, ss. 13(2), 22(3), New Brunswick PPIA, Sch. A, 4, Sch. B, 3.7, Newfoundland AIPPA, s. 38(2), Ontario PHIPA, s. 30(2), Saskatchewan HIPA, s. 23(1), *supra* note 38.

Health information legislation in some provinces allows for “uses consistent” with the purposes set out in an original consent to access information.<sup>44</sup> Some statutes define “consistent purpose,” usually as a purpose with a “reasonable and direct connection” to the original purpose for collection, use or disclosure.<sup>45</sup>

“Consistent Purpose” Provisions in Health Information Privacy Legislation	
Yes	British Columbia, Newfoundland & Labrador, Nova Scotia, Prince Edward Island, Yukon
No	Alberta, Manitoba, New Brunswick, Ontario, Saskatchewan, Nunavut NWT

Though these provisions make it lawful, the basic ethical issue remains as to whether it is appropriate to continue information access for a potentially different research study. That is, is it appropriate to use information for a different purpose, bypassing the need for fresh consent, simply on the grounds of similarity? People may still want to retain that authority even though they would very likely agree with a similar type of use of health information. Indeed, many people may simply attach value to keeping the power to make those decisions for themselves. The process of giving consent, of being recognized as having self-determining power, may be as, if not more, important than the content of the decision itself. Moreover, the determination of what constitutes a “reasonable and direct connection” is not straightforward. What seems directly connected to a previous consent for a researcher may not be perceived as such by the larger public or by the individuals involved. Consistent use is therefore not as obvious as it first seems, even if it can be defended on pragmatic grounds. Indeed, many actions in daily life and in the

---

44 e.g. British Columbia FOIPPA, s. 33.2(a), Newfoundland AIPPA, s. 39(1)(c), Nova Scotia FOIPPA, s. 27(c), PEI FOIPPA, s. 37(1)(b), Saskatchewan HIPA, s. 27(2)(a), Nunavut AIPPA, s. 48(a), NWT AIPPA, s. 48(a), Yukon AIPPA, s. 36(c), *supra* note 38.

45 e.g. British Columbia FOIPPA, s. 34(1), Newfoundland AIPPA, s. 40, Nova Scotia FOIPPA, s. 28, PEI FOIPPA, s. 38, Yukon AIPPA, s. 37, *supra* note 38.

context of health care are based on the construction of what we perceive to be connected to earlier actions to which people consented.

### ***Substitute Decision Maker Provisions***

All health information privacy legislation permits a range of persons to act as SDMs in relation to the collection, use or disclosure of health information.<sup>46</sup> In most legislation, this list includes not only SDMs who act in relation to health care treatment decisions, but also any representatives appointed under non health-related legislation, such as attorneys for property. In some provinces, even a person “with written authorization”<sup>47</sup> can act as SDM in relation to health information. The table on the following page depicts a sampling of the range of SDMs possible for health information decisions in each province.

Generally, health information legislation gives SDMs a wide discretion to “exercise any right or power” of a subject in relation to health information. These rights, of course, include subjects’ rights to refuse and withdraw consent to disclosure and collection of their health information. Beyond this bare empowering provision, health information legislation in most provinces does not address SDMs any further. Two exceptions are Ontario and Alberta, where legislation codifies the specific powers and duties of SDMs.

### ***Common Law of Health Information Privacy***

Although legislation “covers the field” of health information privacy in most provinces, a brief mention of the common law on this point is still useful. To date, Canadian courts have not recognized a freestanding tort of invasion of privacy arising from unauthorized disclosure of health information. However, at common law, health providers generally owe a duty of confidentiality to patients as part of their broader duty of care.<sup>48</sup> There are

---

46 e.g. Alberta HIA, s. 104(1), Manitoba PHIA, s. 60, New Brunswick PPIA, Sch. B, 3.3, Newfoundland AIPPA, s. 65, Nova Scotia FOIPPA, s. 43, Ontario PHIPA, s. 5(2), PEI FOIPPA, s. 71, Saskatchewan HIPA, s. 56, Nunavut AIPPA, s. 52, NWT AIPPA, s. 52, Yukon AIPPA, s. 62, *supra* note 38.

47 e.g. Alberta HIA, s. 104(1)(i), Manitoba PHIA, s. 60, New Brunswick PPIA, Sch. B 3.3 (“or other representative”), Newfoundland AIPPA, s. 65, Nova Scotia FOIPPA, s. 43, Ontario PHIPA, s. 5(2), PEI FOIPPA, s. 71, Saskatchewan HIPA, s. 56, Nunavut AIPPA, s. 52, NWT AIPPA, s. 52, Yukon AIPPA, s. 62, *supra* note 38.

48 *Halls v. Mitchell*, [1928] S.C.R. 125; *McInerney v. MacDonald*, [1992] 2 S.C.R. 138, 93 D.L.R. (4<sup>th</sup>) 415.

Persons Eligible as SDMs Under Health Information Privacy Legislation	
Guardians under vulnerable persons legislation, agents, attorneys (under powers of attorney), “any person” with written authorization.	Alberta, Newfoundland & Labrador, Nova Scotia, Prince Edward Island, Nunavut, NWT, Yukon
Proxies, mental health legislation committees, SDM under vulnerable persons legislation, “any person” with written authorization.	Manitoba
Parents, guardians, or “other representatives” in “appropriate circumstances”.	New Brunswick
Same persons eligible as SDMs for personal care.	Ontario
“another person” designated in writing.	Saskatchewan

no special exceptions to this duty in relation to research, as found in legislation. Breach of this duty can give rise to liability for negligence, where the disclosure leads to damages. It can also be framed as an action for breach of contract between the physician and patient, wherein the duty of confidentiality formed an implied term of the contract.<sup>49</sup>

At common law, unauthorized disclosure to researchers may also found a claim against the provider for breach of fiduciary duties, following the *dicta* of the Supreme Court of Canada in the 1995 *McInerney v. McDonald* decision. In dealing with a patient demanding access to her medical records, the Court in *McInerney* characterized the physician-patient relationship as a fiduciary relationship, in which the patient entrusts information with an expectation

---

49 *Peters-Brown v. Regina District Health Board*, [1996] 1 W.W.R. 337, 26 C.C.L.T. (2d) 316 [Sask. Q.B.].

of confidence. Although US case law seems to make a fundamental distinction between the doctor-patient relation and the researcher-research subject relation,<sup>50</sup> strong arguments have been made in favour of characterizing the researcher-research subject relation as a fiduciary relation.<sup>51</sup> The law of fiduciary duties is also much more developed in Canada as a separate doctrine than in the United States or in other common law countries such as Australia, making it more likely that a Canadian court would characterize these relations as fiduciary.

### III. Legal Highlights for Researchers

Before analyzing the ethical and legal position of researchers in hypothetical scenarios, we should first highlight three key legal points for researchers, depending on the particular province(s) in which our hypothetical occurs.

#### (a) SDM Research Restrictions

The first major point for researchers is that in some provinces, legislation prohibits SDMs from giving consent to research-related acts.<sup>52</sup> In some provinces, this prohibition specifically forbids consent to experimental medical

---

50 Contrast *Moore v. Regents of the University of California*, 793 2.Pd 479 (Cal. 1990), with *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp. 2<sup>d</sup> 1064 (S.D. Fla., 2003) [*Greenberg*]. The difference between both cases is that no traditional doctor-patient relation was attached to interactions between researchers and subjects in the Canavan case. Canadian law of fiduciary duties recognizes different forms of fiduciary relations: in situations where there is a significant power difference in the relation between two parties, in which one party fundamentally relies on the fact that the other party will exercise her significant knowledge and expertise in her best interest, and where there is a relation of trust between the two parties. This seems to have been the case in the context of the *Greenberg* case, where there was a long-standing relation of trust between the researcher and the families involved in the study, and a significant reliance by the family members on the fact that the researcher was acting in their best interest. Under Canadian law, the specific situation in this case would seem to satisfy the criteria for the existence of a fiduciary relation.

51 See Paul B. Miller & Charles Weijer, "Fiduciary Obligation in Clinical Research" (2006) 34 J.L. Med. & Ethics 424.

52 e.g. Alberta PDA, s. 15(2)(c)(ii),(d), British Columbia HCCFA, s. 18(1), RAA, s. 9(1)(d), Manitoba HCDA, s. 14(a),(c)(ii), Newfoundland AHCD, s.

treatment and tissue removal for research purposes.<sup>53</sup> In others, the ban extends further to forbid consent to “participation” in research generally,<sup>54</sup> or to the making of any decision relating to research participation.<sup>55</sup>

Research Participation Restrictions on SDM Decisions	
any procedure for research purpose	Prince Edward Island
tissue removal, participation in research	Alberta
tissue removal, participation in non-approved research	British Columbia, Yukon
tissue removal, experimental medical treatment	Manitoba, Newfoundland & Labrador
tissue removal	Nunavut, NWT
None	New Brunswick, Nova Scotia, Ontario, Saskatchewan

In most provinces, however, these prohibitions can be overcome when an advance directive gives clear and unambiguous instructions that permit the SDM to give such consent.<sup>56</sup>

---

s. 5(3)(a),(c), PEI CTHCDA, s. 12(a), Nunavut GTA, s. 1(1)(d), NWT GTA, s. 1(1)(d), *supra* note 16.

53 e.g. Manitoba HCDA, s. 14(a), (c)(ii), Newfoundland AHCD, s. 5(3)(a),(c), Nunavut GTA, s. 1(1)(d), NWT GTA, s. 1(1)(d), *supra* note 16.

54 e.g. Alberta PDA, *supra* note 16, s. 15(2)(d), *Health Care Consent Regulation*, B.C. Reg. 20/2000., s. 5(1), PEI CTHCDA, *supra* note 16, s. 12(a), *Care Consent Regulation*, Y.O.I.C. 2005/80, ss. 11-13.

55 e.g. Alberta PDA, s. 15, PEI CTHCDA, s. 12(a), *supra* note 16.

56 e.g. Alberta PDA, s. 15, British Columbia RAA, s. 9(1)(d), Manitoba HCDA, s. 14, Newfoundland AHCD, s. 5(3), PEI CTHCDA, s. 12(1), *supra* note 16.

## (b) Application of Common Law

A second key issue for researchers is that, in some provinces, legislation on health care treatment may not even apply to physical access for non-medical purposes. Where this is so, the common law becomes the default source of rules relating to consent, capacity, advance directives and SDMs in the research context.

The first reason health care treatment legislation may not apply is that researchers are in some instances themselves not health practitioners, and/or their purposes for physical and information access are not health-related. In some provinces, legislation on consent, advance directives and SDMs refers to decisions about "treatment" or "health care," while in others it refers to "personal care." Usually, these definitions are confined to decisions about acts with a medical purpose.

Still, some provincial statutes explicitly include decisions about research participation within their scope. In British Columbia, for example, participation in research is specifically included under the definition of "health care," so long as the research has been approved by a designated research ethics committee.<sup>57</sup> Also, in other provinces, the definitions of "treatment," "health care" or "personal matter" are broad enough to support a claim that they could encompass diagnosis and examination procedures to assess a person's condition, even if not for medical purposes. And in some provinces, such as Ontario and Prince Edward Island, the legislation does not extend to incidental physical touching for the assessment of a person's condition, nor to any treatments that pose "little or no risk of harm."<sup>58</sup>

The second reason treatment legislation may not apply, depending on the province, is that enactments in some provinces explicitly state that the common law still governs research.<sup>59</sup> In Ontario, for example, the legislation is deemed not to "affect the law relating to giving or refusing consent on another person's behalf to...a procedure whose primary purpose is research."<sup>60</sup> In Manitoba, the legislation states that nothing in it "abrogates or derogates from" any common law rights or duties.<sup>61</sup> In Newfoundland & Labrador,

---

57 e.g. British Columbia HCCFA, s. 1(c), *supra* note 16.

58 Ontario HCCA, s. 2(1), PEI CTHCDA, s. 1(p)(ii),(vii), *supra* note 16.

59 e.g. Manitoba HCDA, s. 25, Newfoundland AHCDA, s. 5(4), Ontario HCCA, s. 6, para. 1, Ontario SDA, s. 66(13), *supra* note 16.

60 Ontario HCCA, *supra* note 16, s. 6, para. 1.

61 Manitoba HCDA, *supra* note 16, s. 25.

the legislation states that the common law applies “in the conduct of health research” where there is no advance directive.<sup>62</sup>

Under the common law, the starting premise is that any physical touching constitutes a battery unless it falls under a recognized exception, the most common of these being consent. In the medical care context, the common law already has well-established tests for determining whether the consent of the patient to the physical intervention by the health provider(s) was sufficiently informed. Outside the medical context, common law rules require a full disclosure of all of the risks of the proposed physical access, and of the fact that such access is, though posing no risk, also of no medical benefit to the patient.<sup>63</sup> Although few Canadian decisions exist on the common law duties of researchers, this has been the basic principle enunciated.<sup>64</sup>

There are no explicit Canadian common law cases on the nature of the relation between medical researcher and research subject in the context of non-therapeutic research involving the use of samples and tissue, although it can be argued that this relation is also a fiduciary relation.

The common law test for capacity asks whether the individual understands the nature of the proposed treatment and the consequences of the decision. Once a subject is incapacitated, providers may not proceed with any treatment until substitute consent has been given by a guardian or other SDM. The common law recognizes two kinds of SDMs: court-appointed guardians<sup>65</sup> and judges themselves acting under their *parens patriae* jurisdiction.

Judges will not exercise their *parens patriae* jurisdiction except in cases where it would be for the medical benefit of the incapacitated subject.<sup>66</sup> More commonly, in such a case, courts will appoint a suitable guardian, if

---

62 Newfoundland AHCD, *supra* note 16, s. 5(4).

63 See Kathleen C. Glass & T. Lemmens, “Research Involving Humans” in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2<sup>nd</sup> ed. (Toronto: Butterworths, 2002) 459.

64 *Weiss c. Solomon*, [1989] R.J.Q. 731, 48 C.C.L.T. 280 (Qc. Sup. Ct.); *Halushka v. University of Saskatchewan*, [1965] S.J. No. 208, 53 D.L.R. (2d) 436 (Sask. C.A.).

65 *Institut Phillippe Pinel de Montreal v. Dion*, [1983] C.S. 438, 2 D.L.R. (4<sup>th</sup>) 234 (Qc. Sup. Ct.).

66 *Strong (Re)* (1993), 107 Nfld. & P.E.I.R. 350, 49 E.T.R. 307; *M.B. v. Alberta (Minister of Health)* (1997), 207 A.R. 59, 149 D.L.R. (4<sup>th</sup>) 363 (Q.B.).

one can be found. Guardians must act in the best interests of the subject. The common law does not, like most consent legislation, impose specific duties to consider the subject's most recent expressions of her wishes, beliefs and values. Therefore, a guardian at common law may more easily ignore express wishes on the basis that they are not in the best interests of the subject, whereas the SDM under consent legislation is less likely to be able to do so.

Under the common law, guardians must act in the best interests of their wards, so they are generally not authorized to give substitute consent to any procedures that hold no chance of benefit. This, of course, would include all physical access procedures in the kind of study we are considering here, even those with little or no risk of harm. However, researchers could plausibly argue that respect for individual preferences is a kind of benefit, and to this extent a guardian would be justified in giving substitute consent. The idea behind this approach is that by respecting the presumed wishes of the subject, SDMs respect the right of individuals to make self-determining decisions. On this view, a key part of the best interests of the subject includes deference to her individual preferences. It may be possible under common law to argue that research participation is in the self-interest of the patient if such participation can be placed on a logical continuum of the type of altruistic decisions related to health care and medical research that a person has made during her life while being competent. Where an advance directive or other solemn statement of such preferences exists, then, guardians may be able to give consent to physical procedures even where they offer no potential benefit. However, the common law is still quite rigid toward the duties of guardians, and decisions about any procedures that offer no benefit to the subject may well be off limits to them.

### ***Impact of The Tri-Council Policy Statement***

Still, because of the few decisions on point, many questions as to the Canadian common law of research remain unanswered. In particular, we have little judicial guidance on the standard of care researchers owe to research subjects who have lost capacity. For instance, do researchers have a duty to seek a guardian or other SDM? How far does that duty extend? Do researchers have an obligation to continually assess capacity?

For guidance, courts may turn to the TCPS, which addresses all aspects of research involving human subjects. Although it does not have the status of formal law or regulation, the TCPS is a strong indicator of the ethical standards accepted by the research community. To the extent standards of care

have been shaped by community expectations, the TCPS stands poised to fill in where no precedents exist at common law.<sup>67</sup>

Where researchers deal with incapacitated subjects, whether at the recruiting or data collection stage, the TCPS' requirements include:

- The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected;
- The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent; and
- When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.<sup>68</sup>

Interestingly, the TCPS goes on to state that, even where a subject has lost capacity and her SDM has been fully informed and is prepared to consent, researchers must still check for any signs that the subject is dissenting to continued participation. If the subject dissents, this precludes her participation (in the eyes of the TCPS).<sup>69</sup> To explain, the TCPS comments:

Many individuals who are not legally competent are still able to express their wishes in a meaningful way, even if such expression may not fulfill the requirements for free and informed consent. Prospective subjects may thus be capable of verbally or physically assenting to, or dissenting from, participation in research.<sup>70</sup>

---

67 On this topic, see Angela Campbell & Kathleen C. Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill L.J. 473; Lorne Sossin & Charles Smith, "Hard Choices and Soft Law: Ethical Codes, Policy Guidelines and the Role of the Courts in Regulating Government" (2003) 40 Alta. L. Rev. 867.

68 *Supra* note 10 at art. 2.6(a),(c),(d).

69 *Ibid.* at art. 2.7.

70 *Ibid.*

The TCPS demands an ongoing assessment not only of the subject's capacity, but also of her level of comfort with respect to the research procedures. The TCPS also addresses tissue removal from incapacitated persons. Under Article 10.1, all research involving tissue removal must be REB-approved. Researchers must, according to Art. 10.1, show:

- That the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors; and
- In the case of incompetent donors, free and informed consent shall be by an authorized third party.<sup>71</sup>

The TCPS also recognizes the social importance of research with incapacitated persons. Article 5.3 states that "... those who are not competent to consent for themselves shall not be automatically excluded from research which is potentially beneficial to them as individuals, or to the group that they represent."<sup>72</sup> This statement suggests that the common law standard of care, to the extent it is shaped by the TCPS, will take into account the public interest in research, or at least the interest of the group to which the incapacitated person belongs, as a potentially countervailing argument against the strict application of the rules that aim at protecting incapacitated persons.

The group that the TCPS refers to in this case appears to be the type of patient population that an incapacitated person belongs to, such as "people with Alzheimer's disease" or "people suffering from schizophrenia." It is unlikely that the notion of group refers to the community of incapacitated persons at large. Other research ethics guidelines and regulations make reference to the interest of the group to which a research subject belongs. Research involving prisoners, for example, generally imposes as a requirement that research has to benefit prisoners as a class.

### (c) Special Provisions in Health Information Legislation for Researchers

The third legal highlight we wish to note for researchers facing a loss of capacity among subjects is that every province has enacted special provisions to permit researchers to access health information without consent. These pro-

---

71 *Ibid.* at art. 10.1(a),(b).

72 *Ibid.* at art. 5.3.

visions authorize the collection of health information from individuals without consent for REB-approved research studies. The statutes clearly treat this as an exception, and emphasize that this is only appropriate when obtaining consent is impractical, unreasonable, or impossible. Under such provisions, researchers who have obtained REB approval for their work may be able to access health information without individual consents from the subjects.<sup>73</sup>

Generally, these provisions define what constitutes “research” for the purpose of the exception, and set minimum requirements researchers must meet in order to qualify for it. Some provinces’ legislation specifically refers to particular REBs at named hospitals, while others are silent on who decides.<sup>74</sup> An example of the latter is in New Brunswick, where the legislation simply provides an exception for “legitimate research in the interests of science, of learning or of public policy.”<sup>75</sup>

Where REBs are involved, they are generally required to closely scrutinize the research proposal against legislative standards and are usually required to consider several public interest-related factors in deciding whether to approve the research.<sup>76</sup> According to the Ontario Personal Health Information Privacy Act, the REB has to determine that obtaining consent is impractical, that the research could not reasonably be accomplished without

73 e.g. Alberta HIA, *supra* note 38, ss. 5(1)(a), 27(1)(d), British Columbia FOIPPA, *supra* note 38, ss. 33.2(1)(k), 35, Manitoba PHIA, *supra* note 38, ss. 22(2)(f), 24(1)-(4) and *Personal Health Information Regulation*, Man. Reg. 245/97, s. 8.1(1), New Brunswick PPIA, *supra* note 38, Sch. B, 3.4(e), Newfoundland AIPPA, *supra* note 38, s. 41(a)-(d), Nova Scotia FOIPPA, *supra* note 38, s. 29 and *Freedom of Information and Protection of Privacy Regulations*, N.S. Reg. 105/94, s. 9, Ontario PHIPA, *supra* note 38, s. 44, PEI FOIPPA, *supra* note 38, s. 39, Saskatchewan HIPA, *supra* note 38, s. 29, Nunavut AIPPA, *supra* note 38, s. 49, NWT AIPPA, *supra* note 38, s. 49, Yukon AIPPA, *supra* note 38, s. 38.

74 REBs are given an explicit role in the legislative scheme for authorizing researcher access without consent in Alberta (*Designation Regulation (Health Information Act)*, Alta. Reg. 69/2001, s. 1(1)(j)), Manitoba (PHIA, *supra* note 38, s. 1(1) and *Personal Health Information Regulation*, Man. Reg. 245/97, ss. 8.1-8.3,9), Ontario (PHIPA, *supra* note 38, s. 2), and Saskatchewan (HIPA, *supra* note 38, s. 29(1)(b)).

75 New Brunswick PPIA, *supra* note 38, Sch. B 3.4(e).

76 e.g. Alberta, s. HIA 50(1)(b), British Columbia FOIPPA, s. 35, Manitoba PHIA, s. 24(3)-(4), Newfoundland AIPPA, s. 41(a)-(d), Nova Scotia FOIPPA, s. 29 (a)-(d), Ontario PHIPA, s. 44(3), PEI FOIPPA, s. 39(a)-(d), Saskatchewan HIPA, s. 29(2), Nunavut AIPPA, s. 49, NWT AIPPA, s. 49, Yukon AIPPA, s. 38, *supra* note 38.

the information, and that there are appropriate safeguards in place. In addition, the Act provides that REBs must consider the public interest in conducting research, as well as the public interest in protecting privacy, without any indication of priority of one over the other.<sup>77</sup> The Alberta statute seems to emphasize more clearly the public interest basis of the exception: first, where it states that the research must be of sufficient importance that the public interest in the research “outweighs to a substantial degree” the public interest in protecting privacy; second, with an explicit and more detailed provision related to the public goal of the research. REBs have to consider whether a research project may result in the identification, prevention, or treatment of an illness or disease, or the scientific understanding of a health problem, or the improvement of health care services.<sup>78</sup> These provisions reflect a recognition of the public importance of certain forms of research, and reflect a balancing of individual and societal interests. The precise content of these provisions also suggests that practical considerations are important: it may sometimes be virtually impossible to obtain consent from all the people whose information has to be accessed.

The substantial discretion given to REBs in weighing the public interests at stake raises concerns, however, in the Canadian context. Is it appropriate to argue, in the Canadian context, that REB approval is an ethically justifiable substitute for individual consents? In general, it could be argued that REBs are inadequate proxies for subjects’ wishes and interests. They do not know the subjects personally. Some may argue that REB members are not capable of reflecting the diversity (across the cohort) and dynamism (over time) of all the individual views. While we believe that it can be acceptable in many circumstances to forsake individual rights, and to make abstraction of possible differences in individual approaches to research, on the basis of public interest considerations that will benefit the larger population or a larger disease community, we also believe that there has to be a solid mechanism in place to weigh both the public interest and the private interests at stake. We also approve of the statement in the Alberta privacy statutes, that the public interest in the development of the research ought to outweigh, to a considerable degree, the public interest in protecting the privacy of those involved before we should accept access to and use of health information without consent. Where highly personal and intimate – *Charter* protected,

---

77 Ontario PHIPA, ss. 44(3), 37(3), *supra* note 16.

78 Alberta HIA, s. 50(2), *supra* note 16.

even – rights are at stake, a more careful scrutiny of the public interest and more attention to the individual interests at stake seem warranted.

If we accept that a public interest focused review mechanism can override the widely recognized core legal and ethical concept of informed consent, it seems crucial that this review mechanism reflect the public interest. Also, as several authors, including one of us, have pointed out in other publications, it is in this context surprising – even highly problematic – that several provinces that rely on REBs for conducting such public interest analysis have not enacted any legislation or clear regulation of these REBs. REBs are, indeed, very lightly regulated in Canada. They are submitted to guidelines by the federal funding agencies and to “guidance documents” enacted by Health Canada. Yet, there are no strict regulations and no well-organized controls on how they are established, who can become a member, what educational requirements should be in place, and how they should function.<sup>79</sup>

Moreover, there are serious concerns about the ability of research sponsors and researchers to shop around for REB approval, and about the existence of fundamental conflicts of interests in both institutional REBs and commercial REBs, in the context of an increasingly commercialized research sector.<sup>80</sup> Recent recommendations by a Task Force of the National Council on Ethics in Human Research to introduce an accreditation system for REBs in Canada, while likely improving the overall level of review, do not sufficient-

---

79 See in general: Michael Hadskis, “The Regulation of Human Biomedical Research in Canada” in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 3<sup>rd</sup> ed. (Markham: LexisNexis, 2007) 257; 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 *Cahiers de Droit* 578; Paul B. Miller, “Institutional Oversight of Clinical Trials and the Drug Approval Process” (2006) 44 *Osgoode Hall L.J.* 679; Trudo Lemmens, “Federal regulation of REB review of clinical trials: a modest but easy step towards an accountable REB review structure in Canada” (2005) 13:2-3 *Health Law Review* 39; Trudo Lemmens, “Leopards in the Temple: Restoring Integrity to the Commercialized Research Scene” (2004) 32 *J.L. Med. & Ethics* 641; and Trudo Lemmens & Benjamin Freedman, “Ethics Review for Sale? Conflict of Interest and Commercial Research Ethics Review Boards” (2000) 78 *Milbank Quarterly* 547.

80 *Ibid.*, and see the debate in Ezekiel J. Emanuel, Trudo Lemmens & Carl Elliott, “Should Society Allow Research Ethics Boards to be Run as For-Profit Enterprises?” (2006) *PLoS Medicine* 0941.

ly address these concerns and amount to the establishment of another level of soft- (and to some extent self-) regulation.<sup>81</sup> These recommendations, if implemented, will still leave loopholes and are an inadequate substitute for accountable governmental regulation. If legislators want to empower them with the important public policy mandate of evaluating whether the public interest is sufficiently strong to outweigh individual interests and rights, REBs ought to be surrounded by a strong and accountable regulatory structure and be submitted to an adequate system of monitoring, control and sanctions for non-compliance.

#### **IV. Analyses of Scenarios**

The foregoing issues arise in different forms in the four scenarios we now consider.

Having canvassed the legal background and key points for researchers, we now turn to the analysis of the ethical and legal issues that arise in four scenarios that are variations on the basic hypothetical fact situation described above, in which researchers obtain signed consents from capable subjects at the outset of a long-term study. From this basic assumption, four further possibilities exist:

- I. Researchers cannot find a SDM and also cannot find an advance directive with instructions relevant to research;
- II. Researchers cannot find a SDM but do find an advance directive with instructions relevant to research;
- III. Researchers find a SDM but cannot find an advance directive with instructions relevant to research; and
- IV. Researchers find a SDM and also find an advance directive with instructions relevant to research

Within each scenario, we focus on the legal and ethical problems that may arise for researchers in the context of both physical access and information access. In each scenario, we assume that the individual has lost capacity

---

81 See National Council on Ethics in Human Research, "Task Force on Accreditation," online: NCEHR <[http://www.ncehr-cnerh.org/english/task\\_force.php](http://www.ncehr-cnerh.org/english/task_force.php)>.

with respect at least to participation in research, that this incapacity has been confirmed by a health care provider or other person authorized to make that assessment, and that her incapacity is not fluctuating. We also assume that any SDMs or advance directives present are validly appointed or created, and that any disputes about the authority of a SDM or whether the instructions in an advance directive are clear have been settled. If the SDM in a given scenario is a guardian, we assume that the court appointing the guardian has granted him or her authority over personal health care decisions. Finally, we assume that researchers have not taken advantage of the non-consensual collection provisions in health information just discussed. Rather, we assume that direct or substitute consent will be required for information access.

#### (a) Neither SDM Nor Advance Directive

This is the most bare-bones scenario. Here, researchers have only the consent to physical and information access signed by research subjects when they were capable. They have not located a substitute decision maker or an advance directive that has instructions authorizing physical and information access for future purposes. In most cases, research subjects will have able and willing relatives nearby who can act as the SDM, at least on a temporary basis, if the person has not specifically named a person in an advance directive. Thus, realistically, this scenario is a rather remote possibility in most instances where a person loses capacity. Still, the prevalence of elderly persons lacking family nearby is common enough that this scenario will likely occur at some juncture in a large and long-term cohort study.

A key ethical concern in this scenario is that a loss of capacity puts a cover of darkness over the patient's true wishes. If a fundamental element of consent is the ability of the individual to revoke that consent at any time until the moment of actual physical access, then a more cautionary approach would be to question whether consent can really cover circumstances where the patient has lost the power to revoke. According to this view, the darkness cast over the patient's wishes after she loses capacity means we can only make a limited guess, which can only be an imperfect substitution for true consent. If we accept that people ought to be able to make decisions related to research in informed consent forms that also bind others if they become incompetent – which seems to be recognized in law – the question remains whether there should be some time limit on this consent and how flexible and extensive we can interpret these informed consent forms as being.

### *Physical Access*

As mentioned above, in most provinces health care providers proposing to treat an incapable individual have a duty to make reasonable efforts to locate a SDM for that individual. Usually, providers check if the individual has had a guardian appointed for them by a court or tribunal, and also whether they have made an advance directive that appoints a SDM. If neither has occurred, providers must choose the “nearest relative” who is willing and eligible to act as SDM. If providers still cannot find a SDM after these efforts, then they are empowered in some provinces to administer treatment without the individual’s consent and to give substitute consent for that individual. However, these “last resort” provisions only apply where the proposed treatment is medically necessary for the patient’s health. Therefore, it is not likely that researchers, even if they are health practitioners, can themselves give substitute consent for the research subject as a last resort, since the proposed physical access is not medically necessary and cannot directly benefit the patient. As such, researchers who cannot locate a SDM may have no way to obtain the necessary consent to continued physical access.

If researchers have no advance directive and no SDM, can they rely on the original consent as a kind of “once and for all” consent to physical access by the researchers? Legislation in most provinces carefully regulates consent-to-treatment decisions to ensure that they are informed and that they are respected by health providers. However, there are no legislative provisions that speak directly to the duration of an informed consent. At most, legislation merely confirms that the authority to act under consents to treatment is strictly limited by the terms of those consents, whether those terms are time limitations, specific excluded acts, or other conditions. It seems then, that only if a consent is clear, and is directly related to the physical access which is now required in the context of research, can a researcher physically access a patient for new research procedures. An earlier consent form to have blood drawn, for example, cannot be taken as constituting a valid consent for a similar procedure in the future.

### *Information Access*

For information access, researchers in this scenario should be careful in collecting, using or disclosing the subject’s health information without a SDM or an advance directive. Unlike most health care treatment legislation, health information legislation does not generally impose a duty to locate a SDM or advance directive.

As already pointed out, several provincial health privacy statutes allow researchers to obtain and use health information for research purposes if

they obtain permission from a properly constituted REB and if several conditions are met: obtaining consent must be impractical or impossible; the REB has to weigh the public interests involved; and access to the information must be reasonably necessary for conducting the research.<sup>82</sup>

But if these criteria do not apply, and if we have a situation where a research subject who is now incompetent has previously provided consent for information access, can researchers proceed with information access on the basis only of the original consent?

The question here is whether a person should be able to consent to information access of her health information *ad infinitum*? Or should such consent only be valid in relation to the immediate research use of the data, and not for future research uses? If we do not want people to be able to give over their bodies while alive to a team of researchers now and forever, would we therefore also oppose people giving a lifelong subscription to their health information? This touches on the qualitative distinctions between the values of privacy and personal (physical) security. Should access to health information be treated any differently than access to a subject's body?

Depending on its wording, an original consent form for the disclosure of data might legally suffice to authorize post-capacity information access. All provincial privacy legislation allows providers to disclose health information about subjects to researchers with the subject's consent. In some provinces, consents must meet certain legislative requirements to be valid.<sup>83</sup> A problem can arise here if a person has provided consent in one province, and research is taking place in another province. It is possible that consents to disclose validly made in one province may not meet the requirements for validity in another. Assuming consent to disclose was validly made, legislation places no limits on how long the consent lasts or on any other aspect of a consent. The Supreme Court affirmed in the *Frenette* case that a waiver of confidentiality – i.e., an informed consent form providing access to confidential medical information to a third party – is unlimited in scope and time.<sup>84</sup> Although the case was decided on the basis of Quebec Civil Law,

---

82 See *supra* note 76 and accompanying text.

83 See eg Alberta HIA, *supra* note 38, s. 34(1). In Alberta, for instance, consents for providers to disclose information to researchers must refer to the purposes of the study and of the disclosure and be in writing. In others, the legislation is silent on the conditions for validity.

84 *Frenette v. Metropolitan Life Insurance Co.*, [1992] 1 S.C.R. 647, [1992] S.C.J. No. 24.

there seems no fundamental reason why this would be decided differently under common law. Consent forms can, in other words, remain effective *ad infinitum*, unless they contain an explicit time limit. Where the consent itself sets out conditions relating to the recipients of the information, its intended uses or how long the consent lasts, those still govern any person seeking to rely on it. Consent forms can obviously also be explicitly withdrawn by the person who signed them.

Also, as mentioned above, legislation in some provinces allows access to information that is “consistent” with the purposes or uses set out in an original consent. Even new purposes for access can be covered by the original consent, so long as there is a sufficient nexus with the original purpose. This way, in these provinces, researchers are not necessarily bound by the strict terms of the consent to access health information.

This may in some way be at odds with the spirit of some provisions in the TCPS. The TCPS suggests, for example, that storage of biological samples should be “for a defined term” and that the consent form should specify future uses of the sample or the data.<sup>85</sup> Although no firm statement is made about what this time limit should be – two very different time periods are suggested – one could have a situation where a consent to access information contained in a DNA sample is legally valid, even though the TCPS provisions may not have been fully respected.

When consents to access information from a subject’s providers are specific in terms, this can pose a problem for researchers whose purposes for collection may change over time. Original consents will typically name the researchers, the purpose of the study, the uses to which the information will be put, and other matters relevant to the subject’s participation. Where researchers enter a new phase of the same study, or embark on related studies that emerged out of the original study, their purposes for collection and use may begin to drift away from these original terms.

In provinces that have a “consistent use” provision, an interesting question will arise as to what that means. A very narrow consent form, which refers for example to “future research on breast cancer,” would likely enable most forms of breast cancer research on the basis of the original consent form. Other forms of cancer research would not seem to fall under such a rather specific category of research.

---

85 *Supra* note 10 at art. 8.6.

Commentators have pointed out that consent for future research has to remain meaningful. In order to speak of truly “informed” consent, consent forms cannot be so general that they allow everything, without specifically pointing out the risks and potential benefits of the research.<sup>86</sup> If consent forms are too general, the argument goes, they become meaningless and thus invalid. Information about the risks and potential benefits, for example, is considered to be a crucial aspect of informed consent. This seems to clash with the idea of very general consent for future research, since the risks and potential benefits will necessarily be unavailable at the time of the consent.

A controversial issue is whether research subjects have to be informed of the extent to which future patients will benefit from the research. In the context of the growing commercialization of research in Canada, it has happened and will likely happen even more in the future that research subjects sign a general consent form in which vague reference is made to future research that may benefit a specific patient population, but that lacks specific information about the commercial context in which certain genetic tests may be developed on the basis of their donation. What if a commercial genetic test is offered on the market at a significant price which makes it inaccessible to many patients? Is this research within the purview of the original consent form, or could one argue that insufficient information was provided about the implications of the research?

In light of the significant controversy created in similar situations, for example in the context of research on Canavan disease,<sup>87</sup> it seems not only legal and ethically appropriate to provide full information, but seemingly

---

86 The difficulty this creates for genetic database research has been pointed out frequently in the literature. See e.g. Timothy Caulfield & Nola M. Ries, “Consent, privacy and confidentiality in longitudinal, population health research: The Canadian legal context” (2004) 12 *Health L.J.* 1; Timothy Caulfield, Ross E.G. Upshur & Abdallah Daar, “DNA databanks and consent: A suggested policy option involving an authorization model” (2003) 4:1 *BMC Medical Ethics*, online: <<http://www.biomedcentral.com/1472-6939/4/1>>. For an article reporting on the discussion of this problem at an international DNA sampling conference in 1997, see John Lyttle, “Is informed consent possible in the rapidly evolving world of DNA sampling?” (1997) 156 *Canadian Medical Association Journal* 257.

87 See *Greenberg, supra* note 50. For some background on the dispute, see Eliot Marshall, “Families Sue Hospital, Scientist for Control of Canavan Disease” (2000) 290 *Science* 1062.

wise public policy, to interpret consent for future research narrowly. One would have to evaluate the overall purpose and nature of the original research to which research subjects consented before drawing general conclusions. This means that people who consented to giving access to their tissue for research within a governmentally funded genetic database should not be presumed to have consented to have their tissue used by research undertaken by a commercial company that pays to obtain access to the database for research that seems to aim at a different goal. This is not to say that commercial research cannot be of public benefit. Yet people may feel very different about the fact that their tissue donation results in significant commercial benefit for particular individuals. Altruism is behind many decisions to participate in research. The likely motivations behind people participating in the original research project ought to be taken into consideration when interpreting vague consent forms. The public perception that DNA banking and biotechnology developments resulting from it are focusing on commercial interests more than on public health interests are in this context a reason for concern.<sup>88</sup>

Reference can be made here also to the fact that various ethics guidelines and professional conflict of interest policies impose a duty to disclose potential financial interests at stake in medical research. The TCPS, for example, explicitly imposes a duty on researchers to discuss with the research subject and the REB any potential commercial use of genetic research samples.<sup>89</sup>

This approach of being attentive to potentially more controversial uses of research data in the future is also valid in other areas of research. Indeed, some forms of research may be controversial, and may evoke strong reactions among some research subjects because of religious reasons. People from specific ethnic communities may oppose, for example, research that can be seen as associating specific ethnic groups with particular behavior problems. Some research subjects may, for example, have religious or other principled objections to embryonic stem cell research, while strongly sup-

---

88 Mairi Levitt & Sue Weldon, "A well-placed trust? Public perceptions of the governance of DNA databases" (2005) 15 *Critical Public Health* 311. See also Caulfield, *supra* note 7, with references there to studies published by Williams (2005) and Hoeyer *et al.* (2004). Similar findings appear in a survey conducted by Dianne Nicol *et al.* See Dianne Nicol *et al.*, "Best Practice Models for Benefit Sharing in Biobanking" (Paper presented at "Governing Biobanks – What are the Challenges?" University of Oxford, 26 June 2008) [unpublished].

89 *Supra* note 10 at art. 8.7.

porting other forms of research. In those cases, it is wise to interpret consent narrowly, and to solicit further information about research subjects' beliefs and moral values.

In light of the foregoing, it would seem prudent to only collect health information if the subject gives consent framed in language explicitly extending consent for the length of her life, regardless of her legal decision-making capacity. If the consent is restricted to a particular study, researchers should only collect for future studies that are similar to that study when provincial privacy legislation allows this. The purpose and context of research should also resemble the original research project for which consent was secured.

### (b) No SDM, But Advance Directive Exists

In this scenario, no SDM has been found, but an advance directive has been discovered that contains instructions consenting to physical and information access after loss of capacity. The directive does not appoint a SDM; it only contains instructions.

#### *Physical Access*

The existence of an advance directive does not solve all the ethical quandaries we may have with respect to physical access after loss of capacity. This ethical consideration is not confined to advance directives, but applies to all instances where researchers seek to rely on an earlier written consent to physical access after loss of capacity. Advance directives and consent forms fail to account for the possibility that the patient, if capable, might revoke consent to future studies. An ethical argument could be made, therefore, against allowing advance directives to be used for post-capacity physical access or information access. As indicated earlier, it may indeed often be very hard to determine in advance the precise circumstances in which a person will want to participate in research.

The legal position of researchers in this scenario is also uncertain. On the one hand, the instructions in the advance directive can – depending again on the province – arguably be advanced as the necessary consent. This claim might have particular force in those provinces where such instructions have the same effect as a consent given by the person while capable. Alternately, researchers might claim that the advance directive binds any person who might ultimately act as the SDM – including the individual's treating physician – to follow its instructions.

However, as noted above, it remains uncertain whether advance directives can lawfully stand as consents to non-medical physical access. This is because, as noted above, the legislation governing advance directives may

restrict the scope of their instructions (at least those that will be enforced) to decisions about health care treatment. If the instructions in the advance directive authorizing physical access for non-medical reasons fall outside this scope, they do not bind anyone.

### *Information Access*

Here, researchers have an advance directive giving them written authorization for information access after loss of capacity. In relation to information access in this scenario, similar ethical considerations apply as in relation to physical access. In both instances, individuals put their wishes in written form. If an advance directive suffices to permit intrusions on a person's body after they have lost capacity, can there be any independent reason it should not also suffice for future intrusions on their privacy? The answer to this question will determine whether we believe an advance directive should only give consent to physical procedures (medical or research-related), or should act as consent to information access as well: no, if we see privacy as a value subordinate to physical integrity; yes, if we instead conceive of privacy as a value distinct from, but overlapping with, personal security.

The legal issue is: Can an advance directive contain instructions about disclosure of health records later? Or can advance directives only pertain to medical and personal care decisions? On one hand, depending upon how the advance directive has been drafted, it may well meet the requirements for consent under provincial health information legislation. On the other hand, as mentioned above, instructions in advance directives may, depending on the province, be restricted to "health care decisions," "personal decisions," or "treatment" decisions. The definition of "treatment" found in most provincial legislation may arguably be broad enough to encompass the acquisition of health information. However, the problem of purpose remains. That is, to qualify as "treatments" – and thus be the proper subject of an advance directive – the procedures in question must be for a medical purpose. Thus, in most provinces, whether advance directives pertaining strictly to accessing health information are binding remains uncertain. Still, advance directives are at least evidence of the subject's wishes regarding her health information while capable. Finally, it is worth pointing out that the TCPS refers to the use of a "prior directive" to allow donors to decide for the future whether or not they want to allow their tissue to be collected and stored for research purposes.<sup>90</sup>

---

90 *Ibid.* at art. 10.1(c).

### (c) SDM But No Advance Directive

In our third and fourth alternative scenarios, a substitute decision maker has been located. The difference between them is the presence of an advance directive containing instructions authorizing physical and information access. In the third scenario, considered here, the SDM is acting in the absence of an advance directive. This may in practice prove to be the most common scenario of the four. This is because eligible and willing SDMs can usually be located for most incapable persons, while at the same time many people have never made an advance directive.

#### *Physical Access*

The most immediate ethical objection to the giving of consent to physical access by a SDM might go as follows: If the purpose of giving substitute authority is to ensure that the subject's medical wishes are respected and that her health interests are preserved, then SDM expressions of wishes outside the scope of health care decisions are inappropriate and should not be respected and enforced. Substitute decision making is the exception, not the norm, and a commitment to liberty and bodily integrity requires it be closely circumscribed to ensure that it is not transformed into an absolute concession of autonomy. Another concern might be that the SDM can be in a conflict of interest when deciding on participation in research trials. SDMs clearly should not be placed in a situation where they receive enticements or other improper influences on their decision making.

The researcher/physician may have a significant interest in obtaining consent from the SDM. These incentives may, in turn, influence the way she depicts the study to the SDM and how much of the patient/subject's personal health information she shares with the SDM. For instance, will a researcher want to disclose information about a patient that has no bearing on the actual risk to the patient from the study, but would still cause the SDM to become alarmed or otherwise obstreperous for non-medical reasons? It would be tempting for the researcher to withhold such information and reach for the justification that the information was not material to the medical risks of the proposed study and therefore not "compellable" from them. This situation exists obviously also when a research subject is competent. Yet the voluntary nature of research participation is strongly emphasized in all research ethics guidelines and is considered of even greater importance than in the context of clinical care. In clinical care, we presume that actions are undertaken for the benefit of the patient. In research, this is not the case. Research participation should really be an altruistic contribution to the public good, by well-informed research subjects. In addition, the

history of medical research contains many paradigm cases in which the vulnerability of incompetent subjects was abused and the physical integrity of incompetent subjects was invaded without any form of consent. Therefore, it seems appropriate to put more limits on an SDM's ability to provide fresh consent for acts without a medical nexus.

The 2002 version of the World Medical Association Declaration of Helsinki states, for example, that incompetent subjects should only be included if "the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons."<sup>91</sup> Long-term research based on DNA data-banking can benefit the research subject population in the long run, but it can hardly be argued that it is "necessary" to promote the health of this particular patient population.

The guidelines of the Council of the International Organizations of Medical Sciences (CIOMS) make a distinction between research that is of no more risk than routine medical or psychological examination and research that creates "slight or minor increases" above such risk. For the latter, there are four additional requirements, which mainly refer to the fact that the research must focus on conditions that affect the research subjects; that the procedures must be comparable to – and can only be slightly more risky than – the physical access such subjects usually undergo for these conditions; and that the research is sufficiently important.<sup>92</sup> The TCPS prescribes for its part that SDMs can only consent to research for incompetent people when: 1) "the research question can only be addressed using individuals within the identified group(s)" and 2) "the research does not expose them to more than minimal risk without the potential for direct benefit."<sup>93</sup> The reference to minimal risk seems at first sight stricter than under CIOMS, but if one looks at the meaning of the concept of minimal risk under the TCPS, it becomes clear that this is not necessarily the case.<sup>94</sup> It seems likely that several forms of databanking research would be possible under these provisions.

---

91 World Medical Association, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, online:

WMA <<http://www.wma.net/e/policy/b3.htm>> at para. 26.

92 Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, online: CIOMS <[http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm)> at guideline 9.

93 *Supra* note 10 at art. 2.5.

94 Minimal risk is defined as a situation in which the research subjects "can reasonably be expected to regard the probability and magnitude of possible harms

Under these provisions, a determination of the level of risk of the research will be crucial. Many would argue that most forms of databank research will likely be of an acceptable level of risk, although there can be substantial discussion about the potential societal impact of such research, or the risk of discrimination or stigmatization.

In legal terms, the most obvious impediment to consent by a SDM to physical access for research purposes is the specific prohibition against it, mentioned above, found in some provinces' health care treatment legislation. As mentioned above, these prohibitions are framed differently, some in ways that may permit SDMs to consent to minor diagnostic procedures of no risk to the subject. For example, the prohibitions in some provinces only forbid giving consent to experimental treatments and tissue removal. Depending on whether blood samples or other bodily fluids can be considered "tissue," researchers may have an argument that a wide range of tests to measure blood pressure, heart rate, cholesterol level and other vital signs – including the taking of blood and/or other fluid samples – is not caught by this prohibition. Or one could argue that when blood has to be drawn for a diagnostic procedure in these provinces, research on the same blood sample would not constitute a problem. This argument, though, would clearly not succeed in provinces where the prohibition is more broadly worded to forbid SDM consent to any "participation" in research. We also think that it may violate the spirit of the provisions in the other, less stringent provinces, if one opens the door to "mixed" use of tissue removed for clinical purposes. It could open the door to intentional removal of tissue for research purposes, under the disguise of clinical necessity.

Another argument researchers could make in some provinces to justify continuing physical access is that the prohibition forbids only the giving of consent to research. Where the subject has already consented to the physical access when capable, the SDM arguably would be doing no more than affirming the original consent, rather than actually "giving" it in the first instance.

---

implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research." See *ibid.* at C1: Minimal Risk. For a good discussion of the concept, see Paul Miller & Charles Weijer, "Moral Solutions in Assessing Research Risk" (2000) 22:5 IRB: Ethics and Human Research 6.

Some provinces have no such prohibition, however, and in these jurisdictions researchers would have a stronger claim to rely on the SDM's consent to physical access. However, if the health care treatment legislation does not apply to research – a possibility discussed above – this may be a risky course of action for researchers. This is because the SDM would not have any common law authority to give substitute consent, unless they were already appointed by a court as a guardian. If, for instance, a “near relative” is acting as SDM or a SDM has been appointed by an advance directive with no instructions on research, her legal authority derives entirely from legislation. If that legislation does not apply, then she would lack the authority to give valid consent to researchers.

Inverting the scenario by having the SDM oppose continued physical access after loss of capacity also raises ethical and legal concerns. Ethically, the issue is whether the SDM should be able to revoke consent when the incapacitated person has already expressed a desire – in writing, while capable – to participate. In a conflict between a subject's earlier decision and a SDM's later preferences, which should prevail? Three observations seem useful in this context. First, it is worth noting that the SDM's “rights,” such as they are, are derived only from the need to make medical or health care decisions for the subject. Second, capacity is decision-specific, so that while a person may be incapacitated for medical decisions, they may still be capable of understanding and appreciating a request for research-based physical access or information access. When the research procedures are straight forward, might a person still be capable of understanding what will be done to her in a study? Theoretically, yes, but practically this will be very unlikely. If a person is not capable of understanding basic medical care procedures, it is very unlikely that she will be able to understand the purpose of a research study. Third, as pointed out earlier, it may be easier to define in an advance directive what type of research procedures will be acceptable than to define the circumstances under which one would or would not want to undergo a complicated medical procedure.

In principle, a clear consent to future research should certainly be taken as a strong indicator by the SDM of what the now-incompetent person really wished. If we consider these things, we would probably say that in regard to non-medical decisions like research participation, the earlier decision of the subject should prevail over the later objection by the SDM. That being said, there may be circumstances where a SDM finds that continued participation in research seems to trouble the incompetent person. The SDM has a fiduciary obligation towards the incompetent person and should not abandon that duty because of a signed consent form.

Legally speaking, researchers may, depending on the province, have several arguments against the SDM's wish to revoke the subject's earlier consent to physical access. First, depending on the province, they could argue that health care treatment legislation only authorizes SDMs to make decisions about treatment. If research-based physical procedures that pose no risk to the patient fall outside the definition of "treatment" in the relevant legislation, then any decisions on this issue are *ultra vires* the SDM.

A second argument, which assumes that health care treatment legislation does apply, is that the original consent form is clear evidence of the subject's directions while capable and is an expression of her wishes. As such, the SDM is bound to follow the original consent. Third, in those provinces that have specific prohibitions against SDM consent to research, researchers could argue that SDMs are prevented not only from giving consent, but also from disturbing in any way consents previously given by the subject. On this view, the "no research" provisions exist not only to prevent the giving of an original consent by a SDM, but also to preserve any existing decisions already made by the subject while capable. Under this interpretation, SDMs should not be permitted in any way to undo a consent to physical access after loss of capacity. Yet we believe that there are circumstances where the SDM would have a fiduciary obligation to intervene. The SDM has an obligation to act in the best interest of the research subject, and the researcher cannot use a consent form as a shield against the fiduciary claims of the SDM when there are clear signs that the research participation troubles the now incompetent person.

### ***Information Access***

In ethical terms, the key question here is whether there is something distinct in the concept of privacy in health information, something that might warrant as much or even more resistance to substitute decision making with regard to it than is seen in relation to treatment decisions? Or is it ethical to equate the two kinds of decisions when deciding whether substitute decision making should be permitted?

Arguably, privacy in health information is a fundamental component of a person's right to integrity and security of the person. The exposure of sensitive private health information can have a devastating effect that may create the same degree of harm as an unauthorized physical access. But it can also be seen as a transgression that violates a person's sense of personhood. The moral interest in maintaining confidentiality in health information can often be as important as the interest in personal security. At the same time, privacy is a fluid concept that covers a spectrum of interests and

concerns. Some privacy concerns are more important than others. The context in which personal information is rendered accessible is also important. We may feel very comfortable sharing some forms of health information with family and friends, though we would not want such information be publicized widely. Other forms of health information are of a very intimate and personal nature. Still other health data raise for most people few privacy concerns.

If we conceive the role of the SDM liberally, we would likely include in her functions the responsibility to make decisions about her principal's health information as well as her treatment. If the privacy interests protected are very valuable, then ethical objections can be made against allowing SDMs to hand over their wards' health records for any grounds besides medical necessity. But for some information, where few privacy concerns are raised, it would seem more acceptable to allow SDMs to provide access to that information.

As noted above, health information privacy legislation authorizes a wide class of persons to act as SDMs in relation to the collection, use and disclosure of health information, including any "... person with written authorization from the subject." As well, in most provinces, such SDMs can exercise any right or power that the incapable individual would have under the legislation. Therefore, if consent to information access is refused or revoked by the SDM for treatment decisions, or by any other eligible SDM for information access, it may be difficult for researchers to gain the desired information.

Conversely, the SDM can also give consent to the needed information access. The only potential limitation might be found in the bans in consent legislation on SDMs consenting to a subject's "participation" in a research study. If "participation" is understood to include consenting to information access, then this prohibition may act as a barrier to the SDM seeking to assist researchers. Here again, though, the research ethics guidelines may impose further restrictions on the ability of SDMs to allow research to go forward, just as they did in the context of physical access.

#### (d) SDM With Advance Directive

In our fourth and final scenario, a SDM is present, but researchers have an advance directive authorizing physical and information access. As mentioned above, the SDM may be appointed by the advance directive itself, or may derive her powers otherwise – i.e., she may be either a court-appointed guardian or a near relative acting under legislation. However, the key feature of this scenario is the existence of an advance directive containing instructions consenting to physical and information access.

### *Physical Access*

If the SDM wishes to honour the advance directive and consent to physical access, then the legal issues raised thereby are the same as those raised under our second scenario. In some provinces, as noted above, SDMs cannot make decisions in relation to participation in research. However, in some provinces, this prohibition does not apply where an advance directive authorizes such a decision. In these provinces, then, the presence of an advance directive gives clear legal authority to SDMs to consent to physical access.

However, in some provinces, one possible obstacle for a SDM wishing to honour an advance directive could arise from the fact that the physical access it speaks to lacks a nexus with treatment. As already mentioned, under health care treatment legislation in most provinces, advance directives are intended to govern a limited scope of decisions – those relating to the health of the person. They are not intended to be full powers of attorney to decide every personal issue for the person. In this regard, depending on the province, guardians appointed by the court may, if the order appointing them allows, make non-medical decisions that could arguably include decisions about consent to physical access.

The converse variation of this scenario is where the SDM wishes to withhold consent despite the advance directive. Most researchers may be inclined to think that the SDM should follow the advance directive, whether or not the SDM takes her authority from it. This argument emphasizes individual autonomy and gives less credence to the possibility of changing personhood. If one recognizes that people may not fully appreciate now what will happen in the future, or if one believes that an incapacitated person may appreciate a situation very differently, one may be tempted to give the SDM more leeway. In addition, if one believes that the standard should always be “the best interest of the patient” and this best interest is not equated with respecting one’s wishes, one could recognize the role of family members or other SDMs in this decision making process. As indicated earlier also, documents often need interpretation. When such interpretation is required, it would seem normal that the interpretation by an SDM ought to prevail. Researchers are not in a better position to interpret an advanced directive than SDMs. On the contrary, they are in an inherent conflict of interest. They may very well be inclined (consciously or unconsciously) to favour research participation regardless of the possible impact on research subjects.

In legal terms, the issue for researchers is whether the objecting SDM can make a decision at odds with the consent to physical access in the advance directive. As noted above, in most provinces the duty to follow instructions

in an advance directive applies to all SDMs irrespective of their source of authority. However, where the advance directive appoints the SDM to be the actual decision maker, in addition to setting out the instructions to consent to physical access for research purposes, the SDM can at least initially obstruct such access until a legal proceeding is brought to invalidate that decision. In some provinces, though, as mentioned earlier, instructions contained in an advance directive operate automatically without the need for a SDM to implement them. In these provinces, such instructions may well be relied upon as the necessary consent, notwithstanding any objection by the SDM.

### *Information Access*

From an ethical perspective, an advance directive that supports information access after loss of capacity represents a solemn desire by the subject to give lifelong access to their health records. However, the same objection found in the physical access context also arises here: that advance directives should not be used outside the treatment context. On this view, a person can surely commit to paper their wishes about future medical care, housing and other related decisions, but should never be allowed to do so about any decisions relating to their privacy and bodily security in future. Like the sale of vital organs, the sale of “futures” in rights to observe an access may seem of a more dubious nature. Law, goes this view, should not give effect to non-medical instructions in an advance directive. Under this approach, disclosure of health information for other than a medical purpose should not be authorized by an advance directive.

This is not the situation in Canada, however. In legal terms, researchers seeking information access in this scenario can likely derive the needed authority from the presence of both a SDM and an advance directive. As mentioned above, the rights and powers of a SDM acting in relation to health information are very wide, encompassing all those held by the incapable individual. Should the SDM wish to follow the advance directive and allow information access, no legal issues will arise.

However, because of the breadth of her powers in relation to health information, if the SDM chooses to ignore the advance directive’s instructions in relation thereto, researchers may have little recourse. This is because, in most provinces, advance directives are only intended to address health care treatment decisions, not decisions about the disclosure of health information; they are entirely separate questions. If so, then instructions in a directive authorizing information access might be no more legally effective than the written consent researchers obtained while the subject was still capable.

Therefore, the SDM's authority – in relation to health information– would be superior to that of the advance directive. Should the SDM wish to ignore such an instruction in a directive, there may be, depending on the province, little recourse for researchers to obtain the subject's health information.

## **V. Conclusion**

In this paper we have tried to distill a set of basic legal and ethical guideposts for researchers facing subjects who have lost capacity. Because health care treatment legislation and health information legislation differ so much between provinces, providing a uniform answer to every ethical and legal question posed in the scenarios above is virtually impossible. Instead, we have striven to approximate the legal constraints that may – depending on the province – bind researchers. In some provinces, easy legal solutions will present themselves; in others, obtaining physical and information access to incapable subjects is much more difficult. In these instances, researchers would be advised to seek a legal opinion that addresses whether their specific access needs can be met within the relevant provincial legislation.

In general, though, we have highlighted some important legal provisions that may – depending again on the province – be of great benefit to researchers in the loss-of-capacity context. Prominent among these are provisions allowing advance directives to authorize SDM consent to research that would otherwise be prohibited. Another key provision mentioned is the schemes in every province to allow researchers to access information without consent. In general, then, it would seem that accessing information after a subject has lost capacity is less difficult than physical access. This seems reasonable. A physical invasion of a person's private sphere and bodily integrity, however limited, adds an additional layer of privacy concern. Where researchers can make arrangements with SDMs or can secure REB approval for non-consensual access to subjects' medical files, these may well fulfill all of their data gathering needs over the long term. Inconsistencies remain across the different provinces, which may create problems in the development of data gathering procedures for research projects that span across various Canadian provinces. Researchers in Canada would also greatly benefit from more clarity on how to gain physical access for research purposes. In this regard, some thought might be given to the possibility of developing a specific legislative scheme for the governance of complex databases. The question as to how this can be achieved, whether it should be through consistent provincial statutes, or through a federal legislative or regulatory initiative that focuses on biobanks, exceeds the scope of this paper. Such a regulatory scheme

should clarify under what conditions, if any, non-consensual physical access by researchers should be allowed and what type of procedural safeguards should be put in place. As we pointed out, provincial or federal legislators should also urgently address the significant gaps in the regulation of REBs. If we want to rely on REBs for the governance of the complex ethical and legal issues involved in biobank and other forms of research, an accountable, transparent, and consistent regulatory framework is urgently needed. It is clear that legislators, regulatory authorities and researchers must remain extremely attentive to the sensitive ethical issues at work whenever seeking to involve a person who has lost decision-making authority in research, and that legislators and policy makers can only design the best possible regulatory framework that will help shape the contours of human behaviour. Such a framework can never completely replace, and will therefore always have to rely in concrete circumstances on, the appropriate ethical judgment of researchers, SDMs and research subjects.