McGill Journal of Law and Health ~ Revue de droit et santé de McGill

SUBSTITUTE DECISION MAKING ABOUT RESEARCH: IDENTIFYING THE LEGALLY AUTHORIZED REPRESENTATIVE IN FOUR CANADIAN PROVINCES

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Canada's aging population presents new incentives for research on Alzheimer's and other forms of dementia. But the public interest in advancing knowledge about these diseases must be partnered with a concern for exploitation, in particular where a potential research subject is deemed legally incapable of making a decision about research participation.

The Tri-Council Policy Statement requires that the

Le vieillissement de la population canadienne crée de nouveaux incitatifs pour la recherche sur la maladie d'Alzheimer et sur d'autres formes de démence. Toutefois, le souci de faire avancer la recherche sur ces maladies doit aller de pair avec la prévention de l'exploitation, en particulier pour les sujets de recherche potentiels qui sont dans l'incapacité de décider de leur participation à une étude.

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Citation: Sheila Wildeman et al, "Substitute Decision Making About Research: Identifying the Legally Authorized Representative in Four Canadian Provinces" (2012) 6:1 MJLH 189.

Référence : Sheila Wildeman et al, « Substitute Decision Making About Research: Identifying the Legally Authorized Representative in Four Canadian Provinces » (2012) 6 : 1 RDSM 189.

research participation of subjects deemed incapable of consent be contingent upon authorization obtained from their legally authorized representative ("LAR"). However, where the prospective research subject is an adult, the question of who, if anyone, may act as an LAR is often uncertain. While some provinces and territories provide a clear statutory basis for identifying LARs, others do not.

We identified four provincial regimes that differ in their legislative approach to LAR identification. Of the four, British Columbia's health care consent legislation explicitly addresses the question of who, if anyone, may act as LAR for the purpose of authorizing an adult's participation in research, even in the absence of an advance directive or guardian. At the time of our study, Alberta's laws only addressed this question clearly where an advance directive was in place. Legislative reforms in that province have since expanded the circumstances in which an LAR for research may be identified. In contrast, both Nova Scotia and Ontario lacked (and continue to lack) any legislation explicitly addressing who, if anyone, may act as LAR for research. Indeed, Ontario's health care consent and substitute decision making laws explicitly state that they do not apply to procedures undertaken for the primary purpose of research.

A postal survey of five sub-populations (older adults, informal caregivers, physicians, researchers in aging, and REB members) was conducted in each of the four provinces. Respondents were presented with hypothetical scenarios and asked who, if anyone, had legal authority to make decisions about research participation. The most common response across provinces, scenarios, and population groups was that a close family member could act as an LAR, regardless of whether provincial laws clearly supported, clearly contradicted, or were uncertain with regard to that result. We conclude that the combined lack of clarity in, and lack of knowledge about, provincial laws relating to LAR identification that our study exposes indicates a fundamental gap in the system of research regulation. There is a need for increased legal clarity and public education on this important aspect of research governance.

L'Énoncé de politique des trois Conseils requiert que les recherches, sur la santé ou sur un autre domaine, auxquelles participent des personnes incapables de donner un consentement éclairé, soient soumises à une autorisation de la part du représentant légal du participant (RLP). Toutefois, lorsque le sujet de recherche est un adulte, la question de savoir qui peut agir en tant que RLP est souvent floue.

Nous avons identifié quatre régimes provinciaux qui diffèrent dans leur approche législative pour identifier le RLP. La législation sur le consentement dans le cadre des soins de santé mise en place par la Colombie-Britannique aborde explicitement la question de qui, s'il y a lieu, peut agir comme RLP pour autoriser un adulte à participer à une recherche, même lorsqu'il n'y a pas de directive préalable ou de tuteur. Au moment de notre recherche, les lois albertaines traitaient cette question uniquement lorsqu'une directive préalable était en place. Les réformes législatives de cette province ont depuis élargi les situations dans lesquelles un RLP peut être identifié pour une étude. En revanche, la Nouvelle-Écosse et l'Ontario n'avaient pas (et n'ont toujours pas) de mesures législatives abordant explicitement la question de savoir qui, s'il y a lieu, peut agir comme RLP pour une étude. En effet, les lois ontariennes sur le consentement aux soins de santé et sur la prise de décisions au nom d'autrui affirment explicitement qu'elles ne s'appliquent pas aux procédures entreprises lorsque le but principal est de mener des recherches.

Une enquête postale auprès de cinq sous-populations (personnes âgées, aidants naturels, médecins, chercheurs travaillant sur le vieillissement et membres des comités d'éthique de la recherche) a été menée dans chacune des quatre provinces. On a présenté des situations hypothétiques aux participants qui devaient identifier qui, prendre une décision quant à la participation à une étude. La réponse la plus fréquente pour s'il y avait lieu, avait l'autorité légale pour l'ensemble des provinces, des scénarios et des sous-populations était qu'un membre de la famille immédiate pouvait agir comme RLP, indépendamment du fait que cela ait été abordé, appuyé ou contredit par les lois provinciales. Nous concluons qu'il y a un besoin de clarté juridique et de sensibilisation du public en ce qui concerne cet aspect important de la gouvernance de la recherche.

Introduction[1]

When an adult[2] is legally incapable of deciding whether to participate in health research, who (if anyone) has the legal authority to make that decision? Furthermore, how well do Canadians with a stake in health research, such as older adults, informal caregivers of older persons with cognitive impairments, researchers in aging, and members of research ethics boards ("REBs"), understand the state of the law on this question? These two interrelated matters are addressed by our study.

We find that the laws of the four provinces we target are frequently unclear as to whether, or in what circumstances, a guardian, proxy appointed under an advance directive, or non-appointed family member may make a substitute decision about another adult's participation in health research. Moreover, we find that stakeholders in all five subgroups surveyed are frequently mistaken about the state of the law and tend to believe that a non-appointed family member can

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[1] This research was supported by a grant from the Canadian Institutes of Health Research. We thank Caregivers Nova Scotia, Ontario Alzheimer Societies, and the REBs that assisted us in facilitating this study. We also thank the Canadian Association of Retired Persons, the Alzheimer Society of Canada, and the Royal College of Physicians and Surgeons of Canada for their letters of endorsement. Additionally, we thank our advisory committee members on the state of the relevant provincial laws: Gerrit Clements, Dr Lori Weeks, Jill Steinman, Pat Henderson, Sara Gorelick, and Justice David Marshall. Finally, we thank Brad Abernethy for editorial assistance, Michael Hadskis, Jocelyn Downie, Elaine Gibson, and Vaughan Black for comments on a draft, and Joanna Weiss for research assistance.

[2] Our study is rooted in the question of whether the statute laws of selected provinces enable identification of a legal representative empowered to authorize another adult's participation in health research. We set aside questions relating to authorization of a minor's participation in research. This is primarily because where substitute decision making about health care is at issue, the common law recognizes parents as the guardians of their minor children. No such common law authority is forthcoming where adults are deemed to lack decision making capacity at law. Hence, while the case of substitute decision making for children is clear, there is a legal vacuum in the common law in the case of adults on the matter of third party authorization of any form of bodily or other intervention. That said, there remain important areas of controversy as to the scope of parental authority over a child's participation in research which overlap with some of the issues discussed here, e.g. must the research serve the prospective subject's best interests? How are best interests to be defined? See Michael Hadskis, "The Regulation of Human Biomedical Research in Canada" in Jocelyn Downie, Timothy Caulfield & Coleen Flood, eds, *Canadian Health Law and Policy*, 4th ed (Markham: Lexis/Nexis, 2011) 437 at 480-85.

make such decisions, even when this is not supported by legislation. Our findings indicate a disturbing gap between assumptions and reality regarding the legality of health research in Canada, and give rise to specific concerns about liability on the part of researchers, REB members, and research institutions.

I. Background

Historical precedents–from the Jewish Chronic Disease Hospital experiments in the early 1960s,[3] to more recent studies involving persons with chronic schizophrenia[4]–indicate the profound legal and ethical concerns that may arise when research is conducted upon adults with conditions that impair their ability to give valid consent.[5] At the same time, the advance of therapeutic options for such conditions as neurodegenerative disorders, serious mental illness, strokes, and coma-inducing disease or trauma may not be possible without research involving such persons. Thus there is increasing recognition of the need for clarity about the legal and ethical strictures on research into conditions af-

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[3] See *Hyman v Jewish Chronic Disease Hospital*, 206 NE 2d 338 (1965). The study at the centre of this case involved injection of live cancer cells into 22 elderly patients, in the absence of informed consent either from the subjects themselves (many of whom had dementia or impaired communicative capacities) or from family members. "The research went forward without review by the hospital's research committee and over the objections of three physicians consulted, who argued that the proposed subjects were incapable of giving adequate consent to participate" (Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments: Final Report of the President's Advisory Committee* (New York: Oxford University Press, 1996) ch 3).

[4] See Carl H Coleman, "Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment" (2008) 83 Ind LJ 743; Rebecca Dresser, "Mentally Disabled Research Subjects: The Enduring Policy Issues" (1996) 276:1 JAMA 67; Rebecca Dresser, "Research Oversight and Adults with Cognitive Impairment" (2003) 33:6 Hastings Cent Rep 9; Alexander M Capron, "Ethical and Human-Rights Issues in Research on Mental Disorders that May Affect Decision-Making Capacity" (1999) 340:18 New Eng J Med 1430.

[5] Jessica W Berg, "Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines" (1996) 24:1 JL Med & Ethics 18; Richard J Bonnie, "Research with Cognitively Impaired Subjects: Unfinished Business in the Regulation of Human Research" (1997) 54:2 Arch Gen Psychiatry 105; Paul S Appelbaum, "Involving Decisionally Impaired Subjects in Research: The Need for Legislation" (2002) 10:2 Am J Geriatr Psychiatry 120; Dresser, 1996, *supra* note 4; Dresser, 2003, *supra* note 4.

fecting decisional capacity.[6] These questions become increasingly urgent as population demographics motivate governments and corporate actors alike to sponsor research into health conditions associated with aging, such as Alzheimer's and other forms of dementia.

Commentators on the state of research governance in Canada have remarked upon the "patchwork" nature of applicable laws and policies.[7] It is difficult for a specialist in health law, let alone a non-legal professional or layperson, to assemble the relevant sources into a coherent framework for guiding action, complete with the possible implications of non-compliance. Where an adult is deemed legally incapable of providing consent to participate in research, the primary sources of legal and ethical guidance require, *inter alia*, that authorization be sought from the legally authorized representative ("LAR"). But the question of who, if anyone, may act as LAR with respect to an adult's research participation opens onto significant provincial variation, and, in certain provinces, deep uncertainty. With this variability and uncertainty come a host of concerns about the protection of research subjects from harm; about the protection of researchers, members of REBs, and affiliated institutions from liability; and about the possibility that liability worries may have a chilling effect on valuable research.

Against this complex background, we conducted a survey involving LAR identification in four provinces (British Columbia ("BC"), Alberta, Nova Sco-

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[6] DN Weisstub, S Verdun-Jones & J Walker, "Biomedical Experimentation Involving Elderly Subjects: The Need to Balance Limited, Benevolent Protection with Recognition of a Long History of Autonomous Decision-Making" in DN Weisstub, ed, *Research on Human Subjects: Ethics, Law and Social Policy* (Oxford: Pergamon, 1998) 405; National Bioethics Advisory Commission, *Research Involving Persons with Mental Disorders that May Affect Decision-Making Capacity*, Volumes 1 & 2 (Bethesda: National Bioethics Advisory Commission, 1998); Scott Kim et al, "Proxy and Surrogate Consent in Geriatric Neuropsychiatric Research: Update and Recommendations" (2004) 161:5 Am J Psychiatry 797; Elyn R Saks et al, "Proxy Consent to Research: The Legal Landscape" (2008) 8:1 Yale J Health Pol'y L & Ethics 37; Coleman, *supra* note 4.

[7] On the "patchwork" nature of the regulatory sources, see Hadskis, *supra* note 2 at 441, 450-51; Marie Hirtle, "The Governance of Research Involving Human Participants in Canada" (2003) 11 Health LJ 137 at 139-40; Gina Bravo et al, "Comparison of Provincial and Territorial Legislation Governing Substitute Consent for Research" (2005) 24:3 Canadian Journal on Aging 237 [Bravo et al, "Comparison Substitute Consent"]; George N Tomossy & David N Weisstub, "The Reform of Adult Guardianship Laws: The Case of Non-Therapeutic Experimentation" (1997) 20:1 Int'l J L & Psychiatry 113 at 123.

tia, and Ontario) from September 2007 to April 2009. The provinces selected took a range of legislative approaches to third party authorization of an adult's participation in health research. Some had statutes enabling certain determination of the identity and scope of authority of the LAR (in BC, and where an advance directive was in place, arguably also in Alberta). Others had ambiguous statutes giving rise to uncertainty about whether anyone could function as LAR. Finally, in certain circumstances, in the three provinces other than BC, there was simply no statutory foundation upon which to base the identification of an LAR.

Our objective was to learn how representatives of five groups with distinct relationships to the research enterprise (older adults, informal caregivers of older adults with cognitive impairments, physicians, researchers on aging, and REB members) would respond to the challenge of determining who, if anyone, could act as LAR for the purpose of authorizing another adult's research involvement in a variety of circumstances. The survey we used included four scenarios, each of which briefly described a research study in which an adult who lacked legal capacity to consent was invited to participate (See Appendix I). Each concluded by asking who, if anyone, had the legal authority to make a decision about the individual's participation. In each case, one of the listed options was "No one has clear legal authority." None of the four scenarios included prior authorization of substitute decision making about research participation, whether by advance directive or as a term of court-ordered guardianship. The key variables among the scenarios were: (a) whether a guardianship order not specific to research (scenario 2), an advance directive for health care (scenarios 3 and 4), or neither legal mechanism (scenario 1) was in place; and (b) whether there was a prospect that benefits would flow to the individual research subject (scenarios 1–3), or no such prospect (scenario 4).

The survey results featured a high level of consensus among respondents that an LAR could be identified in each scenario and, moreover, that the properly-identified LAR was the close family member featured in the scenario. This was the case regardless of whether that answer was clearly supported by, clearly contradicted by, or a matter of uncertainty under provincial law.

The structure of the paper is as follows. Part II defines some basic terms. Part III introduces the main sources of legal and ethical guidance, both international and domestic, on third party authorization of an adult's participation in health research. Importantly, given that the common law provides no foundation for third party authorization of an adult's research participation (except perhaps where there is an advance directive), Part III also introduces the stat-

utes of arguable relevance to identifying an LAR in the four provinces featured in our survey, classifying these provincial laws as they interact with our four hypothetical scenarios as follows:

I. clear authorization (i.e. there is a clear statutory basis for identifying an LAR),

II. unclear authorization (i.e. there is an ambiguous or uncertain statutory basis for identifying an LAR), or

III. clear lack of authorization (i.e. there is no statutory basis for identifying an LAR).

Part IV describes our survey methodology. Part V describes the results of the survey. Part VI discusses our research findings in light of the preceding legal analysis and other studies. Our conclusion offers recommendations aimed at redressing the legal uncertainty and public confusion about third party authorization of research identified herein.

II. Definitions

A. Consent versus Authorization

With limited exceptions,[8] legal authorization is a necessary condition to enrol an individual in health research. As Baylis, Downie, and Kenny observe:

> For persons with decision-making capacity, this authorization is their informed consent to research participation. For persons with-

[8] See Hadskis, *supra* note 2 at 474; 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*, arts 2.2-2.6 & 3.6-3.8 (December 2010), online: Government of Canada Panel on Research Ethics <www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf> [*TCPS2*]. The *TCPS2* was approved after our study was completed. The exceptions to the requirement of consent stated in the previous version of the *TCPS* are similar. 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*, arts 2.1(c) & (d), 2.3 & 3.1-3.3 (1998 with 2000, 2002 and 2005 amendments), online: Government of Canada Panel on Research Ethics <www.pre.ethics.gc.ca /archives/tcps-eptc/docs/TCPS%20October%202005_E .pdf> [*TCPS1*].

> out decisional capacity … this authorization is the permission to proceed granted by a legally recognized surrogate decisionmaker.[9]

This statement makes a distinction between informed consent obtained from the prospective participant, and third party authorization obtained from a representative of one who is incapable of giving informed consent.

Informed consent is premised upon voluntariness, capacity, and certain informational requisites, such as communication of the risks and possible benefits of the proposed intervention.[10] While the elements of decision making capacity are articulated differently across provinces, as well as across different statutory contexts in a single province, the core elements typically include the ability to understand the information relevant to the decision and to appreciate the consequences of a decision or failure to decide.[11] While most provinces lack a statutory definition of decision making capacity specific to participation in health research, the requirement of decision making capacity is implicit in the requirement of consent.[12] If a person lacks capacity to consent to research participation, then his or her participation is invalid unless authorization is obtained from a legally-authorized representative.

To be valid, third party authorization must also be voluntary, capable, and informed. Furthermore, there must be a legal foundation (and where substitute decision making for an adult is at issue, a statutory foundation) that empowers the individual to give the authorization. Specific terms may condition the validity of the authorization. For instance, in some jurisdictions advance directives legislation requires that a proxy appointed under a directive may authorize an adult's research participation only where the directive expressly permits this.[13]

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[9] F Baylis, J Downie & N Kenny, "Children and Decision-Making in Health Research" (1999) 21:4 IRB: A Review of Human Subjects Research 5.

[10] Patricia Peppin, "Informed Consent" in Downie, Caulfield & Flood, supra note 2 at 156, 162-75; Hadskis, *supra* note 2 at 469-85 (on the application of the law on informed consent to research settings).

[11] See Kathleen Glass, "Refining Definitions and Creating Instruments: Two Decades of Assessing Mental Competence" (1997) 20:1 Int'l JL & Psychiatry 5; *TCPS2*, supra note 8 at 40-44; Hadskis, *supra* note 2 at 480.

[12] Hadskis, *supra* note 2 at 478-81.

[13] This is the case with Manitoba's *Advance Health Care Directives Act*, CCSM c H27, s 14, and Newfoundland and Labrador's *Advance Health Care Directives Act*, SNL 1995, c A-4.1, s 5(3). See Hadskis, *supra* note 2 at 481-85, on the strictures beyond

Legislation and other regulatory instruments may further condition the validity of third party authorization upon the level of risk or prospective benefit ascribed to the research,[14] and may require decision makers to canvass certain considerations–such as the prior capable wishes, current wishes, best interests, or values of the individual. It is also important to note that in the research context, statutes and ethical guidelines may require that researchers obtain the contemporaneous assent, or at least refrain from acting against the contemporaneous dissent, of the prospective research subject.[15]

A final point on the distinction between consent to and third party authorization of an adult's participation in research arises in connection with the recent United Nations ("UN") *Convention on the Rights of Persons with Disabilities*.[16] Canada ratified this convention in March 2010. Article 12 states in part that

1. States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.

2. States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity.[17]

It is essential to recognize that in the context of health research, as in other areas of legal and social practice, the government of Canada has made a formal commitment to support the legal capacity of persons acting under a disability.

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third-party authorization that may apply where a prospective research subject is incapable of consent to research participation.

[14] See Part III(B), below.

[15] See *TCPS2*, *supra* note 8 art 3.10; art 21 CCQ; Part IIIB, below.

[16] *Convention on the Rights of Persons with Disabilities*, GA Res 61/106, UNGA, 76th Mtg, UN Doc A/Res/61/106, (2006), in force May 3, 2008 (ratification by Canada 11 March 2010) [*CRPD*].

[17] For a searching analysis of the implications of Article 12 for Canadian law, see Michael Bach & Lana Kerzner, "A New Paradigm for Protecting Autonomy and the Right to Legal Capacity" (October 2010), online: Law Commission of Ontario <www.lco-cdo.org/disabilities/bach-kerzner.pdf> [Bach & Kerzner, "New Paradigm"]. On the rise of the supported decision making paradigm in some Canadian provinces, see Robert M Gordon, "The Emergence of Assisted (Supported) Decision-Making in the Canadian Law of Adult Guardianship and Substitute Decision-Making" (2000) 23:1 Int'l JL & Psychiatry 61.

Canadian laws must be interpreted to reflect this commitment.[18] This arguably includes providing supports aimed at fostering the capacity of prospective subjects to make their own decisions whenever possible.[19]

B. Research versus Treatment

A second distinction relevant to our study is between research and therapy or medical treatment. Questions of whether and how to distinguish research from treatment for the purposes of ethical and legal norm-setting have attracted controversy in the bioethical and legal literature.[20] Nonetheless, a consistent approach is taken in several of the major ethical and legal documents promulgating research norms. On this approach, "treatment" describes therapeutic interventions undertaken in order to ameliorate a specific pathology affecting an individual subject, while "research" describes interventions aimed primarily at testing a hypothesis in order to generate universalizable knowledge. This accords with the definition of research in Canada's *Tri-Council Policy Statement* ("*TCPS2*"),[21] as well as the preamble to the Council of International Organizations of Medical Sciences' ("CIOMS") *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.[22] This matter takes on particular relevance in the interpretation of substitute decision making laws that speak to health care or treatment, but not, or not explicitly, to health research.[23]

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[18] See *Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817 at paras 69-71, 142 DLR (4th) 554.

[19] See Bach & Kerzner, "New Paradigm", *supra* note 17.

[20] Robert J Levine, "Clarifying the Concepts of Research Ethics" (1979) 9:3 Hastings Cent Rep 21 [Levine, "Clarifying Concepts"]; Trudo Lemmens & Paul B Miller, "Avoiding a Jekyll-And-Hyde Approach to the Ethics of Clinical Research and Practice" (2002) 2:2 Am J Bioethics 14.

[21] *TCPS2*, *supra* note 8 at 15 (defines research as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation"). Compare *TCPS1*, *supra* note 8, commentary under art 1.1.

[22] Council for International Organizations of Medical Sciences, in collaboration with the World Health Organization, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 1982, 1993, 2002) [*CIOMS Guidelines*].

[23] We recognize that the legal definition of research and treatment may differ depending on the purposes of the regulatory instruments employing these terms. But, as recounted in what follows in connection with the thesis of therapeutic misconception, we argue that there are good reasons to ensure that a distinction between research and

A further distinction is sometimes made between "therapeutic" and "non-therapeutic" research. Yet there is controversy about the nature of this distinction and the consequences it may entail. "Therapeutic research" typically describes research protocols or particular interventions within a single protocol that hold out a prospect of therapeutic benefit to the individual participant, while "non-therapeutic research" describes research that offers no benefit to participants.[24] Those who draw this distinction tend to claim that therapeutic research should attract less stringent regulatory requirements than non-therapeutic research. Such arguments, and the category of therapeutic research on which they rely, have been criticized for creating confusion about the different aims and risks of treatment and research.[25]

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treatment is maintained across the field of regulatory instruments concerned with third-party authorization of health care or research.

[24] See Levine, "Clarifying Concepts", *supra* note 20.

[25] See e.g. George J Annas, "Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research" (1996) 12 J Contemp Health L & Pol'y 297 (Annas argues that the term "therapeutic research" is "used to disguise the true nature of experimental protocols and to obscure the ideology of science (which follows a protocol to test a hypothesis) with the ideology of medicine (which uses treatments in the best interests of individual patients)" at 314). Commenting on the distinction between therapeutic and non-therapeutic research, Robert J Levine states:

> The class of activities covered by the term "therapeutic research" is also problematic because all clinical trials of therapeutic agents include some components that may be therapeutic (or at least are so intended) and others that are clearly nontherapeutic. Those who rely on the distinction between therapeutic and nontherapeutic research usually categorize research protocols with one or more components that are intended to be therapeutic as therapeutic research. Thus, all components of such protocols, both therapeutic and nontherapeutic, are justified according to the relatively permissive standards for therapeutic research. Among the nontherapeutic interventions that have been justified on this basis are placebos, some of which have been administered by catheterization of the coronary artery, and repeated coronary angiography and endoscopy in patients who would not have undergone such procedures if they had been treated outside a research protocol. I refer to this phenomenon as the "fallacy of the package deal." ("The Need to Revise the Declaration of Helsinki" (1999) 341:7 N Eng J Med 531 at 531)

Levine also notes that in the US, "federal regulations were revised in the early 1980s to classify interventions and procedures–not entire protocols–as either beneficial or not" ("Some Recent Developments in the International Guidelines on the Ethics of Research Involving Human Subjects" (2000) 918:1 Ann N Y Acad Sci 170 at 173).

Tomossy & Weisstub (*supra* note 7), in canvassing the gaps in Canadian guardianship laws with respect to decision making about participation in research, appear to accept

For this study, the primary question arising out of these controversies is whether some research might, because of its potential to deliver an individualized therapeutic benefit, be classed as "treatment" or "health care" under certain provincial substitute decision making laws. As related below, we do not deny that some research studies may be more likely to yield health benefits to individual research subjects than others. Indeed, we acknowledge that a research protocol offering a prospect of individual health benefits *might* be deemed treatment or health care as a matter of statutory interpretation, while it is impossible that a protocol offering no prospect of individual health benefits would be so classed. At the same time, we reject the stronger claim that research offering a prospect of health benefits may be unambiguously equated with health care for the purpose of interpreting substitute decision making laws. Rather, we acknowledge the possibility of competing legal arguments on this question.

To this definitional and descriptive point, we add a normative argument that bears on our ultimate policy recommendations. That is, there are persuasive reasons for a court to decide that so-called therapeutic research *should not* be equated with health care in the interpretation of substitute decision making laws. The inclusive interpretation diverts attention from the risks generated by elements of research protocols aimed primarily at producing knowledge, as opposed to therapeutic benefit,[26] and from important research-specific imperatives

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the critique that the concept of therapeutic research may inadequately distinguish treatment and research. They further note that "[t]he Law Reform Commission of Canada recommended that this term ["therapeutic research"] be dropped from the medical lexicon" (*ibid* at 114 n 4, citing Law Reform Commission of Canada, "Working Paper No 61: Biomedical Experimentation Involving Human Subjects", (Ottawa: LRCC, 1989) at 5). However, they argue that it is possible to salvage from these critiques a distinction whereby non-therapeutic research includes research protocols that are "primarily non-therapeutic, based on an objective appraisal of the experiment as a whole rather than the stated intent of the researcher" (*ibid* at 115). They class as therapeutic research that which offers a reasonably foreseeable likelihood of direct benefit (*ibid* at 114 n 2). In light of the critiques already noted, the problems attached to this approach include that of defining what it means for a protocol to be "primarily" therapeutic without, again, insupportably blurring the aims and attendant risks of treatment and research.

[26] Franklin G Miller & Howard Brody, "A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials" (2003) 33:3 Hastings Cent Rep 19 at 22. Miller and Brody argue that the contrast between therapeutic and non-therapeutic research is "misleading" because it blurs the distinction between patient-oriented

such as identifying and articulating any conflicts of interest and alerting research subjects where an individualized therapeutic program would present more favourable risk-benefit prospects.[27]

C. Therapeutic Misconception

The normative argument just made is reinforced by the observation that blurring the legal status of research and individualized therapy may create conditions conducive to the therapeutic misconception:[28] the psychological or insti-

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treatment and research interventions aimed at generalizable knowledge. Moreover, they find that the contrast

> diverts attention from key ethical issues. Consider a nontherapeutic trial in which one interviews subjects and takes saliva samples, and a therapeutic trial in which one is testing a new cancer drug that has some promise for creating remission, but also has potentially life-threatening toxicity. Is the latter trial less in need of stringent regulatory oversight because it is "therapeutic"? Or does the therapeutic-nontherapeutic distinction distract the observer from those aspects of the trials that assume far greater moral weight, such as the level of risks and the potential vulnerability of subjects? (*ibid*).

But see Lemmens & Miller, *supra* note 20. These authors argue that Miller and Brody are wrong to assert a fundamental difference between the aims and obligations attendant to research versus treatment. Rather, they believe it is essential to "continue to recognize the primacy of therapeutic obligations in clinical care and research" (*ibid* at 17).

[27] Coleman states the key arguments against aligning therapeutic research with regulatory regimes devoted to medical decision making (including best-interests-based surrogate decision making) as follows:

> Even studies that offer a prospect of direct medical benefit involve additional risks not present when patients undergo individualized medical treatment. There are also risks associated with the fact that the experimental intervention has never been proven to work. Moreover, even when the experimental intervention offered in a study looks especially promising as compared to existing therapeutic options, it will often be possible to obtain that intervention outside of research, either by finding a doctor willing to prescribe an approved drug off-label or seeking a compassionate use exemption to permit the non-research use of an unapproved drug. If the potential direct benefits of a study can be obtained without assuming the added risks of research, it is difficult to see how exposing an incapacitated person to those risks can be justified under a best interests analysis (*supra* note 4 at 768).

[28] See Paul S Appelbaum, Loren H Roth & Charles W Lidz, "The Therapeutic Misconception: Informed Consent in Psychiatric Research" (1982) 5 Int'l J L & Psychiatry 319; Paul S Appelbaum et al, "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception" (1987) 17:2 Hastings Cent Rep 20;

tutional predisposition of persons with an opportunity to participate in research–and potentially others, such as family members or researchers themselves–to exaggerate the possibility of individual benefits and underestimate the risks of research involvement.[29]

The validity of consent to or third party authorization of participation in research is dependent upon researchers clearly communicating to prospective subjects or third party decision makers that research and treatment are distinct. In other words, researchers must make it clear that the purpose of the research enterprise is advancement of knowledge about matters that are in some significant respect uncertain.[30] Again, this may require particular attention to disclosure of the risks and benefits of participation in a research protocol as compared with the risks and benefits of strictly therapeutic options, and identification of the interests and objectives beyond patient well-being that have informed the design or conduct of the research.[31]

Arguably, the therapeutic misconception may be minimized by ensuring that health care consent laws and policies clearly distinguish between treatment and research and address the terms for valid authorization of each.[32] Where prospective research subjects are deemed legally incapable of consent, their vulnerability to exploitation makes it particularly important that the researcher, the prospective research subject (as much as possible), and any substitute decision maker entrusted with advancing the subject's wishes or best interests are alerted to this fundamental distinction. Moreover, to avoid exacerbating the tendency to conflate treatment with research, laws that do contemplate substitute decision making about treatment without explicit contemplation of research arguably should not be interpreted to authorize substitute decision making about research.

Jay Katz, "Human Experimentation and Human Rights" (1993) 38 Saint Louis ULJ 7; Rebecca Dresser, "The Ubiquity and Utility of the Therapeutic Misconception" (2002) 19 Social Philosophy & Policy 271.

[29] See Appelbaum, Roth & Lidz, *supra* note 28; Appelbaum et al, *supra* note 28; Dresser, *supra* note 28.

[30] See Katz, *supra* note 28; Michael Hadskis et al, "The Therapeutic Misconception: A Threat to Valid Parental Consent for Paediatric Neuroimaging Research" (2008) 15:13 Accountability in Research 133; Coleman, *supra* note 4.

[31] See Coleman, *ibid* at 788; Saks et al, *supra* note 6 at 77.

[32] See Katz, *supra* note 28; Jesse A Goldner, "An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously" (1993) 38 Saint Louis ULJ 63.

III. Legal Background: The Challenge of Identifying an LAR for Substitute Decision Making about Research

A. International Sources

In this section, we review international health research norms addressing third party authorization of research participation. Some clearly have the status of international law and others, if not clearly expressive of customary international law, are nonetheless highly influential statements of research ethics norms.[33] We found no source of international legal or ethical guidance that speaks directly to the question of who may act as LAR for third party authorization of an adult's participation in health research. Indeed, some of the international sources canvassed here may be interpreted to indicate that health research (or "experimentation") should not be conducted at all in the absence of the individual's direct consent. We may perhaps read these sources as simply failing to contemplate the possibility of third party authorization, with safeguards. The remaining documents (which contemplate either direct or third party authorization) ultimately defer to domestic law on the matter of identifying an LAR.

One of the foundational sources of research ethics norms is the 1947 *Nuremberg Code*,[34] fashioned by US judges as part of the Military Tribunal process following the Allied victory in World War II. While the status of the *Code* as a source of norms at customary international law is contested,[35] it has nonetheless been recognized as a primary source of ethical guidance (and, on occa-

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[33] George F Tomossy & Jolyon Ford note: "Arguments have been advanced both for ... and against ... whether the basic principles enunciated in the most oft-cited international instruments, the *Nuremburg Code* and *Declaration of Helsinki*, provide a source of norms under customary international law." ("Globalization and Clinical Trials: Compensating Subjects in Developing Countries" in Belinda Bennett & George F Tomossy, *Globalization and Health: Challenges for Health Law and Bioethics* (Dordrecht, The Netherlands: Springer, 2006) 27 at 35). On the complexities of appealing to international law in Canadian courts, see Gibran Van Ert, *Using International Law in Canadian Courts*, 2d ed (Toronto: Irwin Law, 2008).

[34] *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No 10*, vol 2 (Washington, DC: US Government Printing Office, 1948) at 181-82.

[35] Tomossy & Ford, *supra* note 33. See also George J Annas, "Globalized Clinical Trials and Informed Consent" (2009) 360:20 N Eng J Med 2050; Erin Talati, "An Open Door to Ending Exploitation: Accountability for Violations of Informed Consent Under the Alien Tort Statute" (2006) 155:1 U Pa L Rev 231 at 259 n 139.

sion, as a touchstone for legal standard setting) by administrative and adjudicative bodies, both national and international.[36]

A plain reading of the *Code* yields the conclusion that no one may act as LAR. The *Code*'s first principle is that "the voluntary consent of the human subject is absolutely essential." There is no provision recognizing the possibility of third party authorization where legal capacity is lacking. It may be argued, however, that the silence of this early statement of research norms on the matter of third party authorization reflects a failure to contemplate the possibility of such authorization, with appropriate safeguards, rather than a clear intention to proscribe it.

Article 7 of the UN *International Covenant on Civil and Political Rights* follows in the same vein. It states that "[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."[37] Once again, the statement appears unequivocal. However, here too it may be argued that this statement of international norms (acceded to by numerous states, including Canada) fails to contemplate, but does not necessarily prohibit, third party authorization of research participation where other safeguards are in place.[38]

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[36] See Annas, *supra* note 35; Hadskis, *supra* note 2 at 449 ("[t]he Nuremberg Code and the Declaration of Helsinki continue to influence the regulation of research in Canada"). While these instruments do not have direct legal force, they inform the reasoning of policy-makers as well as judges in setting Canadian standards. See also Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill LJ 473 at 484-85, 487 (Campbell and Glass discuss the general concerns that may be raised around employment of professional norms such as the Declaration of Helsinki as guides to legal standards).

[37] *International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 171, Can TS 1976 No 47, 6 ILM 368 (entered into force 23 March 1976, accession by Canada 19 May 1976). [*ICCPR*]

[38] The Office of the High Commissioner for Human Rights, General Comment No. 20 (Forty-fourth session, 1992), states of Article 7 of the *ICCPR* that "special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment. Such persons should not be subjected to any medical or scientific experimentation that may be detrimental to their health." Canada is a party to the First Optional Protocol to the Covenant, which establishes a complaint mechanism

This argument is more difficult to make with respect to the recent UN *Convention on the Rights of Persons with Disabilities*.[39] Article 15 of the *Convention* prohibits "medical or scientific experimentation," again without the "free consent" of the individual.[40] Given that this historic statement of the rights of persons with disabilities explicitly addresses questions of legal capacity, including the duty of states to support legal capacity,[41] a persuasive case may be made that it registers a strict prohibition of research (or "experimentation," which may or may not include research offering a therapeutic benefit), except where there is personal consent. This may be taken as an unequivocal response to the historical record of egregious harms done to persons with disabilities (including psychosocial and intellectual disabilities) in the name of research. Yet we might ask whether the prohibition may be qualified in light of the general commitment of parties to the *Convention* to ensure that persons with disabilities enjoy "full and effective participation and inclusion in society,"[42] a commitment that must guide the interpretation of the *Convention*. This principle may be read to support the inclusion of persons living with profound cognitive disabilities in the social good of health research, at least where stringent protections (including support for decision making capacity) are provided, and where participation will enable a more equitable distribution of the benefits of research.[43]

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whereby individuals may bring complaints against states parties to the Human Rights Committee for breach of covenant rights, following the exhaustion of all domestic remedies. See *Optional Protocol to the International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 302 (entered into force 23 March 1976, accession by Canada 19 May 1976).

[39] *Supra* note 16.

[40] *Ibid*. Article 15(1) states that

> 1. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation.

[41] *Ibid*. Canada is not a party to the Optional Protocol to the Convention. Under the Optional Protocol, persons alleging violations of their rights under the Convention may bring complaints to the Committee on the Rights of Persons with Disabilities. See *Optional Protocol to the Convention on the Rights of Persons with Disabilities*, 13 December 2006, GA Res 61/106, Annex II, UN GAOR, 61st Sess, Supp No 49 at 80, UN Doc A/61/49 (2006) (entered into force 3 May 2008).

[42] *CRPD*, *supra* note 16 art 3(c).

[43] *TCPS2*, *supra* note 8 art 1.1 lays out three general principles intended to inform the interpretation and application of research ethics norms: respect for persons, welfare, and justice. The principle of justice is articulated so as to include the distributive

Other international statements of research norms recognize the legitimacy of third party authorization, while reflecting a concern for the unjustified exclusion of persons with cognitive disabilities from the fruits of research.[44] The World Medical Association's *Declaration of Helsinki*[45] falls into this category, though–like the *Nuremberg Code*–its status as a source of customary international law remains contested.[46] Article 5 states that "[p]opulations that are underrepresented in medical research should be provided appropriate access to participation in research." Article 9 states that among those research populations requiring special protections are persons who "cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence." More directly, article 27 states *inter alia* that "[f]or a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative."[47] Three additional requirements are stated, as follows:

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justice concern of allocating the benefits of research fairly (at 11). The *TCPS2* also underlines the importance of providing meaningful inclusion of vulnerable groups (including those deemed incapable of consent) in research, provided that appropriate protections from exploitation or other forms of oppression are in place (at 10). For arguments that there is no justification–based in justice, welfare, utility, or autonomy–for involving persons who lack legal capacity in non-therapeutic research (research producing no individual health benefit), see Penney Lewis, "Procedures That are Against the Medical Interests of Incompetent Adults" (2002) 22:4 Oxford JLS 575.

[44] See Tomossy & Weisstub, *supra* note 7 at 118-19.

[45] World Medical Association, *Declaration of Helsinki: Ethical Principles For Medical Research Involving Human Subjects*, (June 1964), online: WMA <www.wma.net/en/30publications/10policies/b3/index.html> [*Declaration of Helsinki*]. The Declaration has undergone six revisions since its original formulation in 1964, the latest of these having been made in 2008.

[46] Erin Talati observes that "[t]he Declaration of Helsinki is widely accepted as the most influential guidance document in the creation of statutory protections for human subjects" (*supra* note 35 at 260). See Talati's discussion, *ibid* at 260 n 142, of the recognition of a distinction between therapeutic and non-therapeutic research in earlier versions of the Declaration of Helsinki, with different ethical requirements imposed for each (even allowing physicians to proceed without consent where research was therapeutic). As Talati notes, later versions of the Declaration (from 2000 on) do not preserve this distinction, a change that "may represent recognition of the possibility for exploitation under the therapeutic misconception" (*ibid*).

[47] *Declaration of Helsinki*, *supra* note 45 art 27. The *CIOMS Guidelines* take this same approach, stating that research can proceed if consent is obtained from the legally authorized representative in accordance with applicable law (*supra* note 22 art 4).

> These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.[48]

As we will see, the terms of the *Declaration* find support in Canada's regulatory regime for oversight of clinical drug trials and Canada's *TCPS2*.[49]

One final international document has particular relevance to Canadian law, specifically as it relates to the legal regulation of clinical drug trials. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use has promulgated the 1996 *Good Clinical Practice: Consolidated Guideline* ("*GCP Guideline*")[50] as a statement of research ethics norms common to the US, the European Union, and Japan. This guideline has been endorsed by Health Canada as an interpretive aid for the *Clinical Trial Regulations* under the *Food and Drugs Act*.[51] Section 4.8.12 of the *GCP Guideline* indicates that both therapeutic and non-therapeutic research

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The *Guidelines*, prepared by the CIOMS in consultation with the World Health Organization, seek "to indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements" (at "Background"). For a description of other international codes or guidelines on the conduct of research, see Kevin M King, "A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects" (1998) 34 Stanford J Int'l Law 163. It is important to additionally note among the international legal instruments of significance the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, (Council of Europe Treaty Series No 164), and *Additional Protocol Concerning Biomedical Research* (Council of Europe Treaty Series No 195). Tomossy & Ford canvass the controversies among nations regarding the latter instrument's endorsement of surrogate consent for non-therapeutic research, *supra* note 33 at 36.

[48] *Declaration of Helsinki*, *supra* note 45 art 27.

[49] *Supra* note 8 arts 3.9, 4.6.

[50] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline on Good Clinical Practice: Consolidated Guideline E6(R1)* (1996) [*GCP Guideline*].

[51] *Food and Drug Regulations*, CRC, c 870, Part C Division 5 (*Drugs for Clinical Trials Involving Human Subjects*) [*Food and Drugs Regulations*].

require authorization from a legally acceptable representative.[52] Section 1.37 defines "legally acceptable representative" as "[a]n individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial." The *GCP Guideline*, like the *Declaration of Helsinki*, also stipulates further requirements, including obtaining assent from the subject who is deemed incapable of consent, when possible.[53]

In summary, there is some divergence among key statements of international health research norms with respect to the permissibility, or the conditions of permissibility, of research involving persons deemed incapable of consent. It may be argued that the conventions prohibiting experimentation without the individual's free consent are simply silent on the matter of third-party authorization and the circumstances in which such authorization would be valid. Those sources of research ethics norms that explicitly contemplate the possibility of such research may be understood to seek to bring into harmony the potentially conflicting imperatives of respect for persons and justice in distributing the fruits of research. One condition they impose is that third party authorization must be obtained. The problem, however, of identifying the lawful source of third party authorization remains.

B. Domestic Sources

There is a lack of clear and comprehensive guidance in Canada on the legality (or the conditions of legality) of health research involving adults who are legally incapable of providing consent. In particular, it is often not clear whether substitute decision makers recognized for other purposes are also authorized to make decisions about research.[54] Similar criticism has been made of US laws.[55]

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[52] *GCP Guideline*, *supra* note 50 s 4.8.12.

[53] *Ibid* at ss 4.8.12, 4.8.13. Article 28 of the *Declaration of Helsinki*, *supra* note 45 sets out a requirement to seek assent (where the research subject is deemed capable of assent) and to respect dissent.

[54] Bravo et al, "Comparison Substitute Consent", *supra* note 7; Paddi O'Hara & Ineke Neutel, "A Shadow of Doubt: Ethical Issues in the Use of Proxy Consent in Research, Part II: Competence and Proxy Consent in Terms of Guidelines and Regulations" (2004) 9:1 Can Bioethics Soc Newsletter 7; Tomossy & Weisstub, *supra* note 7 at 134.

[55] Kim et al, *supra* note 6; Saks et al, *supra* note 6.

This section first identifies the sources of liability that may apply where research is conducted in the absence either of consent or third party authorization. Next, it examines key statements of federal law and policy imposing an imperative of third party authorization where prospective research subjects lack capacity to consent, noting the lack of any basis for identifying an LAR in either federal law or policy, or at common law. Finally, this section outlines a set of legal sources that do present a basis for identifying an LAR to authorize research participation. Here we focus on the substitute decision making laws–guardianship, advance directive, and health care consent laws–of the four provinces targeted in our study.[56] Throughout, we supplement our central concern with the legal bases for identifying an LAR with attention to any conditions (e.g. risk-benefit thresholds) placed upon the validity of third party authorization of research.

We do not address federal and provincial laws relating to the protection of privacy and lawful disclosure of health information. In presenting the results of our study, however, we do note that these laws may have affected responses to the last of our four research scenarios.

1. Liability Attaching to Health Research in the Absence of Valid Authorization

In the absence of valid consent or third party authorization, interventions affecting the bodily integrity or property interests of an individual, whether in the name of treatment or research, may give rise to liability. The *Criminal Code*[57] may ground liability where research involving bodily interventions proceeds in the absence of valid consent or third party authorization. Specifically, unauthorized bodily touching may give rise to charges of assault or criminal negligence.[58] In addition, property-based offences may be engaged where bodily materials are seized without authorization.[59]

At common law, an unauthorized touching may ground a tort claim of battery, while a threat of unauthorized touching may ground a claim of assault. In the civil law, such activities may amount to a breach of article 1457 of the *Civil*

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[56] For a more comprehensive analysis of all provincial and territorial laws as they stood in 2005, see Bravo et al, "Comparison Substitute Consent", *supra* note 7.

[57] RSC 1985, c C-46.

[58] Bernard M Dickens, "The Legal Challenge of Health Research Involving Children" (1998) 6 Health LJ 131 at 135.

[59] *Ibid* at 136-37.

Code of Quebec, which outlines the province's general regime of civil responsibility. Where research is conducted in the absence of valid third party authorization, liability in battery or assault may attach to the actions of the researcher, with a potential for vicarious liability on the part of the research institution if the researcher is an employee. In addition, liability in negligence may attach to researchers, research sponsors, research institutions, or REB members if the conduct, approval, or support of research is found to breach the applicable legal standard of care–for example, by failing to ensure sufficient disclosure of risks or otherwise failing to ensure the validity of authorization.[60]

REBs may, in addition, be susceptible to administrative law review, either because they carry out specific statutory mandates[61] or because their position within the decision making apparatus of a university or other institution falls within the reach of administrative law.[62] On this basis, an REB's approval of a research protocol without ensuring valid third party authorization might be quashed as a substantive illegality (e.g. for failing to consider a factor of mandatory relevance). Furthermore, if an REB or research institution were deemed either to be part of the apparatus of government or, alternatively, a private body acting in furtherance of a specific government program or policy,[63] its decision to permit research in the absence of valid third party authorization may be susceptible to challenge under the *Canadian Charter of Rights and Freedoms*.[64]

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[60] Hadskis, *supra* note 2 at 495-99; Mary M Thomson, "Bringing Research into Therapy: Liability Anyone?" in Trudo Lemmens & Waring Duff, eds, *Law and Ethics in Biomedical Research: Regulation, Conflict of Interest and Liability* (Toronto: University of Toronto Press, 2006) 183; Jennifer L Gold, "Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards" (2003) 11 Health LJ 153.

[61] See Michael Hadskis & Peter Carver, "The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards" (2005) 13:2 & 3 Health L Rev 19 (on the "recent proliferation of statutory REB mandates" at 22-23, and at 24-28 on a set of possible bases of administrative law regulation of REB decision making).

[62] *Ibid* at 20-22.

[63] See Patricia Kosseim & Megan Brady, "Policy By Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes" (2008) 2 McGill JL & Health 5 at 13 n 34; *Eldridge v British Columbia (AG)*, [1997] 3 SCR 624, 151 DLR (4th) 577; *Douglas/Kwantlen Faculty Assn v Douglas College*, [1990] 3 SCR 570, 77 DLR (4th) 94; *Slaight Communications Inc v Davidson*, [1989] 1 SCR 1038, 59 DLR (4th) 416; *Blencoe v British Columbia (Human Rights Commission)*, 2000 SCC 44, [2000] 2 SCR 307.

[64] Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (UK)*, 1982, c 11 [*Charter*] (e.g. as interfering with the section 7 right to liberty and bodily

Whether traced to government or private actors, research norms and practices must also conform to the requirement of non-discrimination imposed by federal and provincial human rights codes. Research that imposes a disproportionate burden on persons with disabilities (including cognitive disabilities) may attract penalties, financial or otherwise.

Failure of a researcher to obtain valid third party authorization may also breach medical ethics codes promulgated by provincial colleges of medicine. Breach of these codes may result in professional disciplinary processes.[65] Additionally, legal action may be grounded in breach of privacy interests when personal information is appropriated or used for research purposes without consent or third party authorization.[66]

a. Federal Sources of Research Norms Mandating an LAR

In addition to the foregoing sources of liability, penalties may apply where non-compliance with research-specific codes or guidelines is established. Two sources of research norms at the federal level are of particular relevance.

As noted, the *TCPS2*[67] sets out guidelines for research on humans that are applicable to institutions and researchers receiving funding from one of Canada's three federal research funding agencies.[68] While the *TCPS2* is not a statutory instrument, a requirement of adherence to its terms is incorporated into these agencies' funding agreements with research institutions.[69] Failure to comply may result in termination of funding and an obligation to repay funds

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integrity). Note that a recent judgment of the Supreme Court of Canada indicates that administrative decisions involving adjudicative discretion should be reviewed under common law administrative law principles, even where the decision engages *Charter* values (*Doré v Barreau du Quebec*, 2012 SCC 12 (available on CanLII)).

[65] Hadskis & Carver, *supra* note 61. Compliance with *TCPS2* guidelines is specifically required by some provincial medical associations. See Hadskis, *supra* note 2 at 443, 449.

[66] See Elaine Gibson, "Health Information: Confidentiality and Access" in Downie, Caulfield & Flood, *supra* note 2 at 286-88; Hadskis, *supra* note 2 at 485-90.

[67] *Supra* note 8.

[68] These are: the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

[69] See Hadskis, *supra* note 2 at 442-43.

conferred.[70] Among the *TCPS2* guidelines relevant to research involving persons deemed legally incapable of giving consent is article 3.9(b), which states that researchers must obtain "consent from authorized third parties in accordance with the best interests of the persons concerned."[71]

The *TCPS2* also includes commentary on the assessment of decisional capacity,[72] and a requirement that research involving persons who lack capacity to consent not "expose the participants to more than minimal risk without the prospect of direct benefits for them."[73] It further requires that the wishes of

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[70] See Natural Sciences and Engineering Research Council of Canada, *Tri-Agency Process for Addressing Allegations of Non-Compliance with Tri-Agency Policies,* online: NSERC <www.nserc-crsng.gc.ca/NSERC-CRSNG/governance-gouvernance/process-processus_eng.asp>.

[71] *TCPS2*, *supra* note 8 at 41. The *TCPS2* at 27 defines "authorized third party decision maker" as "any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project." The *TCPS1* also stated a requirement of third party authorization where the research subject is incapable of consent, and indicated that the identity of the LAR must be determined in light of provincial law. See *TCPS1*, *supra* note 8 s 2E ("Competence"), especially arts 2.5, 2.6.

[72] The *TCPS2*, *supra* note 8 at 41 acknowledges that the standard of legal capacity applicable to decisions about research participation may shift depending on the jurisdiction. Yet this section nonetheless advises that capacity to decide about research participation demands an ability to understand the information relevant to the decision and to appreciate that information or evaluate the decision's likely consequences for oneself, reflecting the standards in place in certain Canadian jurisdictions, most notably Ontario's, which were subject to judicial interpretation in the case *Starson v Swayze*, 2003 SCC 32, [2003] 1 SCR 722. The *TCPS2* further provides at 40 that "[t]his ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought."

[73] *TCPS2*, *ibid* art 4.6(b). This article stipulates two additional conditions:

> (a) the research question can be addressed only with participants within the identified group; and …
>
> (c) where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

Also see article 3.9(a-e). "Minimal risk" is defined in the *TCPS2* as "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research." The passage adds:

prospective subjects with "some ability to understand the significance of the research" be ascertained by researchers and that those who dissent not be involved in the research.[74]

The other federal source of relevant research-specific norms is the *Clinical Trials Regulations*.[75] These regulations under the *Food and Drugs Act*[76] apply to clinical trials of drugs for human use.[77] Consequences of non-compliance may include "warning letters, suspension or cancellation of an authorization to sell or import a drug for the purposes of a clinical trial, injunctions, and criminal prosecutions."[78]

Under the regulations, sponsors of research must obtain REB approval "at each clinical trial site,"[79] and approving REBs must attest to upholding the standards of "good clinical practices."[80] Some guidance on the substance of those standards is given through Health Canada's endorsement of the *GCP*

> In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (at 23).

The minimal risk standard has been subject to critical commentary (see e.g. Loretta M Kopelman, "Moral Problems in Assessing Research Risk" (2000) 22:5 IRB: A Review of Human Subjects Research 3), while attracting in some quarters at least a partial defence (see e.g. Paul B Miller & Charles Weijer, "Moral Solutions in Assessing Research Risk" (2000) 22:5 IRB: A Review of Human Subjects Research 6).

[74] *TCPS2*, *supra* note 8 art 3.10. For commentary on the requirements of respect for assent and dissent, see Betty S Black et al, "Seeking Assent and Respecting Dissent in Dementia Research" (2010) 18:1 Am J Geriatr Psychiatry 77.

[75] Food and Drugs Regulations, supra note 51.

[76] *Ibid*.

[77] A description of the terms of the regulations is provided in Hadskis, *supra* note 2 at 444-46.

[78] *Ibid* at 445; see Health Products and Food Branch Inspectorate, "Policy-0001: Compliance and Enforcement Policy, Version 2" (date of implementation: 31 May 2005) at 8-10, online: HC <www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/pol_1_e.pdf>.

[79] *Food and Drug Regulations*, *supra* note 51 s C.05.006(1)(c).

[80] *Ibid* ss C.05.010, C.05.012(*h*).

Guideline.[81] As noted earlier, the *GCP Guideline* states that research involving persons who lack capacity to consent requires permission from their "legally authorized representative."[82] The *GCP Guideline* adds that a researcher should inform and seek assent from the subject in accordance with his or her understanding.[83] Article 4.8.14 states further conditions that apply specifically to "non-therapeutic"[84] clinical trials:

> (a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.
>
> (b) The foreseeable risks to the subjects are low.
>
> (c) The negative impact on the subject's well-being is minimized and low.
>
> (d) The trial is not prohibited by law.
>
> (e) The approval/favourable opinion of the [REB] is expressly sought on the inclusion of such subjects, and the written approval/favourable opinion covers this aspect.

Moreover, subjects are to be withdrawn "if they appear unduly distressed."[85]

2. Identifying an LAR: Legal Foundations

We have seen that health research conducted without valid authorization may attract various forms of liability. Moreover, we have seen that both the *TCPS2* and the *Clinical Drug Trial Regulations* indicate that research involving persons who are incapable of consent is permissible only if the researcher obtains valid third party authorization, among other conditions. We must turn to

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[81] *GCP Guideline*, *supra* note 50. See the statement of Health Canada adopting the Guideline, "Clinical Trials Regulations" (17 October 2007) online: HC <www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/pol/clini-reg-eng.php>.

[82] *GCP Guideline*, *supra* note 50 ss 3.1.6, 4.8.12, 4.8.14.

[83] *Ibid* s 4.8.12.

[84] *Ibid* s 4.8.13 defines a non-therapeutic trial as "a trial in which there is no anticipated direct clinical benefit to the subject."

[85] *Ibid* s 4.8.14.

provincial law to determine who, if anyone, possesses the legal power to give third party authorization of research.

a. Constitutionality

The legal sources that may enable identification of an LAR must be constitutionally valid. In Canada, legislative authority over matters relating to health is shared between provincial and federal governments,[86] with general legislative authority falling to the provinces.[87] On the matter of jurisdiction over health research, whether that jurisdiction is exclusively federal, exclusively provincial, or shared is a matter of some controversy.[88] As we have seen, both federal laws, such as the clinical drug trials regulations under the *Food and Drugs Act*,[89] and provincial laws (like those canvassed below) speak to the regulation of health research.

Furthermore, all legislation and government action must conform to the *Charter*.[90] Laws contemplating third party authorization of research offering no prospect of individual benefit are susceptible to *Charter* challenge, al-though

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[86] The federal government's claim to legislative powers with respect to health arises in virtue of the federal spending power, along with, *inter alia*, its jurisdiction over criminal law, trade and commerce, quarantine and the establishment of marine hospitals, and the promotion of peace, order and good government under s 91 of the *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, reprinted in RSC, 1985, App II, No 5 [*Constitution Act, 1867*].

[87] The provinces' legislative powers with respect to health arise in virtue of, *inter alia*, their authority over property and civil rights (s 92(13)), hospitals (s 92(7)), and matters of a local or private nature (s 92(16)) under the *Constitution Act, 1867*, *supra* note 86. See *Schneider v British Columbia*, [1982] 2 SCR 112, 139 DLR (3d) 417.

[88] See *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 SCR 457; Erin Nelson, "Regulating Reproduction" in Downie, Caulfield & Flood, *supra* note 2 at 326-34 (discussing the *Assisted Human Reproduction Act* reference). And see Jennifer Llewellyn, Jocelyn Downie & Robert Holmes, "Protecting Human Research Subjects: A Jurisdictional Analysis" (2003) Health LJ Special Edition: Health Law in the 21st Century 207 (the authors argue for substantial if not exclusive federal jurisdiction over research involving humans).

[89] *Food and Drugs Regulations*, *supra* note 51.

[90] Kosseim & Brady, *supra* note 63.

some argue that such laws (or the constitutionally-sensitive interpretation and application thereof) could be justified under section 1.[91]

b. No Common Law Basis for Identification of an LAR

There is no common law basis for identifying an LAR. While the common law recognizes parental authority to make health care or other decisions in the best interests of their minor children,[92] there is no comparable common law foundation for establishing third party decision making for a legally-incapable adult. Though this is clearly recognized in the academic literature,[93] it does not

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[91] See Dickens, *supra* note 58 at 145-46 (citing sections 7 (life, liberty and security of the person), 8 (right to be free from unreasonable search and seizure), 12 (right to be free from cruel and unusual punishment) and 15(1) (non-discrimination)). Dickens indicates that such laws might be justified under s 1 of the *Charter* if the government were to demonstrate that the contribution of the laws to advancing the interests of the individuals or groups concerned, or the public interest, outweighs the harm done to the protected interests.

[92] See *B(R) v Children's Aid Society of Metropolitan Toronto*, [1995] 1 SCR 315 at 372, 122 DLR (4th) 1, per La Forest J: "[T]he common law has always, in the absence of demonstrated neglect or unsuitability, presumed that parents should make all significant choices affecting their children, and has afforded them a general liberty to do as they choose." Where it is alleged that parental decision making about the health care of minor children comes into conflict with the best interests of the child, a legal challenge may be raised under provincial child welfare legislation or by way of an application to a court to exercise its *parens patriae* jurisdiction to protect the best interests of the child (see Joan Gilmour, "Children, Adolescents, and Health Care" in Jocelyn Downie, Tim Caulfield & Colleen Flood, eds, *Canadian Health Law and Policy*, 3rd ed (Markham: LexisNexis, 2007) 205 at 206-07).

[93] See Gerald B Robertson, *Mental Disability and the Law in Canada*, 2d ed (Scarborough: Carswell, 1994) at 473; Gilbert Sharpe, *The Law & Medicine in Canada*, 2d ed (Toronto: Butterworths, 1987) at 78-79; Bernard M Dickens, "The Role of the Family in Surrogate Medical Consent" (1980) 1:3 Health L Can 49; Marc E Schiffer, *Psychiatry Behind Bars: A Legal Perspective* (Toronto: Butterworths, 1982) at 187; Lorne Elkin Rozovsky, "Consent to Treatment" (1973) 11 Osgoode Hall LJ 103 at 110. As Robertson points out, in the domain of health care, "an application may be brought to have the court exercise its *parens patriae* jurisdiction and authorize the treatment" (Robertson, *ibid* at 473). As we discuss below, it is not clear that such authorization would extend to research.

See also Manitoba Law Reform Commission, *Substitute Consent to Health Care* (Winnipeg: Manitoba Queen's Printer, 2004). Unlike most Canadian provinces and territories, Manitoba has no statutory basis for vesting medical decision making authority in a family member or other in case of an adult individual's incapacity: "[a]t

appear to be widely understood beyond the domain of academics or specialized legal professionals. It is worth noting that the common law in England has developed differently than the common law in Canada, by allowing medical treatment without third party authorization where the patient is incapable of consent, and when the care is necessary (but not urgently necessary) to the patient's health.[94] English legislation was recently passed codifying this principle (which has the effect of protecting treating physicians from liability); the legislation also fills historical gaps in the common law of England on the legality of research involving persons deemed incapable of consent.[95]

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common law, only a court-appointed guardian (such as a committee) or the court itself, under its *parens patriae* jurisdiction, can consent to or refuse treatment on behalf of an incapable patient" (at 9). At the time of the Commission's research, substitute consent to treatment was authorized in the province only in the narrow circumstances covered by the *Mental Health Act*, SM 1998, c 36, CCSM c M110, the *Vulnerable Persons Living With a Mental Disability Act*, SM 1993, c 29, CCSM c V90, or, where an advance directive for health care was in place, the *Health Care Directives Act*, SM 1992, c 33, CCSM c H27 (at 10-12). The Commission observed, however, that despite the lack of legal justification outside these limited contexts, "[i]n most cases, the health care provider will turn to the person's family for consent because, even though there is no legal justification for doing so, it is the most reasonable course of action in the circumstances" (at 19). In view of the consequent risks of liability, along with the possibility that patient self-determination may be compromised, the Commission recommended that substitute decision making legislation be adopted (at 19-21).

[94] *In re F* (1989), [1990] 2 AC 1 HL (Eng). This represents an extension of the defence of necessity (not limited to emergency situations) that has never been recognized in Canada.

[95] With the *Mental Capacity Act 2005* (UK), c 9, English law has codified the authority of health professionals to give treatment according to their understanding of the individual's best interests and without third-party authorization, unless an advance directive applicable to the circumstances is in place (s 5). In the case of research (or "intrusive" research–defined as research interventions that would require consent as a matter of law if the subject was capable of consent (*ibid* s 30(2)))–the requirements under the *Mental Capacity Act 2005* differ. Apart from stating certain threshold conditions (including a requirement of minimal risk and of prospective benefits likely to outweigh the risks), the Act requires third-party authorization (s 32). The researcher must identify a family member, unpaid caregiver, or other person who fits the statutory criteria for acting as a "consultant." Where that person indicates that the prospective research subject would not wish to be involved in the research, that person must not be involved, unless the research is already underway and withdrawal would compromise his or her health (ss 32(2-3), (5-6)). Respect for the subject's contemporaneous dissent is also required (s 33). The conditions placed upon clinical

In the absence of a common law foundation, third party authorization of medical interventions or research for an adult must be based in one of three sources: (1) guardianship legislation, which typically requires a court order indicating the guardian's identity and scope of authority; (2) legislation vesting a narrower form of decision making authority in a family member or another in the event of an individual's incapacity (e.g. health care consent legislation); or (3) an advance directive, the authority of which may be recognized under legislation or at common law. We return briefly to advance directives below.

There remains the possibility of an application to a superior court to exercise its *parens patriae* jurisdiction to authorize a particular intervention. However, this is at best an uncertain route to authorization of research involvement.[96] The Supreme Court of Canada's decision in *E (Mrs) v Eve* confirms that the *parens patriae* jurisdiction of superior courts may be exercised only to advance the interests of the individual acting under a legal incapacity.[97] Specifically, the Court relied upon this principle to refuse an application by Mrs. E for authorization to consent to the surgical sterilization of her intellectually disabled daughter. In his judgment on behalf of the Court, Justice La Forest characterized the requested procedure as "non-therapeutic." In other words, the proposed surgical sterilization was intended to alleviate concerns that were not clearly or directly related to Eve's health. Rather, the Court understood the application to be primarily motivated by Eve's mother's concerns about the supervisory and child-rearing responsibilities potentially falling to her as a result of Eve's reproductive potential.[98]

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drug trials in England are separately addressed under the *Medicines for Human Use (Clinical Trials) Regulations 2004* (SI 2004/1031, as amended by SIs 2006/1928, 2006/2984, and 2008/941). These regulations also include a requirement of third-party authorization (*ibid*, Schedule 1, Part 1 s 1(4), Part 5).

[96] Tomossy & Weisstub, *supra* note 7 at 127 (their emphasis is on the uncertainty of a court actually authorizing non-therapeutic research).

[97] [1986] 2 SCR 388 at 400-01, 31 DLR (4th) 1 [*Re Eve*].

[98] *Ibid* at 401. It should be noted that the identification of Eve's interests with strictly-defined medical or therapeutic interests has attracted critical commentary in the years since this decision. See Sheila Wildeman, "The Supreme Court of Canada at the Limits of Decisional Capacity" in Jocelyn Downie & Elaine Gibson, eds, *Health Law at the Supreme Court of Canada* (Toronto: Irwin Law, 2007) 239 at 261-65; M Anne Bolton, "Whatever Happened to Eve? A Comment" (1987-88) 17:2 Man LJ 219; Colleen M Olesen, "Eve and the Forbidden Fruit: Reflections on a Feminist Methodology" (1994) 3 Dal J Leg Stud 231; Kristin Savell, "Sex and the Sacred:

Just as the *parens patriae* jurisdiction does not admit authorization of non-therapeutic sterilization, so this jurisdiction may also be incompatible with authorization of health research, which describes interventions intended to produce societal benefits, not (or not primarily) to advance the interests of the individual subject. On this argument, then, even a court may not be able to authorize "non-therapeutic" research.

Controversy persists as to whether the *parens patriae* jurisdiction might ever be compatible with the authorization of research and if so, under what conditions. This controversy is echoed in debates about the scope of parental guardianship at common law and the scope of broadly-stated statutory guardianship (including adult guardianship) powers.[99] Bernard Dickens has opined that the most defensible, or least risky, interpretation of *Re Eve*'s relevance to research is that the court's *parens patriae* jurisdiction (and we may argue, by analogy, the authority of parental and perhaps other guardians) is limited to authorizing interventions that offer a reasonably foreseeable therapeutic benefit to the subject. Those prospective benefits may arguably include psychological and social benefits.[100] Dickens further suggests, however, that parents may be able to enrol children in research that lacks a therapeutic benefit as long as the risks are "minimal" (i.e. no greater than the background risks routinely faced in the child's daily life).[101] Might guardians of adults be argued to be similarly empowered; i.e., might such authority be recognized by way of interpretation of the broad or vague powers conferred by some guardianship laws?[102] These controversies concern the scope of authority of one already vested with legal pow-

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Sterilization and Bodily Integrity in English and Canadian Law" (2004) 49:4 McGill LJ 1093.

[99] Dickens, *supra* note 58 (in *Re Eve*"[t]he court was concerned with the scope of its own power rather than that of Eve's mother, but it approached its rights when acting *in loco parentis* in close analogy to the rights of natural parents" at 132-33).

[100] See Dickens, *ibid* (noting that both the understanding of "health" expressed in *Re Eve* and the definition of the World Health Organization comprehend "physical, mental and social well-being" at 134); Françoise E Baylis & Jocelyn Downie, "An Ethical and Criminal Law Framework for Research Involving Children in Canada" (1993) 1 Health LJ 39 at 49; Norman L Cantor, *Making Medical Decisions for the Profoundly Mentally Disabled* (Cambridge, Mass: MIT Press, 2005).

[101] Dickens, *supra* note 58 at 135-36. See also Tomossy & Weisstub, *supra* note 7 at 126-27.

[102] Of course, controversy would likely arise around whether this authority is implicit in generally worded provisions conferring guardianship powers, i.e. whether the interpretation would amount to a legitimate realization of statutory purposes or an illegitimate instantiation of judicial "legislation".

er to make decisions on behalf of another individual. They do not contradict the earlier point that there is no common law foundation for identification of an LAR, except to the extent that a court might itself possess this power, were authorization of research to be found to fall within the *parens patriae* jurisdiction.

In sum, there is no common law basis in Canada on which third party authorization of an adult's participation in research (or, for that matter, health care) may be said to vest in a family member or other individual. Moreover, the Canadian jurisprudence on the limits of the court's *parens patriae* jurisdiction offers no clear basis for asserting that a court could directly authorize research if faced with an application to do so. However, some argue that research presenting a prospect of therapeutic benefit, and potentially even research offering no prospect of direct benefit but no more than minimal risk, might fall under the court's *parens patriae* jurisdiction or the powers of parental or statutory guardians.

c. Advance Directives

The validity of advance directives at common law is a separate matter. In *Malette v Shulman*,[103] the Ontario Court of Appeal upheld the validity of an instructional directive about health care in the absence of a legislative basis for the validity of the document. Ontario currently has a legislative regime for advance directives that provides for appointment of a proxy for substitute decision making about health care.[104] Moreover, Ontario's health care consent law requires substitute decision makers to follow the instructions (or prior express wishes) of those they represent.[105] *Malette v Shulman* continues to be of importance in grounding the authority of instructional directives which do not appoint a proxy, and serves as persuasive authority on the legal status of this sort of document in other jurisdictions lacking applicable legislation. The validity of advance directives for research participation, however, remains uncertain as a matter of common law.[106] As we will see, certain provinces have adopted legislation that clarifies the conditions of validity of research-specific directives.

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[103] *Malette v Shulman* (1990), 72 OR (2d) 417, 67 DLR (4th) 321 (Ont CA).

[104] *Substitute Decisions Act*, SO 1992, c 30, s 46.

[105] *Ibid* s 46(7). See also *Health Care Consent Act*, *1996*, SO 1996, c 2, Schedule A, ss 5 & 21.

[106] See *TCPS2*, *supra* note 8 at 42-44 (acknowledging that "[t]he efficacy of research directives is unknown and their legal status has not yet been recognized or tested,"

d. Provincial Laws and Legally Authorized Representatives

As discussed earlier, neither international statements of research norms nor federal law and policy can be relied on to identify an LAR where an adult lacks capacity to decide about his or her participation in research. In what follows, we address whether the laws of the four provinces targeted in this study enable identification of an LAR for authorizing an adult's participation in research. These laws may be divided into three categories:

I. clear authorization (i.e. there is a clear source of law allowing identification of an LAR),

II. unclear authorization (i.e. the law is ambiguous; whether there is a source of law allowing identification of an LAR is legally contestable), and

III. clear lack of authorization (i.e. there is clearly no legal basis for identification of an LAR).[107]

Category III encompasses situations in which statutes clearly state that there shall not be an LAR in an identified circumstance and situations in which no statute applies, even in an ambiguous or legally-contestable manner. This assumes the point made in the last section: that there is no common law foundation for third party authorization of health research (at least in the absence of an advance directive, in which case the common law offers an uncertain foundation for recognition of an LAR per category II).

Categories II and III are both described by the phrase supplied within our study: "no one has clear legal authority." Category II, however, also admits of alternative responses, adopting a stance of certainty about identification of an LAR in the face of uncertainty or ambiguity. Such responses, while defensible, ignore the unsettled status of the law on point. In contrast, the third category admits of no such alternative response, as we see it, even on a generous construction of the law.

In what follows, we describe these different categories further with reference to the four provinces targeted in our study and the primary mechanisms

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but advising that such directives be consulted by researchers and LARs for guidance about the advisability of involving the individual in research). See also Hadskis, *supra* note 2 at 484-85.

[107] Bravo et al, "Comparison Substitute Consent", *supra* note 7.

through which an LAR for research may be empowered: general health care consent legislation applicable in the absence of an advance directive or court-appointed guardian, court-ordered guardianship, or an advance directive.

i. Category I: Clear Authorization

1. British Columbia

Of the four provinces targeted in this study, BC most clearly addresses the question of who may make substitute decisions about research and on what conditions. The power of a third party to authorize health research involving another adult in BC flows from the *Health Care (Consent) and Care Facility (Admission) Act* ("*HCCFA*").[108] This statute allows substitute decision making about "health care," which is defined in section 1 to include "participation in a medical research program approved by an ethics committee designated by regulation." The individual authorized to make decisions about health care (and, by implication, REB-approved research) may be a court-appointed guardian authorized under the *Patients Property Act*,[109] a proxy appointed by the individual through an advance directive in accordance with the *Representation Agreement Act*,[110] or a "temporary substitute decision maker": a family member or close friend, designated in descending order of priority under the *HCCFA*.[111] By regulation, family members recognized as default or "temporary" decision makers cannot authorize "removal of tissue from a living human body ... for medical education or research,"[112] or participation in "health care or medical research" not approved by a prescribed REB.[113] Such decisions are also excluded from the authority of proxies (or "representatives") appointed under the *Representation Agreement Act*, except where an advance directive expressly permits the activity.[114]

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[108] RSBC 1996, c 181 [*HCCFA*].

[109] RSBC 1996, c 349, s 6. While new guardianship legislation has long been anticipated in BC, this remains the relevant Act.

[110] RSBC 1996, c 405.

[111] *HCCFA*, *supra* note 108 s 16(1).

[112] *Ibid* s 34(2)(f); *Health Care Consent Regulation*, BC Reg 20/2000, s 5(1)(d) [*BC Consent Regulation*].

[113] *BC Consent Regulation*, *ibid*, s 5(1)(f).

[114] *Representation Agreement Act*, *supra* note 110 s 9(2)(a). Note that reforms to this Act (in force as of September 1, 2011) remove the former requirement under section 9

One complexity arising under the *HCCFA* is that the provision giving proxies appointed under a representation agreement, or court-appointed guardians, authority to make substitute decisions about health care (major or minor, as defined in the *HCCFA*) is premised on a health provider's determination that the individual "needs the health care."[115] This arguably disables the appointed proxy or guardian from making decisions about research, especially research holding out no prospect of therapeutic benefit. In contrast, a "temporary decision maker" may make decisions about "minor health care" without a parallel restriction to interventions that the subject needs.[116] In other words, where REB-approved research lacks a therapeutic benefit satisfying the section 11 criterion of "need" and falls into the class of "minor health care" (interventions not involving "major surgery"; "a general anaesthetic"; "major diagnostic or investigative procedures"; or "any health care designated by regulation as major health care," such as radiation treatment or electroconvulsive therapy),[117] the decision making authority of the designated proxy or court-appointed guardian apparently gives way to that of the "temporary decision-maker." No one appears to be empowered to authorize research involving interventions classed as "major health care," absent a prospect of therapeutic benefit.

It is worth adding that in making decisions about either health care or research, the temporary decision maker must consult with the person represented and must decide in accordance with that person's instructions, expressed while capable, or in the absence of such instructions, in accordance with the person's best interests.[118] The criteria for decision making by proxies appointed in ac-

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that a person consult with a lawyer or other prescribed person in order to include such terms in a representation agreement. It is important to note, as well, that recent reforms to the *HCCFA*, *supra* note 108 ss 19.1-19.91 (also in force 1 September 2011), recognize instructional directives (termed "advance directives" under the Act), whereby an individual may indicate consent to or refusal of specified health care without appointing a representative. Such directives displace recognition of a default statutory decision maker under section 16 of the HCCFA. Moreover (as per section 19.3(1)(b) of the *HCCFA*), they have the effect of indicating the prior capable wishes of the adult to a representative (if any) appointed under the *Representative Agreement Act*, *supra* note 110.

[115] *HCCFA*, *supra* note 108 s 11.

[116] *Ibid* s 15.

[117] *Ibid* s 1; *BC Consent Regulation*, *supra* note 112 s 4.

[118] *HCCFA*, *supra* note 108 s 19. The *Act* was reformed in June, 2011. Prior to that, a temporary decision maker who lacked information about the individual's prior capable wishes was to decide in light of the person's "known beliefs or values," and only in the absence of such knowledge, in accordance with best interests. Now "known be-

cordance with the *Representation Agreement Act*[119] and guardians appointed under the *Patients Property Act*[120] are stated in different terms, which could lead to different outcomes in certain circumstances.

2. Alberta – Personal Directives

Alberta's *Personal Directives Act* also falls into the first category.[121] Like BC's legislation, this statute expressly contemplates research. However, the argument for identification of an LAR is less direct. Section 15 of the *Personal Directives Act* states: "an agent has no authority to make personal decisions relating to the following matters unless the maker's personal directive contains clear instructions that enable the agent to do so." Included in the ensuing list is "participation by the maker in research or experimental activities, if the participation offers little or no potential benefit to the maker."[122]

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liefs and values" are among the considerations informing a best interests-based decision. Section 19(3) elaborates on "best interests" as requiring consideration of

> (a) the adult's current wishes, and known beliefs and values
>
> (b) whether the adult's condition or well-being is likely to be improved by the proposed health care,
>
> (c) whether the adult's condition or well-being is likely to improve without the proposed health care,
>
> (d) whether the benefit the adult is expected to obtain from the proposed health care is greater than the risk of harm, and
>
> (e) whether a less restrictive or less intrusive form of health care would be as beneficial as the proposed health care.

[119] *Supra* note 110. A proxy appointed under a representation agreement must take account of the subject's current wishes or, if those cannot be ascertained or are "not reasonable to comply with," his or her wishes expressed while capable, or, in the absence of knowledge of these, his or her known beliefs or values. In the absence of any of the foregoing information, the decision is to be made in light of the individual's best interests (s 16).

[120] *Supra* note 109. Less clarity about the considerations required for valid decision making is conveyed under this Act. Guardians appointed under this Act have all the powers of a guardian of the person (s 17) and are to exercise authority for the benefit of "the patient and the patient's family" (s 18).

[121] RSA 2000, c P-6.

[122] *Ibid* s 15(d).

This limitation gives force to directives that expressly authorize an LAR to make decisions about research that offers little or no potential benefit to the individual who made the directive. Furthermore, it implicitly authorizes an LAR to make decisions about research participation in the absence of a specific instruction, in instances where the research offers *more* than little or no benefit. Some may dispute the second part of this claim, arguing that the statutory language does not amount to "clear authorization" of substitute decisions about research meeting the stated benefit threshold. Moreover, important arguments may arise about how to interpret this threshold. However, we conclude that the statute is more clearly permissive of substitute decisions about research, even where the advance directive fails to contemplate research offering little or no potential benefit, than the ambiguous statutes that we have included in Category II. We have identified no case law on this question. In sum, we understand the *Personal Directives Act* to authorize an appointed proxy to make substitute decisions about the above-noted circumscribed category of research, even in the absence of terms specific to research in the directive.

ii. Category II: Unclear Authorization

The second type of legal situation encountered among the four provinces is one where there is no clear basis in law for third party authorization of research. This category includes situations that allow some scope for arguing, in the face of statutory ambiguity, that legislation *might* ground third party authorization, at least in some circumstances. While such arguments would be novel–we have not found any case law directly on this point–they are not unreasonable, at least where research holds out a prospect of therapeutic benefit.

We include the following in this category: first, the statutes of the four provinces that refer to third party authorization of health care or medical treatment without specifically addressing research; second, the statutes that provide for court-appointed guardianship, again, without specifically addressing research; and third, the special case of Ontario's health care consent, advance directive, and guardianship laws, which explicitly exclude from their ambit interventions undertaken "for the primary purpose of research." We have already noted that, as a matter of common law, uncertainty also attaches to the legal effectiveness of advance directives as they apply to research participation.

1. Nova Scotia – Consent to "Health Care" or "Medical Treatment"

Nova Scotia's health care consent laws authorize substitute decisions about "health care" or "medical treatment" without mentioning research. More specifically, both the *Hospitals Act*[123] and the *Involuntary Psychiatric Treatment Act*[124] contemplate substitute decisions about "treatment" and "health care,"[125] but neither term is defined to include health (or other) research.

Additionally, Nova Scotia's advance directives legislation in force at the time of our study, the *Medical Consent Act*, allowed appointment of a proxy decision maker for the purpose of substitute decisions about "medical treatment," but did not specifically address research. This Act was repealed and replaced after our study was completed.[126] Potential confusion around this legislative reform, and the implications of such confusion for our study, are discussed in Part V.

Again, the best interpretation of laws that authorize substitute consent to health care or treatment without specifically contemplating research is that they give rise to ambiguity, thereby grounding competing legal arguments regarding identification of an LAR for research involvement purposes. "No one has clear legal authority" is the characterization that best recognizes this ambiguity. However, because there are reasonable arguments for identification of an LAR based on an analogy between research that offers a prospect of therapeutic benefit and treatment, we recognize this as an alternative interpretation that is defensible where the research does hold out such a prospect.

2. Nova Scotia and Alberta – Guardianship

Legal uncertainty or ambiguity is also encountered in connection with the provincial guardianship regimes in Nova Scotia and Alberta.[127] The situation

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[123] RSNS 1989, c 208.

[124] SNS 2005, c 42 [*IPTA*].

[125] *Ibid* ss 17-18, 39-40; *Hospitals Act*, *supra* note 123 ss 52-53.

[126] RSNS 1989, c 279 as repealed by *Personal Directives Act*, SNS 2008, c 8, s 40 (in force April 1, 2010).

[127] Our assessment of the provincial guardianship laws of the four provinces we targeted corresponds with the broad conclusions of Tomossy & Weisstub on the state of Canadian guardianship laws in respect to authorization of research participation:

with regard to the substitute decision making powers of guardians in BC was discussed above, and the situation in Ontario is discussed below.

Nova Scotia's *Incompetent Persons Act*[128] confers upon court-appointed guardians broad authority over the person and finances of persons deemed incompetent. Yet, read in light of common law restrictions on guardianship, the power conferred by this statute is limited to decisions that promote the interests of the ward. Here we may recall the limitations on the *parens patriae* jurisdiction stated in *Re Eve*, where the Supreme Court drew upon cases decided under superior courts' wardship jurisdiction as a "solid guide to the exercise of the *parens patriae* power even in the case of adults."[129]

The best interests limitation on guardianship powers may be explicitly stated in guardianship statutes, or implied by operation of the common law.[130] This limitation (in Nova Scotia, an implicit one) renders a guardian's power to authorize research unclear, given that the primary aim of research is to advance knowledge as opposed to delivering an individualized therapeutic benefit.[131] However, where a prospect of therapeutic benefit to the participant is present-

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"The issue of participation in research is either specifically excluded, not mentioned at all, or if referred to, dealt with in an ambiguous manner" (*supra* note 7 at 123).

[128] RSNS 1989, c 218, ss 9-12.

[129] *Supra* note 97 at paras 36, 73 ("The *parens patriae* jurisdiction is, as I have said, founded on necessity, namely the need to act for the protection of those who cannot care for themselves. The courts have frequently stated that it is to be exercised in the 'best interest' of the protected person, or again, for his or her 'benefit' or 'welfare'"). The argument that a statutory guardian is limited by the best interests principle is derived in part from this limitation upon the court's *parens patriae* jurisdiction, which informs interpretation of vaguely-stated statutory guardianship powers.

[130] Robertson, *supra* note 93 at 171.

[131] See Tomossy & Weisstub, *supra* note 7. "[E]xisting guardianship laws are generally poorly suited to resolving questions that cannot be answered easily through the application of a 'best-interests' calculation. Non-therapeutic experimentation, and indeed any other activity that does not lead to a concrete benefit for the subject, throws the proverbial wrench into the machinery of substitute decision making. It is difficult enough for guardians, and also for the judiciary, to rationalize exposing an incompetent adult to risks, however minute, for a hypothetical treatment or cure, let alone in those cases where the benefits will never accrue to the subject, but rather to others with the same affliction or disability. This effort is frustrated further because it entails placing the interests of society ahead of those of the subject, which may constitute a breach of the guardian's cardinal duty to protect his ward" (at 123-24). On this basis, the authors recommend legislative reforms specifically contemplating and setting conditions upon a guardian's ability to authorize research (at 124-25).

ed, it may be argued that the guardian's authority extends to decision making about research participation.[132] That said, the fact that even research offering some prospect of benefit necessarily also involves interventions directed solely at producing knowledge–and, moreover, these research-related interventions may be less likely to benefit the individual than would a non-research-related therapy–renders the authority of the guardian to consent, even to so-called therapeutic research, uncertain. In short, even in situations involving a prospect of therapeutic benefit (as in our scenario 2),[133] the ability of a court-appointed guardian to authorize research participation in the absence of a specific legislative provision or court order is unclear.[134]

Alberta's *Dependent Adults Act*[135] (in force at the time of our survey) contemplated a range of decision making powers that might be conferred by a court upon a guardian. Research participation was not addressed in the non-exhaustive list of forms of decision making authority potentially conferred. However, among the decision making powers listed was authority "to consent to any health care that is in the best interests of the dependent adult."[136] For the reasons previously discussed, the *Dependent Adults Act*, like Nova Scotia's guardianship statute, is properly classed as offering an unclear foundation for third party authorization of research participation. There is scope to contest the consistency of such authority with the purposes of this guardianship regime. And this uncertainty extends even to research offering a prospect of benefit.

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[132] Our study did not include a scenario in which a guardian is in place and authorization of no-benefit research is in issue.

[133] Scenario 2 involves a guardian. See Tables 1 and 4 (Table 4 is located in the Appendix).

[134] See Coleman, *supra* note 4. Coleman notes that in the US, some guardianship statutes require specific court approval before a guardian may authorize research (at 760-61). Where guardianship statutes are silent on this question, Coleman suggests, it is unclear whether the decision making authority extends to research, or specifically those elements of a research intervention that are directed at generating universalizable knowledge rather than individualized therapy (at 761).

[135] *Dependent Adults Act*, RSA 2000, c D-11, repealed by *Adult Guardianship and Trusteeship Act*, SA 2008, c A-4.2, s 153 (the latter statute came into force on 30 October 2009). We address the implications of repeal of the *Dependent Adults Act*, along with the implications for our study of the repeal of Nova Scotia's *Medical Consent Act*, *supra* note 126, in Part V, below.

[136] *Dependent Adults Act*, *supra* note 135 s 10(3)(h).

However, there may be occasions where there are compelling arguments for deeming a given research intervention to be in the best interests of a particular patient (e.g. where there are no comparable therapeutic options and the subject's condition is dire enough to arguably warrant the risks of an unproven intervention). Given this possibility, and the related possibility that a court may be persuaded that the decision making powers of a guardian encompass decisions about research (at least, where a prospect of therapeutic benefit is offered), we acknowledge this as a reasonable alternative interpretation. This interpretation, however, captures the state of the law less accurately than the response "no one has clear legal authority."

3. Ontario – Explicit Exclusion of Substitute Consent to Research

Ontario's laws demand separate analysis. In that province, the laws that address general health care consent, advance directives, and guardianship explicitly exclude third party authorization of research from their ambit. Ontario's *Health Care Consent Act*[137] confers the power to make substitute decisions about "health care" on guardians of the person, proxies acting under a power of attorney for personal care, or, in the absence of these, a decision maker prescribed by statute. It further states: "This Act does not affect the law relating to giving or refusing consent on another person's behalf to any of the following procedures: … A procedure whose primary purpose is research."[138]

Similarly, the *Substitute Decisions Act*,[139] which confers substitute decision making authority on proxies acting under a power of attorney for personal care and court-appointed guardians, states: "Nothing in this Act affects the law relating to giving or refusing consent on another person's behalf to a procedure whose primary purpose is research."[140] Because no other statute addresses third party authorization of research in Ontario, apart from provincial legislation on the collection, use, and disclosure of personal health information,[141] the best interpretation of Ontario's law is that it offers no legal basis for third party authorization of another adult's participation in health research beyond the confines of the laws concerning personal information.

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[137] *Supra* note 105.

[138] *Ibid* s 6.

[139] *Supra* note 104.

[140] *Ibid* s 66(13).

[141] See e.g. *Personal Health Information Protection Act*, SO 2004, c 3, Schedule A, ss 26(4), 44 [PHIPA (Ont)].

It may be argued, however, that in some circumstances, where research offers a prospect of individualized therapeutic benefit, the intervention can be understood as initiated not for the "primary purpose" of research, but for pursuing the possibility of therapeutic benefit for the individual. This would require an assessment of the prospective benefits held out by the research, along with an assessment of the individual's condition and any therapeutic alternatives. Were it determined that research was not the primary purpose of the intervention, the intervention might possibly be deemed a form of health care (or personal care), such that the substitute decision maker under the *Health Care Consent Act* or, alternatively, a power of attorney for personal care or guardian under the *Substitute Decisions Act*, could act as LAR. While this constitutes a possible alternative argument to "no clear authorization" where there is a prospect of health benefit, it is both uncertain in law and intensely fact-dependent.

iii. Category III: Clear Lack of Authorization

A third type of legal situation arises where there is no statutory foundation on which basis anyone may be recognized as empowered to authorize an adult's participation in research.

1. No Prospect of Benefit to the Individual's Health – No Guardian, Not BC

It is uncertain whether, on an expansive approach to guardianship powers, a guardian could authorize health research even where no individual health benefit is offered. This has been argued with reference to the implicit authority of parents to involve their minor children in activities that offer no benefit so long as they do not "unreasonably risk harm."[142]

There is no comparable uncertainty, however, in the case of statutory decision makers accorded discrete powers to authorize "health care" or "treatment," rather than the broad or open-ended decision making authority granted some statutory guardians. On a purposive (indeed, even on a plain meaning) reading the authority conferred by such terms necessarily involves a therapeutic dimension, whereby some benefit to the individual's health (even broadly construed, to include social or emotional well-being) is engaged.[143] This leads to the ob-

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[142] Dickens, *supra* note 58 at 134-35.

[143] See Baylis & Downie, *supra* note 100 at 49; Dickens, *supra* note 58 at 134; Cantor, *supra* note 100.

servation that, where research offers no prospect of an individual health benefit, there is no basis in law for grounding identification of an LAR in a health care consent or advance directive statute that authorizes substitute decisions about health care or treatment, but not research. As noted, in BC, statutorily designated substitute decision makers have express authority to make decisions about REB-approved research, without limitations based in likely health benefits to the prospective research subject.

2. Further Special Circumstances

At the time of our survey, the "clear lack of authorization" category applied in Alberta, where no guardian or advance directive was in place, and in Nova Scotia, where no guardian or advance directive was in place and where the proposed research was to occur outside the context of a hospital or community treatment order. Prior to recent law reforms, these provinces lacked legislation (in Nova Scotia, legislation that extended beyond the hospital or community treatment order setting) that conferred the authority to make substitute decisions about treatment or health care upon a family member or other party. Therefore, in the absence of a court-appointed guardian or advance directive, there was no statutory foundation for substitute decision making powers relating to treatment or health care that might be argued to encompass decisions about research (or specifically, research offering a prospect of therapeutic benefit).

iv. Application to the Four Scenarios in our Survey Questionnaire

Based on our analysis of provincial health care consent and guardianship laws (as well as the common law) as they stood at the time of our survey, the most defensible response to each of the four scenarios posed in the questionnaire, in all the provinces canvassed except for BC (and with the further exception of cases falling under the advance directive legislation in Alberta), was "no one has clear legal authority." Whether an alternative response might have a reasonable chance of success in court is a more nuanced matter.

Table 1 summarizes the state of the provincial guardianship, advance directive, and health care consent laws in force at the time of the survey, as they interact with the scenarios posed in the survey questionnaire (the scenarios

themselves are located in Appendix I).[144] The key elements of each of the four scenarios are described in turn, followed by a province-by-province indication of whether the laws canvassed clearly authorize an LAR, are unclear on this point, or clearly fail to authorize an LAR. Where the law is classed as unclear–or, in the first scenario as it applies in Nova Scotia, where the respondent assumed the research would occur in a hospital–we add (italicized and in parentheses) a statement of the response or responses that may be considered reasonable alternative interpretations. These alternatives are less optimal than the primary response which explicitly recognizes the legal uncertainty or ambiguity on point. As noted, both Alberta and Nova Scotia introduced law reforms which came into force after our survey was completed, the possible implications of which we discuss in Part V.

Table 1. The State of Provincial Laws on LARs at the Time of the Survey

Who may authorize research participation?			
Research Scenario 1. No court-appointed guardian, no advance directive. Research involves potential benefit to individual, little risk.			
British Columbia	**Alberta**	**Nova Scotia**	**Ontario**
If research is REB approved, and qualifies as "minor" rather than "major" health care, **clear authorization**: statutory default decision maker is LAR	**Clear lack of authorization**	If research is to occur outside hospital, **clear lack of authorization.** *(If respondent assumes research will occur in hospital, there is a reasonable alternative response that is uncertain in law: statutory default decision maker is LAR, given pro-*	**Authorization unclear** *(Reasonable alternative response uncertain in law: Statutory default decision maker is LAR, given prospect of individual therapeutic benefit)*

[144] All questions in Table 1 assume (as stipulated in our questionnaire) that the research has been approved by an REB. See the Appendix for additional information.

		spect of individual therapeutic benefit)	
Research Scenario 2. Court-appointed guardian. Research involves potential benefit to individual, little risk.			
British Columbia	**Alberta**	**Nova Scotia**	**Ontario**
If the research is REB approved, and qualifies as "major" or "minor" health care that the subject "needs," **clear authorization**: guardian is LAR. (Otherwise, if the research is REB approved and qualifies as "minor" health care, but there is no medical "need": statutory default decision maker is LAR).	**Authorization unclear** *(Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual's best interests - or, in the further alternative, if the research simply does not increase risks beyond background risks - guardian is LAR)*	**Authorization unclear** *(Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual's best interests - or, in the further alternative, if the research simply does not increase risks beyond background risks - guardian is LAR)*	**Authorization unclear** *(Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual's best interests so that the intervention is not deemed "a procedure whose primary purpose is research," guardian is LAR. In the further alternative, if the research simply does not increase risks beyond background risks, guardian is LAR)*
Research Scenario 3. Advance directive addressing health care but not research. Research involves some risk, outweighed by potential benefit to individual.			
British Columbia	**Alberta**	**Nova Scotia**	**Ontario**
If the research is REB approved and is "major" or "minor" health	If there is a prospect of more than "little or no benefit," **clear**	**Authorization unclear** *(Reasonable alternative response: if*	**Authorization unclear** *(Reasonable alternative response: if*

care that the subject "needs," **clear authorization**: proxy appointed in directive is LAR (Otherwise, if the research is REB approved and qualifies as "minor" health care, but there is no medical "need": statutory default decision maker is LAR).	**authorization**: proxy appointed in directive is LAR	*there is a prospect of individualized therapeutic benefit whereby research is deemed "medical treatment," proxy appointed in directive is LAR)*	*there is a prospect of individualized therapeutic benefit whereby intervention is deemed not to be "a procedure whose primary purpose is research," but "treatment" or "personal care," proxy appointed in directive is LAR)*
Research Scenario 4. No guardian. Research offers no prospect of benefit to individual.			
British Columbia	**Alberta**	**Nova Scotia**	**Ontario**
If research is deemed "minor" rather than "major" health care, **clear authorization**: statutory default decision maker (to decide in light of prior capable wishes / values, as the best interests standard will not be satisfied)	**Clear lack of authorization**	**Clear lack of authorization**	**Clear lack of authorization**

Against the background of the foregoing legal analysis, we ask: how do those with a stake in the research enterprise understand the laws concerning–and frequent instances of legal ambiguity surrounding–who, if anyone, may

make a substitute decision about another adult's involvement in health research? That is the question addressed in the remaining parts of this article.

IV. The SCORES Survey

A. Study Design, Populations and Sampling[145]

The data used for this article originate from a wider study of knowledge, opinions and practices regarding *Substitute Consent for Research in Elderly Subjects* (SCORES). The SCORES study included a postal survey conducted in Alberta, BC, Ontario, and Nova Scotia.

The aim of this part of the study was to compare the state of the law in the four provinces against how the law is understood by five population subgroups, differently situated in relation to research. The selected provinces represented a range of statutory approaches to resolving (or leaving unresolved) the question of who, if anyone, is legally empowered to authorize an adult's research participation. We determined, in light of a previous survey of the relevant Canadian laws,[146] that the laws of the four provinces selected were broadly representative of approaches taken to this issue in common law Canada.

The five groups surveyed were: i) community-dwelling adults aged 65 and over; ii) informal caregivers of cognitively-impaired older adults; iii) physicians; iv) researchers in aging; and v) Research Ethics Board (REB) members. A proportional random sample of 2,000 older adults was obtained from Human Resources and Social Development Canada. Seven hundred and two informal caregivers from Nova Scotia and Ontario were accessed through provincial Alzheimer Societies. We were unable to recruit caregivers from Alberta and BC for reasons including denial of access to membership lists, associated confidentiality concerns, and insufficient in-house personnel to support distribution of the mailings. We obtained proportional random samples of physicians from provincial medical colleges, except in BC, where we had to purchase a

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[145] The material included in this section is substantially the same as the comparable section in other papers published as a result of this study. See Gina Bravo et al, "Are Canadians Providing Advance Directives About Health Care and Research Participation in the Event of Decisional Incapacity?" (2011) 56:4 Can J Psychiatry 209 [Bravo et al, "Advance Directives"]; Gina Bravo et al, "Research with Decisionally Incapacitated Older Adults: Practices of Canadian Research Ethics Boards" (2010) 32:6 IRB: Ethics & Human Research 1 [Bravo et al, "Practices of Canadian REBs"].

[146] Bravo et al, "Comparison Substitute Consent", *supra* note 7.

commercial list of physicians (n = 3,000). Specialities unlikely to encounter adults with cognitive impairments in their practice, such as paediatrics and pathology, were excluded. We tried to establish the most complete list of Canadian researchers in aging and REBs by searching the Internet and relevant web sites (e.g. the Canadian Institutes for Health Research, National Council on Ethics in Health Research, and universities and hospitals conducting health research). Given the relatively small size of the latter two groups (608 researchers in aging and 701 REB members), all identified members were contacted. Sample sizes for the three other groups were established to ensure that confidence intervals did not extend beyond the observed proportions by more than 0.05, and participation rates observed in a similar study conducted in Quebec were applied.[147]

B. The Questionnaire

The postal survey included four scenarios (reproduced in Appendix I) each culminating in the question of who, if anyone, is legally authorized to make a decision about research. These scenarios track the four situations represented in Tables 1 and 4. The first scenario features no court-appointed guardian or advance directive regarding health care; the second scenario features a court-appointed guardian (with broad decision making authority); and the third scenario features an advance directive appointing a proxy in respect to health care. Scenarios 1–3 assert that the prospective benefits of research participation outweigh the risks. While perhaps artificial, this stipulation of the risk-benefit ratio is intended to clearly transmit the conditions in which the legality of third party authorization is at stake. Otherwise, it would have been even less clear whether, or to what extent, contestation about risks or benefits presented in the scenario affected responses. The fourth scenario proceeds from the same facts as scenario 3, except that the proposed research is now said to offer no benefit to the prospective subject, although it may in the future benefit others in his position (specifically, future nursing home residents).

In the final, "no-direct-benefit" scenario, our evaluation of responses was not affected by whether respondents assumed that the advance directive from the previous scenario was still in place. Also, regarding our evaluation of re-

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[147] Bravo G, Pâquet M & Dubois MF, "Knowledge of the Legislation Governing Proxy Consent to Treatment and Research" (2003) 29 J Med Ethics 44 at 45-46; Gina Bravo et al, "Quebec Physicians' Knowledge and Opinions Regarding Substitute Consent for Decisionally Incapacitated Older Adults" (2004) 26:5 IRB: Ethics & Human Research 12 at 14 [Bravo et al, "Physicians' Knowledge"].

sponses from BC, both the second scenario (involving a guardianship order) and the third (involving an advance directive) supported option B (the family member) as the correct answer, whether the respondent regarded this as justified by the family member's status as guardian (scenario 2) or proxy (scenario 3), or by his or her default status as temporary decision maker. Therefore, our evaluation of the BC responses to these two scenarios was unaffected by whether or not the research was perceived to fall within the subject's health "needs" (which, as stated earlier, limits the authority of guardians and proxies). Given that the proposed research in these two scenarios satisfies the definition of "minor" health care under the BC legislation, the family member is clearly authorized to make the decision, even if only as the "temporary decision-maker."

There were two alternative responses to the scenarios (i.e. reasonable responses which differed from the ones we deemed most defensible) not addressed in the earlier discussion of how provincial laws may be interpreted generally and in their interaction with the basic elements of the scenarios.

1. Regarding scenario 3 (the "advance directive addressing health care but not research" scenario), the most defensible answer from Alberta was B. This is because, as discussed above, Alberta's *Personal Directives Act* implicitly admits of third party authorization of research where there is more than "little or no benefit" offered to the subject. However, if the respondent felt that the intervention offered "little or no" benefit (despite the statement that the likely benefits "outweigh" the risks), the appropriate answer would be E. In acknowledgment of the difficulty of quantifying prospective benefits, we recognize E as a reasonable alternative response.

2. Regarding scenario 4 (the "no-direct-benefit" scenario), the most defensible answer from BC is B. We have seen that "temporary decision makers" (family members) are empowered to decide whether an adult may participate in no-benefit research as long as the research is REB-approved. However, the BC statute requires that the decision be made in accordance with the subject's prior capable wishes or values, or in the absence of these, his or her best interests. The scenario gives no information about the subject's capable wishes or values. Nor is there any evidence of contemporaneous wishes (of important relevance to the decisions of representatives under the *Representation Agreement Act*). Therefore, while it is correct to state that the temporary decision maker is clearly authorized to make a decision about the subject's participation, there is insufficient information to know whether there is a basis

> of prior capable wishes or values, or alternatively, contemporaneous wishes, on which to permit rather than refuse research participation. In recognition of the potential for confusion between the decision maker's authority to make the decision (i.e. to decide in light of the mandatory considerations) and his or her authority to permit (rather than refuse) the research in light of those considerations, we recognize E ("No one has clear legal authority") as a reasonable alternative response from BC.

Table 4, found at Appendix II, gives a summary presentation of the correct responses (including the reasonable alternative response, where one existed) to the scenarios. In all cases except the two noted above (scenario 3: Alberta and scenario 4: BC), the reasonable alternative answer identifies the family member as LAR despite the legal contestability of this answer.

A last clarification is required with regard to our evaluation of scenario 4. In this scenario, the proposed research offers no prospect of individual benefit; moreover, there is no guardianship order or advance directive with a term specific to research authorization in place. We analyzed this scenario in a manner that reflected the absence of any basis for identifying an LAR in the advance directives or more general health care consent legislation of three of the four provinces we targeted. That is, no health care consent or advance directives legislation (apart from BC's), offered a basis for identifying an LAR where the research at issue offered no prospect of benefit. Recall that Alberta's advance directives legislation contemplated such authority only where an advance directive expressly confers it.

However, some respondents may have identified this as a situation in which federal or provincial privacy legislation (applying to the collection, use, and disclosure of personal information[148] or personal health information[149]) would

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[148] See e.g. *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5 [*PIPEDA*]; *Personal Information Protection Act*, SBC 2003, c 63 [PIPA (BC)]; *Freedom of Information and Protection of Privacy Act*, RSBC 1996, c 165 [FIPPA (BC)]; *Personal Information Protection Act*, SA 2003, c P-6.5 [PIPA (Alta)]; *Freedom of Information and Protection of Privacy Act*, RSA 2000, c F-25 [FIPPA (Alta)]; *Freedom of Information and Protection of Privacy Act*, RSO 1990, c F.31 [FIPPA (Ont)]; *Freedom of Information and Protection of Privacy Act*, SNS 1993, c 5 [FIPPA (NS)].

[149] *Health Information Act*, RSA 2000, c H-5, s 2 [HIA (Alta]; PHIPA (Ont), *supra* note 141 s 1. Also see *PIPEDA*, *supra* note 148 s 2(1). The scope of application of these and similar statutes is addressed by Gibson, supra note 66 at 263-73. At the time of

serve as the proper source of substitute decision making authority. Arguably, the interest in protection of privacy or personal information was the only legal interest implicated by the observational study described in scenario 4.[150] Might one or more of the set of laws relating to personal information and privacy be relied upon to identify the family member present in the scenario as LAR in scenario 4, rather than selecting the answer we identified as correct in all provinces but BC ("No one has clear legal authority")?[151]

As noted, our analysis focused on the terms of provincial health care consent and guardianship laws. We leave the analysis of federal and provincial laws concerning personal information and privacy as they intersect with health research for another occasion. The importance of this caveat to the evaluation of scenario 4 is diminished, however, by the fact that the scenario arguably provides insufficient information to establish whether (or perhaps, which) laws aimed at the protection of privacy and personal information, or personal health information specifically,[152] would apply. Among the matters relevant to that determination would be whether the nursing home featured in the scenario is a private or public body,[153] whether the research was privately or publicly funded

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writing, a new law in Nova Scotia, the *Personal Health Information Act*, SNS 2010, c 41, has recently passed third reading but has not yet been proclaimed in force.

[150] It is also the case that a range of interventions typically understood to fall within the terms of health care consent legislation (e.g. psychological counselling, behavioural therapy, observation for diagnostic purposes) do not require bodily touching.

[151] The substitute decision making provisions in provincial privacy legislation are discussed in Noela J Inions, "Substitute Decision-Makers in Privacy Legislation that Affects Health Information in Alberta" (2005) 14:1 Health Law Review 26.

[152] *Supra* notes 148, 149.

[153] Nursing homes likely fall into the public sector (here any provincial legislation specific to the regulation of nursing homes would have to be consulted), but we do not wish to do an end-run around alternative arguments in any of the four provinces. In Nova Scotia and Ontario, the federal legislation (PIPEDA, *supra* note 148) applies to private organizations in respect to certain circumscribed activities involving the handing of personal information (although Ontario's health-specific legislation, PHIPA (Ont), *supra* note 141, applies to public and private health providers dealing with "personal health information"). Both provinces have general public sector legislation (FIPPA (NS), *supra* note 148; FIPPA (Ont), *supra* note 148). In BC, private organizations are subject to the PIPA (BC), *supra* note 148, while public organizations are subject to the FIPPA (BC), *supra* note 148. In Alberta, private sector organizations are subject to the PIPA (Alta), *supra* note 148, while public sector organizations are subject to the FIPPA (Alta), *supra* note 148. Like Ontario, Alberta also features special legislation addressing the handling of health-specific personal information (HIA (Alta), *supra* note 149).

(i.e. did it constitute "commercial activity," thereby engaging the federal legislation in those provinces in which that legislation may apply?),[154] and whether the study, involving observation of residents going about their daily routines, would qualify as collection or disclosure of personal information (or alternatively personal health information) in the control or custody of an entity regulated under one of these statutes.[155]

These questions would require separate analyses in light of the different privacy and personal information regimes of the four provinces targeted in our study (and, at least in Nova Scotia and Ontario, possibly also the federal regime).[156] Beyond the problem of uncertain application (which is exacerbated by the lack of relevant details)[157] lies the question of whether the legislation that could apply may be understood to authorize a family member to act as LAR where, as in scenario 4, there is no guardianship order or advance directive specific to decisions concerning research (or, for that matter, the disclosure of personal information).[158] We may also ask what if any continuing rele-

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[154] PIPEDA, *supra* note 148 ss 2(1), 4(1)(a).

[155] See e.g. PIPEDA, *ibid* s 2(1) "personal health information", "personal information"; FIPPA (BC), *supra* note 148, Schedule 1 "personal information"; HIA (Alta), *supra* note 149, s 1(1)(k) "personal health information"; FIPPA (Alta), *supra* note 148, s 1(n) "personal information"; PHIPA (Ont), *supra* note 141, s 4(1) "personal health information"; FIPPA (NS), *supra* note 148, s 3(i) "personal information". On the range of questions relevant to determining whether or which legislation might apply, see Hadskis, *supra* note 2 at 485; Gibson, *supra* note 66 at 286-88.

[156] In BC and Alberta, privacy legislation applying to private entities has been declared substantially similar to the federal legislation, which results in an exemption from the application of Part I of *PIPEDA*, *supra* note 148. *Organizations in the Province of Alberta Exemption Order*, SOR/2004-219; *Organizations in the Province of British Columbia Exemption Order*, SOR/2004-220. This is also true of Ontario's health-specific privacy legislation, the *Health Information Custodians in the Province of Ontario Exemption Order*, SOR/2005-399.

[157] One or more of the potentially-applicable statutes relating to privacy and the protection of personal information (or personal health information specifically) might possibly provide a basis for authorizing the study featured in scenario 4 without requiring consent. However, the conditions precedent to such authorization are not addressed in the scenario, and therefore could not be said to be met. See e.g. FIPPA (BC), *supra* note 148 s 35; PHIPA (Ont), *supra* note 141 s 44.

[158] See PIPEDA, *supra* note 148, Schedule 1, s 4.3.6; FIPPA (BC), *supra* note 148 s 33, and BC Reg 323/93, s 3(b); HIA (Alta), *supra* note 149 s 104(1); FIPPA (Alta), *supra* note 148, s 84(1); PHIPA (Ont), *supra* note 141 ss 21, 23 & 26; FIPPA (NS), *supra* note 148 s 43.

vance health care consent legislation would have, even if privacy and personal information statutes were engaged. Finally, we must consider how likely it is that the respondents to our questionnaire (or more than a small minority of them) would be familiar with the intricacies of personal information and privacy law. In light of all these considerations, the restriction of our analysis to health care consent and guardianship legislation is of limited importance.

C. The Postal Survey[159]

The postal survey arm of the SCORES project was carried out from September 2007 through April 2009. In order to maximize response rates, Dillman's suggestions on the content and design of the questionnaire, as well as the number of mailings, were followed.[160] In the first mailing, potential participants received a personalized cover letter, a copy of the questionnaire, an addressed stamped envelope, and a postcard bearing his or her name. The purpose of the postcard was to identify those who had returned the questionnaire without removing the anonymity of their responses, as it was to be mailed separately from the questionnaire. Letters of endorsement from the Canadian Association of Retired Persons, the Alzheimer Society of Canada, and the Royal College of Physicians and Surgeons of Canada were included in the mailings for three groups, respectively: older adults, caregivers, and physicians. Two weeks after the first mailing, a postcard was sent to non-respondents and two months later a new copy of the questionnaire was sent. All mailings to older adults, physicians, and researchers were managed by the research team. The Alzheimer Society and some REBs protected the anonymity of their members by managing the mailings themselves. The REBs of the University Institute of Geriatrics of Sherbrooke, Dalhousie University, and Sunnybrook Health Sciences Centre approved the study protocol, postal questionnaires, and accompanying letter.

The questionnaire was returned by 2,060 people, resulting in an eligible overall response rate of 32.7%. Variation in the response rate across provinces and groups can be seen in Table 2. As a result of the proportional sampling strategy, most of the respondents originated from Ontario. Respondent characteristics are given in Table 3 and complementary group-specific information is

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[159] The material included in this section is substantially the same as the comparable section in another paper published as a result of this study: Bravo et al, "Advance Directives", *supra* note 145 at 210-11.

[160] See Don A Dillman, *Mail and Internet Surveys: The Tailored Design Method* (New York: John Wiley & Sons, 2000).

provided in a separate publication.[161] 54.3% of the respondents were women, and the age of respondents ranged from 21 to 95 years. In general, this study had a heterogeneous assemblage of respondents in terms of socio-demographic status, profession, and experience with research.

Table 2. Response Rates and Sample Size per Group and Province

	NS	ON	AB	BC	Overall*
Older adults	40.2% (37)	37.5% (388)	41.3% (92)	38.8% (151)	39.0% (679)
Caregivers	54.2% (32)	60.0% (349)	--	--	59.9% (384)
Physicians	23.3% (35)	19.8% (299)	16.3% (68)	14.2% (90)	18.3% (495)
Researchers	30.0% (12)	33.6% (87)	37.4% (37)	33.1% (39)	34.3% (177)
REB members	55.6% (74)	43.1% (197)	47.2% (25)	52.3% (23)	47.3% (325)
Overall	40.1% (190)	34.4% (1320)	28.0% (222)	25.6% (303)	32.7% (2060)

* Province was missing for 25 respondents

Table 3. Respondents' Characteristics[a]

	Older adults	Informal caregivers	Physicians	Researchers	REB members
Variable	(n=679)	(n=384)	(n=495)	(n=177)	(n=325)
Province					
Nova Scotia	5.5%	8.4%	5.1%	6.9%	23.2%
Ontario	58.1%	91.6%	55.8%	49.7%	61.8%
Alberta	13.8%	-	16.2%	21.1%	7.8%
BC	22.6%	-	22.9%	22.3%	7.2%
Age (years)	75.2 ± 6.9 (65 to 95)	65.6 ± 12.0 (31 to 88)	51.4 ± 11.6 (29 to 94)	49.8 ± 8.8 (28 to 73)	50.7 ± 11.3 (21 to 78)
Sex (female)	56.8%	74.8%	33.7%	54.7%	56.9%

[161] See Bravo et al, "Advance Directives", *supra* note 145 at 214-15.

Religious denomination					
Protestant	50.6%	56.5%	25.8%	29.3%	28.9%
Catholic	22.1%	25.4%	21.4%	14.4%	21.9%
Other religion	11.2%	6.3%	23.6%	11.4%	12.2%
No formal religion	16.1%	11.7%	29.2%	44.9%	37.0%
Highest level of schooling					
Less than high school	20.1%	11.8%	0	0	0
High school graduate	53.9%	45.9%	0	0	1.9%
Profess. school / college	14.0%	20.3%	0	0	22.7%
University	12.0%	22.0%	100%	100%	75.4%
Appointed on REB as					
Researcher	-	-	-	-	38.2%
Physician					26.1%
Ethics expert					11.8%
Lawyer					7.0%
Lay person					18.8%
Administrator					7.0%
Student representative					3.2%
Other					4.1%

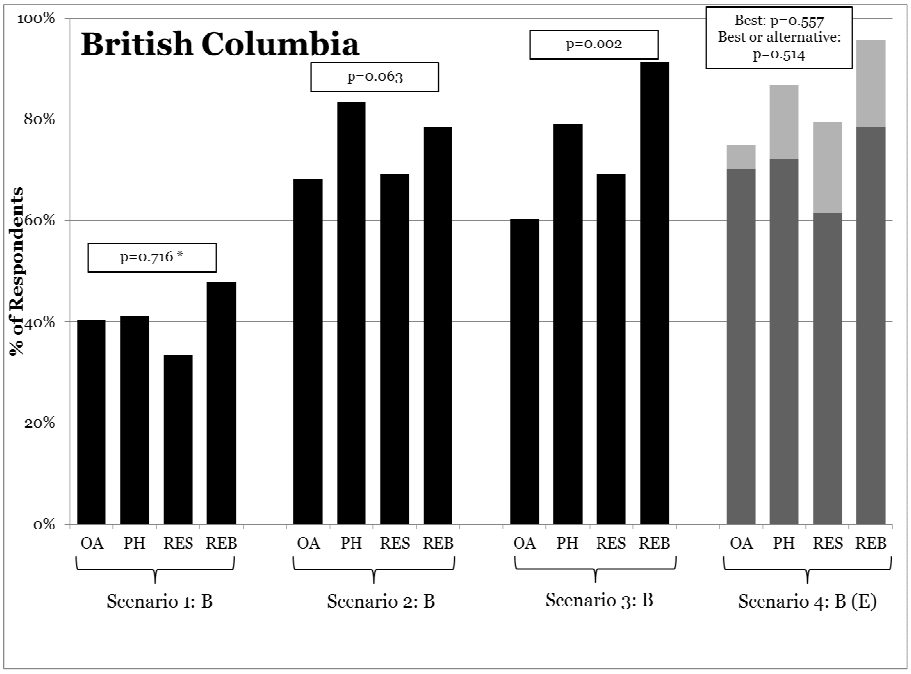
[a] Data reported as percentage or mean ± standard deviation (with the range in parentheses for some variables). These were already reported in Bravo et al, "Advance Directives", *supra* note 145 .

[b] More than one answer could be given.

V. Responses to the Questionnaire

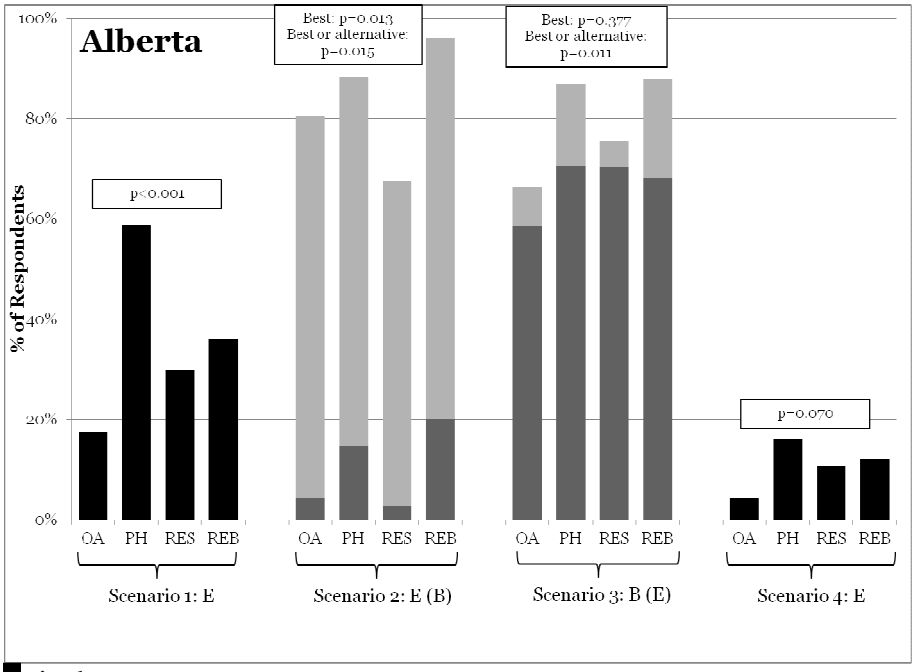
Figures 1–4 show the percentage of respondents who provided the correct– or best and alternative–responses to each scenario. In each figure, the single correct or best answer is given beside the scenario number, with its alternative in parentheses (when relevant). Like Table 4, these Figures represent our evaluation of responses in light of the health care consent (including advance directive) and guardianship laws in force at the time the survey was conducted.

Figure 1. % of Respondents with Correct or Best/Alternative Answers in British Columbia



■ single correct response
■ best answer
□ alternative answer
OA: older adults; PH: physicians; RES: researchers; REB: REB members.
* p value above bars is for comparison across groups.
When comparing single correct / best answer across scenarios, $p<0.001$ for all groups.

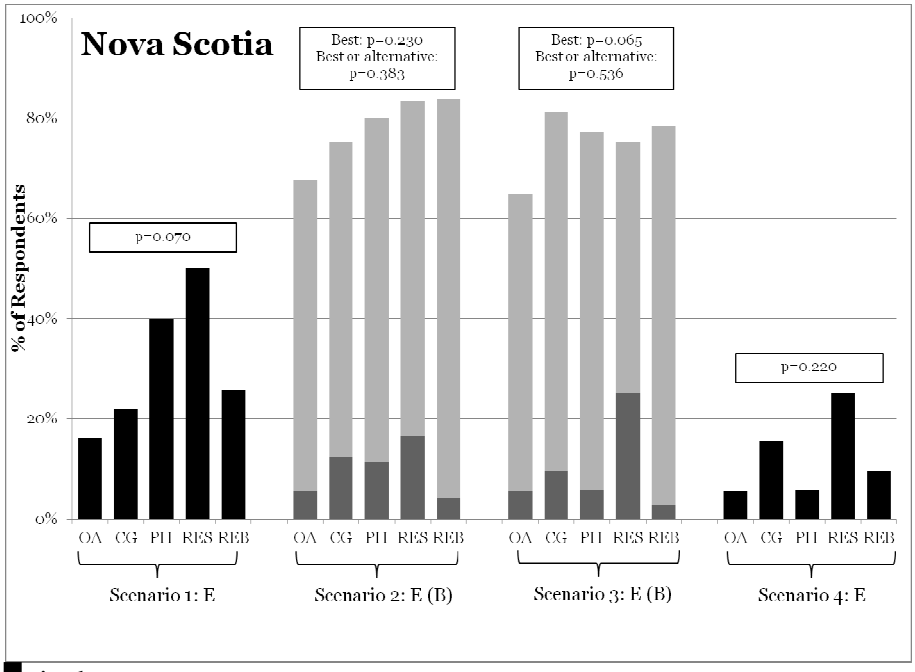
Figure 2. % of Respondents with Correct or Best/Alternative Answers in Alberta



■ single correct response
■ best answer
□ alternative answer

OA: older adults; PH: physicians; RES: researchers; REB: REB members.
p value above bars is for comparison across groups.
When comparing single correct / best answer across scenarios, $p<0.001$ for all groups.

Figure 3. % of Respondents with Correct or Best/Alternative Answers in Nova Scotia



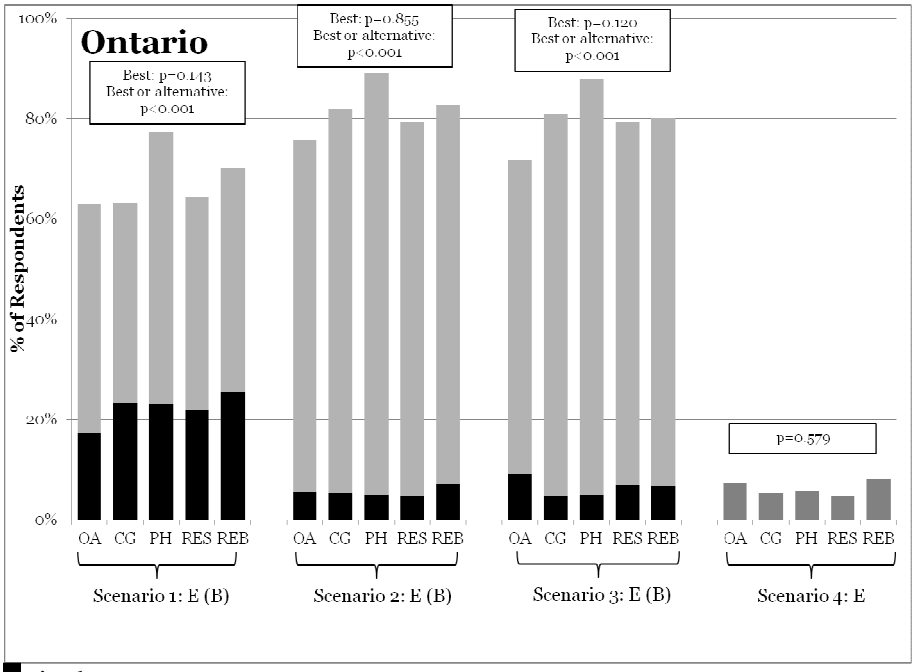
■ single correct response
■ best answer
□ alternative answer

OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members.

p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, p=0.088 for OA, p=0.241 for CG, p<0.001 for PH, p=0.029 for RES and p<0.001 for REB.

Figure 4. % of Respondents with Correct or Best/Alternative Answers in Ontario



single correct response
best answer
alternative answer

OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members.

p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, $p<0.001$ for all groups.

These results indicate that all respondent groups, including those who conduct or oversee research, were widely mistaken about the state of the law where there was one clear answer, or alternatively, favoured an uncertain appraisal of the state of the law by identifying the family member as LAR where "no one had clear legal authority" was the optimal answer.

Figure 1 presents responses from BC. Except for scenario 3 (the "advance directive addressing health care but not research" scenario), rates of identification of the correct or best answer were similar across groups. While 11% of older adults and 5% of researchers acknowledged they did not know the answer in scenario 3 (option F), this percentage was less than 2% in the two

other groups. All respondent groups from BC were less likely to correctly identify the family member as LAR in scenario 1 as compared with the other three scenarios. This may reflect the absence of an obvious legal instrument (court-ordered guardianship or an advance directive) in this scenario.

Figure 2 presents responses from Alberta. Here the percentage of respondents with the best answer was statistically different across groups for the first two scenarios. A higher percentage of physicians and REB members identified the best or alternative response in their answers to these scenarios. In response to scenario 1, well under half of the respondents in each group, except physicians, correctly indicated that no one has clear legal authority (option E). However, this was nonetheless the most-favoured response for that scenario across all groups except the older adults, who identified the family member as LAR (option B) more frequently (42% selected B, versus 17% selecting E).[162]

In response to scenario 2 (guardianship), less than 20% of each Alberta group indicated that there was no clear legal authority. The most-favoured response to this scenario across all Alberta groups was that the family member was LAR, which we recognized as a reasonable alternative response. In scenario 3, a majority of each group was correct in identifying the family member as LAR. Finally, in scenario 4, the "no-individual-benefit" scenario, under 16% of respondents from each Alberta group correctly indicated that no one had clear legal authority. The family member was the favoured selection in response to this scenario among all groups.

Figure 3 shows that, in Nova Scotia, there was no statistical difference across groups in all scenarios. Statistical power is, however, low in Nova Scotia, given the relatively small sample size. In response to scenario 1, more researchers and physicians seem to correctly indicate that no one has clear legal authority, although the difference is not statistically significant. Between 20% and 40% of the other groups selected this response; among these groups, the favoured answer was the family member. In scenarios 2–4, "no one has clear legal authority" was correctly identified by less than 20% of each group except

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[162] 36% of REB members and 30% of researchers selected option E ("no one has clear legal authority") in Alberta; the next most frequent selections among the REB members, in descending order, were option B (the family member) (16%), option A (Mrs. Bristol herself) (12%), and a combination of A & B–perhaps seeking to indicate the need for a form of co-decision making or the importance of assent (12%). Among the researchers, the next most frequent selections were option B (16%), option A (16%), and options A & B (11%).

the researchers, who came in closer to 25% in scenarios 3 and 4. All groups favoured the family member in response to scenario 4.

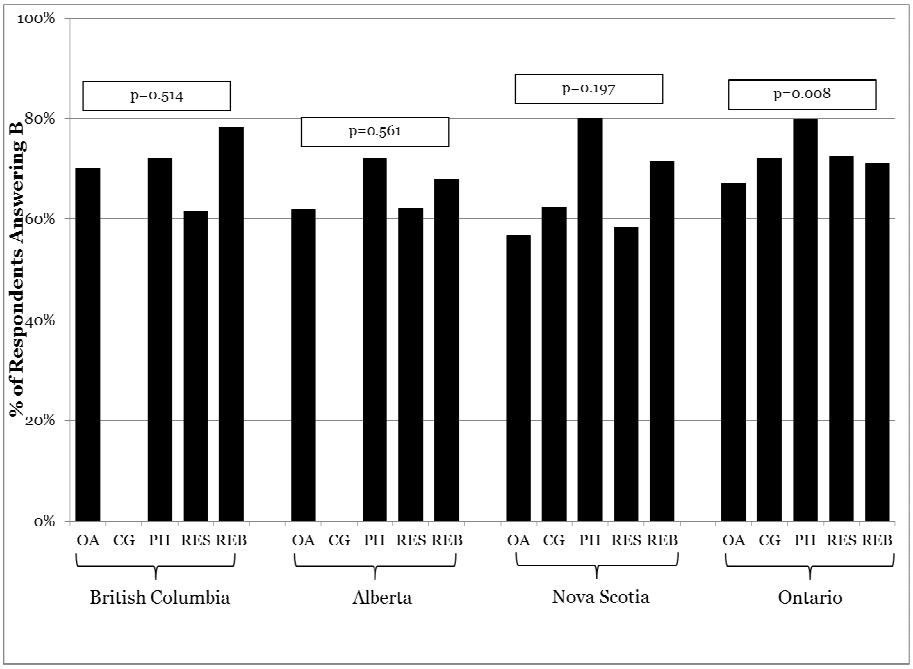
In Ontario (see Figure 4), the percentage of respondents with the best answer was not statistically different across groups for all four scenarios. Physicans however chose the alternative answer more often than other groups. The rates at which "no one has clear legal authority" was selected in Ontario were not markedly higher than in the other two provinces lacking clear statutory foundations for identification of an LAR. The favoured answer among all Ontario groups for scenarios 1–4 was that the family member was the LAR.

Figures 1–4 present only the rates at which correct answers (or best and reasonable alternative answers) were selected, but do not show the rates of other relevant responses. In connection with scenario 4 (no individual benefit), clear majorities of every group in every province indicated that the family member was the LAR. This was correct in BC, but in every other province the response had no clear basis in the laws that we have examined. Figure 5 shows this pattern.

In sum, setting aside BC (which provides a clear foundation for identifying an LAR in each of the four scenarios), and the advance directive scenario as applied in Alberta (also enabling LAR identification), the correct or best response to the remaining scenarios in Alberta and all of the scenarios in Nova Scotia and Ontario was option E "no one has clear legal authority" (See Table 4). Yet of the 52 scenario/group/province combinations proper to Alberta, Ontario, and Nova Scotia,[163] in only four instances was the most favoured response not the erroneous or, in some cases, defensible but still legally risky option B (the family member). In 45% (23 of 52) of these combinations, more than 70% of group participants identified the family member as LAR. The exceptions all arose in response to scenario 1 (no advance directive or court-appointed guardian), where "no one has clear legal authority" was favoured among the Alberta physicians (59%), Alberta REB members (36%), Alberta researchers (30%), and Nova Scotia researchers (50%).

[163] In Alberta, there were only four groups rather than five, as caregivers were not canvassed. (Three provinces) x (four scenarios) x (five groups) – (the advance directives in Alberta exception) – (Albertan caregivers in the other three scenarios) = 60 – 5 – 3 = 52.

Figure 5. Selection of B – "Family Member" – in Response to the "No-Individual-Benefit" Scenario



OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members
p values are for within-province comparison across groups

In other words, putting aside the divergent responses to scenario 1, the other three scenarios elicited relative agreement across provinces and population groups that the family member was the LAR–regardless of whether the applicable provincial laws were clearly supportive, unclear, or clearly contrary.

Perhaps our most striking result concerned scenario 4 (no individual benefit), in response to which a clear majority of every subgroup indicated that the family member was the LAR. In BC, this was the correct response. However, based on our analysis of health care consent and advance directives laws (there was no guardianship order in place), the response had no clear basis in law in Alberta, Nova Scotia, or Ontario. In these provinces, the proportion of respondents identifying the family member as LAR was not markedly lower than in scenarios 2 and 3, and was markedly higher than in response to the first scenario.

As noted, even those who conduct or oversee research were widely mistaken about the state of the law where there was one clear answer. Furthermore, they favoured a riskier appraisal of the state of the law when no one had clear legal authority. For example, in response to scenario 3 (featuring an advance directive for health care), the proportions of researchers asserting that the family member was the LAR for the purpose of decision making about the proposed research were 50% and 71% in Nova Scotia and Ontario, respectively. Among REB members in those two provinces, the proportions identifying the family member as LAR were 76% and 72%. In response to scenario 4 (no individual benefit), the proportions of researchers identifying the family member were 62%, 58%, and 72% in Alberta, Nova Scotia, and Ontario, respectively. Among REB members, the rates were 68%, 72%, and 71%.

VI. Discussion

In Canada, a complex set of federal and provincial laws and policies apply to the regulation of health research involving persons deemed incapable of consent. While third party authorization is a minimal legal requirement, provincial laws may fail to offer a clear or explicit basis for identifying an LAR.[164] In both Canada and the US, governments have been urged to devise regulatory regimes specific to this area of social policy, including but not limited to laws enabling LAR identification.[165] This advice is part of a broader concern to ensure that research regulation is sensitive to the dual values of advancing scientific knowledge and protecting vulnerable populations.

We put four scenarios to stakeholders in four Canadian provinces, and asked who, if anyone, was legally empowered to give third party authorization for an adult's participation in research. The key variables in the scenarios were the presence or absence of a court-appointed guardian or advance directive for health care, and the presence or absence of a prospect of individual benefit. Two provinces in which our survey was conducted featured clear legislative terms enabling LAR identification in at least one of the scenarios; the other two provinces did not. Yet, as illustrated in section IV, respondents in all provinces and across all five sub-populations surveyed tended to identify the family member as LAR, with only small minorities acknowledging the uncertainty or legal ambiguity attaching to LAR identification.

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[164] See Bravo et al, "Comparison Substitute Consent", *supra* note 7 and Part III, above.

[165] In the US context, see Saks et al, *supra* note 6; in the Canadian context, see Bravo et al, "Comparison Substitute Consent", *supra* note 7.

From this tendency of respondents to identify a family member as LAR regardless of uncertain or absent legal authority, one may speculate that their understanding of the laws governing third party authorization of research may have been driven less by familiarity with provincial laws than by certain broad, culturally-shared conceptions of acceptable conventions. Based on the greater proportion of respondents across all groups who attributed decision making authority to the family member in scenarios 2 and 3 in comparison with scenario 1, one may further speculate that respondents' perceptions of authority turned in part upon the presence of an overt or obvious legal mechanism for conferring some form of substitute decision making authority (i.e. a guardianship order or advance directive), even where extension of that authority to decisions about research participation was unclear.

The utility of our study is twofold. First, it draws attention to the complexity and diversity of provincial approaches to this aspect of research regulation. While it is sometimes said that Canada's federalist order is enriched by a multiplicity of provincial legal regimes functioning as independent laboratories for policy innovation, in this instance the public interest is arguably impeded by provincial differences imposing divergent and sometimes uncertain requirements. In particular, these differences raise the possibility that research norms will be poorly understood, and that research of potential value, particularly multi-centre national research, may be impeded or chilled. Second, our study demonstrates that REB representatives, researchers, physicians, and laypersons tend to believe that a close family member may act as LAR, even in circumstances in which provincial laws are ambiguous or offer no foundation at all for third party authorization of research. This raises concerns about the adequacy of public and professional understandings of legal requirements for research involving persons deemed incapable of consent. Related concerns include harm to research subjects in the absence of clear transmission and understanding of legal requirements, as well as liability on the part of researchers, REB members, and research institutions in the absence of valid third party authorization.

A. Other Studies

In what follows, we consider our findings in light of other studies before taking up certain limitations of our study.

1. The Quebec Study

Some of the authors had conducted a similar study in Quebec prior to this one.[166] In Quebec, article 15 CCQ authorizes close family members to make substitute decisions about health care on behalf of a minor or an adult deemed legally incapable of consent.[167] In contrast, article 21 CCQ places a set of conditions upon involving persons in research where they lack capacity to consent.[168] One of these conditions is that, except in the situation of a parent and minor child, substitute consent must be obtained from the mandatary (in other words, the proxy appointed under an advance directive), tutor (partial or tem-

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[166] See Bravo, Pâquet & Dubois, *supra* note 147; Bravo et al, "Physicians' Knowledge", *supra* note 147.

[167] More detailed analysis of the sources of legal regulation of medical and research interventions in Quebec is provided in Simon Verdun-Jones & David N Weisstub, "Consent to Human Experimentation in Quebec: The Application of the Civil Law Principle of Personal Inviolability to Protect Special Populations" (1995) 18:2 Int'l J of Law & Psych 163.

[168] Article 21 places certain restrictions on involvement in research even where capacity to consent is in place, stipulating that the benefits of the proposed research (or "experimentation") must outweigh the risks. Commentators have remarked that this section implicitly includes societal benefits and not merely individual-specific benefits. See WF Bowker, "Experimentation on Humans and Gifts of Tissue: Articles 2-23 of the Civil Code" (1973) 19:2 McGill LJ 161 at 166-67. Article 21 para 3 CCQ states that "[c]onsent to experimentation may be given, in the case of a minor, by the person having parental authority or the tutor and, in the case of a person of full age incapable of giving consent, by the mandatary, tutor or curator." The Code does not define "experimentation." Some commentators have opined that these codal provisions relate only to non-therapeutic research (see Verdun-Jones & Weisstub, *supra* note 167 at 175-79). Yet this is contestable, as the Code does not explicitly distinguish therapeutic from non-therapeutic experimentation. Indeed, where a novel intervention is directed at an individual who lacks capacity to consent, art 21 para 2 CCQ requires that the "experiment" must offer a "potential to produce benefit to the person's health"–therefore, the term is compatible with interventions that have an anticipated therapeutic effect. Article 21 para 2 CCQ also stipulates that where an experiment is directed at an identifiable group, it must have the potential "to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap." This allows for the possibility of no-individual-benefit research, but does not preclude application of this provision of the Code to research featuring an anticipated benefit (along with anticipated risks). Article 21 CCQ further prohibits the involvement of minors or persons incapable of consent in "experiments" involving "serious risk" to their health, and requires respect for dissent in cases in which the person "understands the nature and consequences of the experiment."

porary guardian), or curator (plenary guardian). Each of these regimes requires a formal court process to trigger substitute decision making authority.

A majority of respondents to the Quebec survey correctly identified the individual himself or herself as having legal authority to consent to or refuse treatment if he or she is legally capable of making the decision; moreover, a majority correctly identified the LAR where the individual was deemed incapable of making a decision about treatment (under article 15 CCQ, a close family member without formal court appointment). In contrast, a minority of respondents (ranging from 2% of older adults to 44% of REB members) correctly responded that no one was legally authorized to make the decision where the scenario involved the prospective research participation of an adult who was legally incapable of consenting and who lacked a formally-appointed representative (a curator, tutor, or mandatary). The Quebec respondents tended to incorrectly identify the close family member as being automatically authorized to make a substitute decision about an adult's participation in research. Based on this result, the authors recommended increased efforts to educate the public about Quebec's laws.

In the present study, we began by determining whether and how the common law Canadian provinces and territories deal with the question of who, if anyone, may make a substitute decision about research.[169] We concluded that in many provinces, the matter is unsettled–yielding, at best, competing arguments rather than clear legislative or judicial statements.[170] Against this background, we assessed how a set of stakeholders understood the state of the law in their province. This promised to be a distinct exercise from the Quebec study, where the law on point had been explicit. It is therefore difficult to compare the results of the present study with those obtained in Quebec.

The present study therefore raises some difficult questions that were not raised in the Quebec study, namely: How do people make sense of legal uncertainty? And how should a survey of knowledge be interpreted where the object of knowledge is itself markedly ambiguous or contested? We address these questions after noting some further studies of relevance to this one.

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[169] See Bravo et al, "Comparison Substitute Consent", *supra* note 7.

[170] *Ibid*.

2. Laws Relevant to Research Involving Persons Incapable of Consent

Apart from the aforementioned Quebec study, we were unable to locate any other studies, Canadian or otherwise, of people's knowledge of laws concerning substitute decision making about research.[171] However, we were able to draw upon articles analyzing the state of the law. These included one that some of the authors of this study had previously written, commenting on the diversity and frequent ambiguity of Canadian substitute decision making laws concerning LAR identification for research purposes,[172] and also the work of Tomossy & Weisstub on the uncertainty of provincial guardianship laws, particularly with respect to authorization of non-therapeutic research.[173]

Another relevant study of legislative regimes was a 2008 article produced by Elyn Saks et al. That article provides a comprehensive account of US substitute decision making laws, some of which expressly address "whether proxies may consent to research, and if so, which individuals should serve as proxies, and for which sorts of research they can provide consent,"[174] and some of which are ambiguous in one or more of these respects. The authors conclude that a model statute may be desirable, and that in any case, "it is certainly desirable that states adopt clear, well thought out statutes that specify who may serve as a Legally Authorized Representative."[175] Our own conclusions, following examination of the laws in four Canadian provinces and individuals' understandings of who, if anyone, may act as LAR in research contexts, closely parallel those of Saks and her co-authors.

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[171] The authors of the Quebec study conducted a similar study in France, which arrived at similar results. See Bravo et al, "Substitute Consent for Research Involving the Elderly: a Comparison Between Quebec and France" (2008) 23:3 Journal of Cross-Cultural Gerontology 239. In addition, a further study has recently come to our attention: Mary Dixon-Woods & EL Angell, "Research Involving Adults who Lack Capacity: How have Research Ethics Committees Interpreted the Requirements?" (2009) 35:6 Journal of Medical Ethics 377. Dixon-Woods & Angell find in decision letters of research ethics committees in England and Wales evidence of confusion about recently-introduced laws concerning substitute decision making about research.

[172] *Ibid*.

[173] Tomossy & Weisstub, *supra* note 7.

[174] Saks et al, *supra* note 6 at 79.

[175] *Ibid*.

3. Understanding of Substitute Decision Making Laws (Not Specific to Research)

We may also compare our study to two others, one from Scotland and the other from Australia, which assessed knowledge of substitute decision making laws relating to health care (as well as finances in the Australian study). However, because these studies did not address third party authorization of research, they are only indirectly relevant to our study.

Booth et al surveyed relatives of intensive care patients in Scotland to ascertain their knowledge of the law relating to health care interventions where the prospective patient is incapable of making a treatment decision.[176] At the time, there was no clear legal foundation in Scotland for third party authorization of treatment where an adult lacked legal capacity, except where a court-appointed guardian was in place.[177] Legislation had been introduced to address aspects of this legal state of affairs. But that law was not in force at the time of the study, and in any case, it refrained from giving substitute decision making authority to a close family member in the absence of a court-appointed guardian or an advance directive appointing the family member as proxy.[178]

Relatives of 100 intensive care patients completed the authors' structured questionnaire. Only 10% were aware that reforms to the law on consent to

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[176] MG Booth et al, "Relatives' Knowledge of Decision Making in Intensive Care" (2004) 30 J Med Ethics 459.

[177] *Ibid*. The survey was completed during a period of law reform, with the most salient reforms not coming into force until the survey was completed (the article was submitted in June, 2002; the reforms came into effect July 1, 2002). The relevant post-reform legislation is the *Adults with Incapacity (Scotland) Act 2000*, 4 ASP 2000 [*Scotland Act*]; on the coming into force of the relevant provisions, see *The Adults with Incapacity (Scotland) Act 2000 (Commencement No. 2) Order 2002*, Scot SI 2002 No 189 (c 14). It appears that the primary questions asked in the survey were not affected by the reforms.

[178] The *Scotland Act*, *supra* note 177 ss 47-50, brought into force after the Booth et al, *supra* note 176 study, authorizes physicians to treat patients who lack capacity in the absence of third party authorization, in order to promote their health, unless there is a proxy appointed under an advance directive or a court-appointed guardian (in which case authorization must be sought). Scottish law refrains from giving authority to the nearest relative in the absence of such a formally-appointed representative. Notably, where research is in issue, section 51 of the *Scotland Act* imposes a set of threshold risk/benefit conditions as well as a requirement of third party authorization, to be obtained from a guardian, agent under an advance directive, or–failing that–the nearest relative.

treatment were underway.[179] A majority (88%) incorrectly believed that prior to any law reforms, they "had the right … to give or withhold consent on behalf of an incompetent patient."[180] The authors observe that this suggests "a general lack of knowledge" about the state of the law in Scotland relating to medical treatment of persons who lack the relevant decision making capacity. They add:

> Relatives' false perception of their power to consent was probably reinforced by the almost routine practice of involving relatives in discussion concerning life sustaining treatment as a substitute for direct discussion with the patient. Certainly, getting the relative to sign a consent form would have given the impression to the relative that their opinion did have legal weight. It was our impression that not all doctors were entirely clear on this either.[181]

The study did not take up the question of third party authorization of research, only of treatment. Nonetheless, it is worth considering whether our respondents may similarly have drawn upon prior experience (in particular, common practices whereby health providers look to family members for substitute decision making about health care; in Canada, unlike Scotland, these practices are typically grounded in law) in identifying the family member as LAR, even where there was no basis, or no clear basis in law for this conclusion.

Another study of comparative interest, conducted in Queensland, Australia, explored the "knowledge and experiences of older people"[182] with respect to enduring powers of attorney for financial and health care decisions. The authors found that "a majority of older people lacked a level of understanding of enduring powers of attorney concepts that would enable them to make informed legal choices."[183] However, there was "more detailed" knowledge of the legislation on the part of family members of older persons with cognitive disabilities, which the authors attributed to "their experience of arranging and sometimes implementing an [enduring power of attorney]."[184]

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[179] See Booth et al, *supra* note 176 at 460.

[180] *Ibid*.

[181] *Ibid*.

[182] Deborah Setterlund, Cheryl Tilse & Jill Wilson, "Older People and Substitute Decision Making Legislation: Limits to Informed Choice" (2008) 21:3 Australasian Journal on Ageing 114 at 130.

[183] *Ibid* at 132.

[184] *Ibid* at 130.

It was also found that knowledge of the relevant substitute decision making laws was negatively correlated with "structural factors of lower income, [non-Anglo-Australian] cultural background, disability, rural location, nursing home residence and [female] gender."[185] Lower income and disability were particularly associated with "limited understanding of the law."[186] Perhaps unsurprisingly, lack of knowledge about the relevant substitute decision making laws was found to "limit the ability to make informed choices and to self monitor arrangements" about finances and health care.[187] The authors concluded that the government should "raise awareness in the community generally and in the older population in particular regarding both the advantages and disadvantages of substitute decision making arrangements," while "tak[ing] account of the diversity of views that older people have of substitute decision making arrangements" and the effect of structural factors on people's perceptions of substitute decision making laws.[188]

In interpreting the results of our study, it is important to keep in mind that respondents may have had concrete experiences, for example, with substitute decision making about health care (or for that matter, virtual experiences, say, with television programs featuring substitute decision making about health care) that rightly or wrongly inform their understanding of substitute decision making about research. That is, despite a "limited understanding of the law," respondents may have given answers based in their understanding of what common practices are or perhaps their opinions about what the law should permit. Yet here it is important to acknowledge that even highly educated stakeholders may be influenced by forms of misinformation or partial understanding that may be particularly entrenched in professional circles.[189]

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[185] *Ibid* at 132.

[186] *Ibid*.

[187] *Ibid* (focus group discussions further indicated that "the reluctance of many participants to consider substitute decision making arrangements may reflect also emotions associated with the acknowledgement of possible incapacity and mortality" at 132).

[188] *Ibid*.

[189] See e.g. Kimberly Nalder, "The Paradox of Prop. 13: The Informed Public's Misunderstanding of California's Third Rail" (2010) 2:3 California Journal of Politics & Policy 1. This analysis of the results of a poll assessing voter knowledge of a high profile, contentious Californian law ("Proposition 13") found that standard predictors of better understanding of political and legal matters (in particular, higher education and wealth) were actually correlated with a higher likelihood of error in

B. Limitations[190]

Among the limitations of our study is the fact that response rates were less favourable in some groups and provinces. The sample size, however, is relatively large. Moreover, the analyses suggest that participants were representative of their population, with the exception of the physician group, which required weighting.

A further limitation, noted earlier, is that our study did not evaluate responses in light of federal or provincial laws relating to personal information and the protection of privacy, or how the substitute decision making regimes featured therein may bear upon health research in general and our study in particular. To this we may add that our search for case law was restricted to identifying precedents directly taking up the question of who, if anyone, may function as LAR for research authorization purposes, either at common law or under the legislation canvassed. We identified no case law of direct relevance to this question. Yet there remains scope for future research involving a more searching case law review aimed, for instance, at identifying precedents involving other areas of substitute decision making authority that are of potential relevance to the research context.

In what follows, we discuss three further limitations of our study. These relate to our focus on respondents' understanding of laws that in some cases were ambiguous or were subject to law reform processes during the study period.

1. Surveying Knowledge in the Face of Uncertainty

What can be gained by surveying knowledge of the law where the law is (in many instances) markedly ambiguous or uncertain? Here we should distinguish situations in which individuals are personally uncertain about the law but there is general agreement that the law itself is clear, and situations in which the law is generally recognized as ambiguous or uncertain as between competing interpretations (and there is no case law establishing a definitive interpretation).

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respect to the content of the law in question–a phenomenon that Nalder speculates may reflect high levels of public misinformation as well as interest-sensitive selectivity of understanding.

[190] Some of the statements on general strengths as well as limitations of our study in this part are taken from a previously published article reporting on other aspects of the study, Bravo et al, "Advance Directives", *supra* note 145 at 212-215.

In analyzing the results of the Quebec study, the authors speculated that some respondents may have lacked a defensible claim to knowledge of the law as it applied to the scenarios, but may nonetheless have provided what they thought was "the most sensible answer" rather than admit lack of knowledge.[191] Therefore, correct survey responses might not indicate that respondents were familiar with the relevant laws (again, in Quebec the laws on point were relatively clear), but rather that the laws coincided with respondents' intuitive judgments.

Turning to the present study, one may similarly speculate about whether people were disposed to provide the answer they deemed most sensible, or in accordance with their particular values and cultural assumptions, rather than indicate that they did not know the answer or that the law was uncertain. It is arguable, however, that information about the way that stakeholders understand the laws governing research, particularly where those understandings are rich with value-laden assumptions, may spur public reappraisal of the laws in place and the processes for promulgating and enforcing those laws.

Here we may raise a further question, going to the defensibility of our evaluation of survey responses. We distinguished situations where there was a single correct answer (meaning that we could identify no plausible alternative argument) from situations where there was a "best" answer along with a reasonable alternative. It may be argued that our characterizations of responses as correct or incorrect, or more to the point, as either "best" or a "reasonable alternative," are inextricably bound up with our own value-laden policy preferences or subjective impressions and thus are reflective of personal bias rather than objective evaluation.

Our response is twofold. First, we have provided the bases for our interpretations in Parts II and III. Should one wish to argue that our interpretations reflect contestable premises, including contestable normative assumptions, these premises may be exposed and opposed. Second, where we privilege the claim that no one has clear legal authority–as we do in all but two situations where we recognize a best and reasonable alternative answer–this amounts to an objective acknowledgement of the presence of legal controversy. In other words, option E indicates that there are competing legal arguments, as yet unresolved by an authoritative judicial statement. This is not a matter of privileging one competing argument over another; rather, it is a matter of recognizing that there are competing arguments.

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[191] Bravo, Pâquet & Dubois, *supra* note 147 at 48.

A final, more general point must be made with respect to surveying legal knowledge in the face of uncertainty. Even where one is a legal professional, it may be unclear whether the appropriate response to an invitation to characterize an area of law that is in some respect uncertain is to acknowledge that uncertainty, or to give one's opinion about the best argument in light of the normative or policy considerations one deems most compelling or most likely to be accepted by a court.

This conundrum is illuminated by a recent study of how law students evaluate legal texts. The authors of the study distinguish internal from external approaches to legal (or specifically statutory) ambiguity.[192] According to the authors, the internal approach to legal ambiguity is that which individuals tend to apply when asked simply whether a statute is ambiguous. This interpretive approach is "internal" in that it involves consulting and asserting one's own judgment about the best interpretation of the law–a process whereby, the authors suggest, individuals draw upon their particular normative predispositions or policy preferences and characterize the law as ambiguous or unambiguous (likely the latter), depending on which answer best accords with those predispositions or preferences. In contrast, an external approach to legal ambiguity tends to be elicited where the respondent is instructed to make an effort to consider whether "ordinary readers of English" would agree on the meaning of legal text.[193] Such an approach is "external," according to the authors, in that it reduces the bias of individual policy preferences in favour of a more empirically grounded attempt to predict collective opinion. Put differently, the latter approach is distinguished by an effort to take account of others' competing normative and policy orientations, rather than simply one's own, when assessing legal ambiguity.[194]

The respondents to our survey were asked to determine who, if anyone, was authorized to make a substitute decision about research in a set of scenarios. It is possible that more respondents would have acknowledged legal uncertainty if the survey had directed them to consider whether, say, Canadians could be expected to agree on how the law applies to the problem at hand. However,

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[192] Ward Farnsworth, Dustin F Guzior & Anup Malani, "Ambiguity about Ambiguity: An Empirical Inquiry into Legal Interpretation" (2010) 2:1 Journal of Legal Analysis 257.

[193] *Ibid* at 258.

[194] We use this example despite the differences between the exercise grounding the study done by Farsnworth, Guzior & Malani, *ibid* (involving interpretation of specific statutory language), and our study (which asked respondents to apply their understanding of the law without providing the relevant statutory text).

asking who is legally authorized to make a substitute decision about research, while providing "no one has clear legal authority" as one option arguably engages not only respondents' estimations of the principled or policy-based cases for one or another answer (the normative dimension of law-interpretation), but also and primarily their understanding of whether the matter is settled or contestable, and so potentially a matter for litigation (the positive dimension of law-interpretation). Of course, one may expect that many responses will be less than fully informed or considered; as noted, we speculate that some of the responses to our survey may register the common sense intuitions of respondents rather than informed assessments of the state of the law.

2. Surveying Knowledge in the Absence of Legal Consultation

A second limitation of our study is that the responses we received are not necessarily those that would inform the decisions or actions taken by the respondents in a concrete instance of proposed research. Respondents were instructed to "read each vignette carefully and answer to the best of your knowledge according to the law in your province." If such a situation actually arose, those surveyed might consult with legal advisors or otherwise seek information about institutional policies before reaching a conclusion. Such consultation might result in a shift in respondents' understanding from that which is recorded in the survey. This may particularly be so in the case of the REB members who completed our survey, given that each REB responsible for reviewing biomedical research within institutions that receive federal research funds is required to include a member who is knowledgeable about relevant law,[195] and that member's opinion would presumably be given particular weight where problems of LAR identification arise.

The assumptions about the state of the law that our study registers, however, may conceivably inform a range of decisions and actions on the part of respondents, from the decisions of older adults about whether to engage in advance planning specific to research participation, to the activities of physicians in giving advice about advance planning, to the activities of REBs in approving research and the work of researchers in conducting it. Indeed, given that 44.3% of the researchers who participated in our study indicated that they had con-

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[195] *TCPS2*, *supra* note 8 art 6.4(c); *TCPS1*, *supra* note 8 art 1.3(c). Both editions state that it is "advisable but not mandatory" that at least one REB member be knowledgeable about relevant law where the research under review is not biomedical research. As indicated in Table 2, REB members appointed for their legal expertise were included in our respondent pool (they comprised 7% of the REB respondents).

ducted research that involved decisionally-incapacitated older adults in the past five years, and 43.5% of the 46 REB Chairs who participated in a qualitative interview indicated that their committee had reviewed protocols involving decisionally-incapacitated older adults in the last 12 months, we may surmise that the responses from these groups sometimes reflected past practice as well as present understanding.[196]

3. Surveying Knowledge in the Face of Legal Reforms

A third limitation of our study arises from the legal reform processes that took place in Alberta and Nova Scotia during and just after the period in which our surveys were completed. These reforms did not come into force until after all of our surveys were returned. However, some respondents were likely aware of the proposed reforms. While our survey was underway, both of the relevant statutes received Royal Assent (a stage in the legislative process that is potentially confused with coming into force). This may have led to confusion about the state of the law on the part of some Nova Scotia and Alberta respondents at the time the surveys were completed.

The first of our surveys was mailed out in September 2007; the last returned to us was received in April 2009. In Alberta, the *Dependent Adults Act*[197] was subject to law reform processes during the period in which we conducted our survey and was subsequently replaced by the *Adult Guardianship and Trusteeship Act*.[198] The latter Act received Royal Assent on 2 December 2008 and was brought into force on 30 October 2009, shortly after our survey responses were returned. Certain provisions within Alberta's *Adult Guardianship and Trusteeship Act*[199] would have altered our evaluation of the Alberta responses had they been in force at the time of the survey. This applies in respect to scenarios 1 (no court-ordered guardian or advance directive for health care)[200] and 2 (court-appointed guardian).[201] Our evaluation of the Alberta re-

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[196] Bravo et al, "Practices of Canadian REBs", *supra* note 145 at 3-6.

[197] *Supra* note 135.

[198] *Ibid*.

[199] *Ibid*.

[200] In scenario 1, the correct answer under the *Dependent Adults Act* was E ("no one has clear legal authority"). However, under the *Adult Guardianship and Trusteeship Act*, the best answer shifts to B (the family member) with E as a reasonable alternative. Mrs. Bristol's son Jacob satisfies the criteria for recognition as the "specific decision maker" for "health care" under section 89 of the Act, while section 88(2)(d) excludes from the ambit of his authority "health care that involves participation ... in research"

sponses to scenarios 3 and 4 would not differ with the introduction of the new Act.

In Nova Scotia, the *Medical Consent Act*[202] was subject to law reform processes during the period in which we conducted our study and was subsequently replaced by the *Personal Directives Act,*[203] again after our survey was complete. The new Act received Royal Assent on 27 May 2008, and was brought into force on 1 April 2010. Nova Scotia's new *Personal Directives Act* would have altered our evaluation of responses to scenario 1 (no court-appointed guardian, no advance directive) had it been in force at the time of our survey.[204]

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offering "little or no potential benefit to the adult." This provision arguably implicitly authorizes statutory decision makers (and so "Jacob", in scenario 1) to act as LAR where research offers more than "little or no potential benefit." We would have recognized E as a reasonable alternative, because scenario 1 states that the research study is "potentially" of "some" benefit to participants, leaving open for debate the question of whether the study satisfies the statutory threshold of offering more than "little or no potential benefit."

[201] In the pre-reform situation in Alberta, the best answer to scenario 2 was E ("no one has clear legal authority"), with B (the family member) as a reasonable alternative, given the possibility that a court would recognize this decision as falling within the best-interests based decision making authority of the guardian. Under the *Adult Guardianship and Trusteeship Act*, B would be the best answer, with E as the reasonable alternative. In other words, Jacob (introduced in scenario 1) continues to have authority to make the decision as statutory decision maker, if not as the court-appointed guardian. As in scenario 1, E would be recognized as a reasonable alternative because of the potential for debate about whether the study (now the one described in scenario 2) meets the statutory threshold of offering more than "little or no benefit."

[202] *Supra* note 126.

[203] SNS 2008, c 8.

[204] The correct pre-reform response to this scenario was E ("no one has clear legal authority"), as there was no statutory basis for substitute decision making about health care, let alone research, outside the hospital setting. Had the *Personal Directives Act*, *ibid* been in force, the best answer would still have been E, but we would have recognized B (the family member) as a reasonable alternative. This is because the *Personal Directives Act* empowers the nearest relative (stipulated in a statutory list) to make substitute decisions about "health care" whether in or beyond hospital, in the absence of a personal directive. While the Act is silent on research, it may be argued that "health care" should be interpreted to include interventions holding out a prospect of individual therapeutic benefit.

However, our evaluation of the responses to scenarios 2–4 would not shift as between the pre- and post-reform situations in Nova Scotia.[205]

Readers may therefore approach our results from Alberta with respect to scenarios 1 and 2, and Nova Scotia with respect to scenario 1, with this qualification in mind. However, we suggest that the number of respondents who were cognizant of these reforms and who would have responded in a manner that reflected awareness of the specific terms of the legislation that was not yet in force was likely small.

Conclusions and Policy Recommendations

Important interests and values are at stake in the regulation of substitute decision making about research. Contemporary pressures to increase research activity focused on health conditions correlated with aging, including conditions involving cognitive impairment, demand renewed efforts to protect prospective research subjects who are vulnerable to the designation of legal incapacity and the resulting possibility of exploitation. Yet our study found that Canadian laws are both unclear and poorly understood when it comes to the crucial matter of identifying who, if anyone, is authorized to make a substitute decision about an adult's participation in research. This finding holds even for REB members, potentially compromising their oversight role in the research process.

More specifically, our survey reveals a widespread tendency among Canadians–including older adults, researchers, and REB members–to identify a family member as authorized to make a decision about an adult's research participation, even where such authority is either uncertain or clearly lacking at law. The combined lack of clarity in, and lack of knowledge about, provincial laws relating to LAR identification that our study exposes indicates a fundamental gap in the system of research regulation. Attendant to this is a potential for harm to prospective research subjects; a potential for liability on the part of researchers, REB members, and research institutions;[206] and a potential for impeding the progress of research on conditions involving cognitive impairment.

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[205] Scenario 4 deserves specific consideration. With the coming into force of the *Personal Directives Act*, our evaluation of Nova Scotia responses to this scenario would not shift: E remains the sole correct answer. For the *Personal Directives Act* does not introduce a statutory basis for authorizing research offering no individual benefit to the research subject–at least (and this is an important qualification), not in the absence of prior capable wishes or values deemed relevant to participation in a specific no-benefit research project. Scenario 4 features no information about prior capable wishes or values.

[206] See Hadskis, *supra* note 2; Thomson, *supra* note 60; Gold, *supra* note 60.

These problems are compounded when considering multi-site and cross-national research.

We conclude that there is a need for coordinated efforts among the provinces and territories to develop a harmonized approach to the laws concerning the involvement in research of persons who lack capacity to consent–beginning with the question of who, if anyone, may function as LAR in the research context. Any province or territory may opt to depart from a harmonized approach where local conditions are deemed to warrant this–but such departures should be specifically justified and weighed against the merits of harmonization. We further conclude that there is a need for enhanced clarity in and enhanced awareness about existing provincial laws of relevance to the question of who, if anyone, may function as LAR. Addressing one issue without the other will not solve the problem; neither clarity without awareness nor awareness without clarity will materially improve on the current situation.

More specifically, the primary recommendations arising from our study, apart from the overarching concern for harmonization, are as follows. Where there is a clear legal basis for identifying an LAR for research purposes in a given province or territory, the provincial or territorial government should devise a program of public education targeting researchers and REB members, as well as the general public, to ensure understanding of those laws. Where the law is unclear, government should undertake processes of public deliberation on the way to law reform, followed by efforts to ensure that researchers, REB members, and the general public understand the laws enacted. Policymakers in those provinces and territories not surveyed in this study should consider whether their laws offer a clear basis for authorizing substitute decision making about research, and should make efforts to ensure public understanding if the laws are clear or initiate law reforms if they are not.

We offer in addition a few closing observations on the policy concerns that should inform law reform initiatives, apart from the important goal of bringing increased clarity, certainty, and potentially also uniformity to this area of law. First, the tendency of respondents to our questionnaire to identify a close family member as LAR, whether or not this was supported in law, requires careful consideration of whether the law should be brought into accord with this common understanding. Of course, neither common understanding nor public preference necessarily makes good policy. In its 1998 report, the US National Bioethics Advisory Commission explored the possibilities for third party authori-

zation of research.[207] Among the possibilities noted were giving exclusive authority to court-appointed guardians or agents appointed under an advance directive. However, as the report pointed out, guardians are rarely in place and appointing a guardian is both costly and time-consuming. Additionally, the blunt instrument of full guardianship may not serve the wider interests of the individual (or family) concerned. Research directives, on the other hand, may arguably promote autonomy while advancing the important goal of encouraging deliberation and discussion regarding preferences about research participation. However, few persons have executed advance directives specifically addressing research.[208] Moreover, research directives may raise particular challenges when applied to specific research protocols, the precise nature and consequences of which the individual may not have contemplated.[209]

Allowing a family member to function as LAR for the purpose of substitute decisions about research in the absence of a guardian or advance directive poses less of an impediment to research than either of the other two options. But is this option sufficiently protective of the interests of prospective research subjects? That is, are there good reasons to suspect that a non-appointed family member is less well-positioned than a guardian or proxy appointed under an advance directive to fulfill the function of third party authorization: namely, to ensure, as far as possible, that the rights and interests of the prospective research subject are actively defended? Or do all three types of substitute decision maker face similar challenges?

This leads us to our second closing observation: that it is important to keep in mind that third party authorization is but one of a set of arguably vital protective measures. Studies demonstrate that family members are susceptible to inaccuracies about or departure from the capable preferences of their relatives when making substitute decisions about treatment.[210] It is not unreasonable to

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[207] National Bioethics Advisory Commission (1998), *supra* note 6, Vol I (December 1998), ch 3 nn 165 and following, online: <bioethics.georgetown.edu/nbac/capacity/Advance.htm#Para26>.

[208] Bravo et al, "Advance Directives", *supra* note 145 at 215; Appelbaum, *supra* note 5 at 122.

[209] But see the policy proposals intended to offset such concerns in Anne Moorhouse & David N Weisstub, "Advance Directives for Research: Ethical Problems and Responses" (1996) 19:2 Int'l JL & Psychiatry 107; Tomossy & Weisstub, *supra* note 7 at 130-134.

[210] T Tomlinson et al, "An Empirical Study of Proxy Consent for Elderly Persons" (1990) 30:1 Gerontologist 54; Allison Seckler et al, "Substituted Judgment: How Accurate are Proxy Predictions?" (1991) 115:2 Ann Intern Med 92; David Shalowitz,

suspect that there is an even lesser likelihood that substitute decisions about research will reflect prior capable wishes.[211] One response to this would be to strictly prohibit research involving persons who are incapable of consent, unless perhaps it can be established that the research offers subjects a likely health benefit,[212] or unless the wish to be included in research is clearly indicated in an advance directive. The alternative response would require attending carefully to the adequacy of additional safeguards beyond third party authorization, including standards and practices of capacity assessment and thresholds of maximal risk, in addition to considering protective mechanisms not yet existing in Canada, such as independent advocates responsible both for advising LARs and for ongoing oversight of research.[213]

A final point for policy consideration returns us to our earlier arguments (raised in connection with the distinction between research and treatment) on the merits of legislation that clearly addresses whether, and on what conditions, an LAR may make a substitute decision about research. Such legislation could, for example, stipulate the sort of information that must be disclosed by researchers and considered by the LAR where authorization of research is in issue. This might include information about aspects of the research that serve investigative purposes exclusively, information about how the risks and foreseeable benefits of the proposed research compare with those of available non-research-based therapies, and information about any conflicts of interest.[214] Arguably, such disclosures are essential to counteracting the therapeutic misconception and thereby promoting both the validity of third party authorization and the protection of prospective research subjects who lack decisional capacity.

These closing remarks take us beyond the confines of our study to future inquiry into this area of law and policy. Indeed, this study has touched on just

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Elizabeth Garrett-Mayer & David Wendler, "The Accuracy of Surrogate Decision Makers: A Systematic Review" (2006) 166:5 Arch Intern Med 493.

[211] Coleman, *supra* note 4 at 767.

[212] See Lewis, *supra* note 43.

[213] Stefan Eriksson, "On the Need for Improved Protections of Incapacitated and Non-Benefiting Research Subjects" (2010) 24:7 Bioethics 1 at 6.

[214] On disclosure of conflicts of interest as a condition precedent to informed consent to participation in research, see Hadskis, *supra* note 2 at 493-95, discussing imperatives stated in Chapter 7 of the *TCPS2* in respect to researcher disclosure of conflicts of interest to REBs. Hadskis notes that among the possible dispositions that an REB may arrive at on identifying a conflict of interest is a requirement that the researcher "disclose this conflict to potential participants during the consent process" (at 495).

one piece of the research regulation puzzle: the question of who, if anyone, is authorized to make a substitute decision about health research, and how various stakeholders answer that question. Numerous additional legal and ethical concerns flow from the prospect of health research involving persons who are deemed legally incapable of consent. These range from the legal standards in light of which this capacity should be assessed, to the institutional and interpersonal practices relevant to supporting this capacity, to the means of discerning assent and dissent, to the risk-benefit thresholds to serve as conditions precedent to third party authorization, to the factors that should be disclosed to and taken into account by third party decision makers. All of these matters must continue to inspire ethical and legal inquiry, and moreover, should be pursued within the public sphere as urgent questions for collective deliberation and debate.

Appendix

I. SCORES Vignettes - Research Participation

What follows is the section of the SCORES questionnaire aimed at assessing respondents' understanding of who, if anyone, has legal authority to make a decision about an adult's participation in research. The research-related vignettes numbered 1–4 below (and in the text of our discussion) were numbered 4–7 in the questionnaire. The vignettes numbered 1–3 in the questionnaire concerned authority to make a decision about health treatment.

It is important to know that treatment vignette 3, which immediately preceded the first research vignette–and which concerned authorization to consent to or refuse a recommended hip replacement–introduced the characters of "Mrs. Bristol" and "Jacob." In treatment vignette 3, Jacob was characterized as Mrs. Bristol's "only child," whom she went to live with after her husband died. That vignette further stated that Mrs. Bristol "never selected a substitute decision maker while she was fully capable of making decisions," and that "she has not been assigned a guardian by a court."

From the SCORES Questionnaire

In this first section, we describe hypothetical situations involving an older adult who requires health care or is eligible to participate in a study. Please assume that all characters are adults, that each study has been approved by a recognized research ethics board, that all those legally authorized to give consent are willing and available, and that the risks and potential benefits are as stated. These risks and potential benefits may be psychological and social as well as physical.

Please read each vignette carefully and answer to the best of your knowledge according to the law in your province.

	Research Vignettes
1	The hip replacement was successful and Mrs. Bristol is back at Jacob's home. A researcher is conducting a study to see if classical music relieves anxiety in Alzheimer patients. There is little risk and potentially some benefit to the participants. Mrs. Bristol is not capable of deciding whether to participate in the study. **In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mrs. Bristol in the study?***(Check ALL the answers you think are correct)* A. Mrs. Bristol herself B. Her son Jacob C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know
2	A court has granted guardianship of Mrs. Bristol to her son Jacob. He is now authorized to make all decisions regarding his mother's personal and health care. The guardianship order does not specifically address research. Jacob receives a call from a researcher who would like Mrs. Bristol to participate in a study. The study will test a new diet that might prevent weight loss in people with Alzheimer's disease. There is little risk and potentially some benefit to the participants. **In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mrs. Bristol in the study?***(Check ALL the answers you think are correct)* A. Mrs. Bristol herself B. Her son Jacob C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know
3	Mr. Johnson has lived in a nursing home since he was diagnosed with moderate dementia a year ago. Mrs. Johnson visits her husband every day. Many years before losing decision-making capacity, Mr. Johnson

	wrote a legally-binding document in which he identified his wife as the person who should make health-care decisions on his behalf if he were no longer able to do so himself. In this document, he did not make his wishes know in regard to participation in research. A researcher is testing a new pill that might slow memory loss due to dementia. This pill must be taken daily for 3 months. Its main side effect is a tendency to cause minor reversible liver problems. The study involves some risks to the participants but also potential benefits for them personally that outweigh the risks. Mr. Johnson is not capable of deciding whether to participate in the study. **In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mr. Johnson in the study?** *(Check ALL the answers you think are correct)* A. Mr. Johnson himself B. His wife C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know
4	Two years later, Mr. Johnson is deemed a good candidate for a study about the quality of life of nursing home residents. The study involves observing residents as they go about their daily routines. Mrs. Johnson is assured that the study involves little risk to her husband. It will not benefit him personally but might benefit future residents. Mr. Johnson is not capable of deciding whether to participate in this study. **In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mr. Johnson in the study?** *(Check ALL the answers you think are correct)* A. Mr. Johnson himself B. His wife C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know

II. Correct, Best and Alternative Reponses

Where there are best and alternative responses, the alternative response is given in italics in parentheses.

Table 4. The Correct, Best, and Alternative Responses to Each Scenario

Research scenario	BC	Alberta	Nova Scotia	Ontario
1. No court-appointed guardian, no advance directive. Research involves potential direct benefit, little risk.	B	E	E	E *(B)*
2. Court-appointed guardian. Research involves potential direct benefit, little risk.	B	E *(B)*	E *(B)*	E *(B)*
3. Advance directive addressing health care but not research. Research involves some risk but outweighed by potential direct benefit.	B	B *(E)*	E *(B)*	E *(B)*
4. No-direct-benefit research, no guardian.	B *(E)*	E	E	E