Canadian Consent and Capacity Regulation: Undermining Dementia Research and Human Rights?

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The participation of persons with dementia in health research is necessary to evaluate the safety and efficacy of new drugs and therapies. Access to samples and data from this population for data-intensive research is also key to understanding disease and drug mechanisms. Persons with dementia, however, may experience diminished or fluctuating capacity to consent. This paper provides a comprehensive, updated overview of Canadian regulatory frameworks that govern the

La participation des personnes atteintes de démence à la recherche en santé est nécessaire à l'évaluation de la sécurité et de l'efficacité des nouveaux médicaments et traitements. L'accès aux échantillons et données concernant cette population à des fins de recherche est un élément clé de la compréhension des maladies et du mode de fonctionnement des médicaments. Toutefois, les personnes atteintes de démence peuvent éprouver une diminution ou une variation

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involvement of adults with diminished capacity in health research. These frameworks include human subjects research regulation, as well as provincial and territorial laws that specify who is authorized to make research-related decisions on behalf of adults lacking the capacity to consent, and in what circumstances. We find that Canada has a number of statutory prohibitions, conditions, discrepancies, and silences that may exclude persons with dementia from data-intensive research. While such limits protect against exploitation, they may also exclude persons with dementia from research needed to advance the standard of care, and undermine their human rights to equal recognition and full participation in society. We also compare the criteria that representatives must consider when making research-related decisions, including instructions in formal advance directives; previous wishes, values, and beliefs; consultation with the person; and welfare. These treatment-centric criteria, however, are prioritized differently across provinces and can apply awkwardly in data-intensive research contexts, which may discourage representatives from engaging with ethically approved research. Through a case study of the Canadian Longitudinal Study of Aging, we consider how legal consent and capacity principles apply to a pan-Canadian research platform. In particular, we explore whether broad consents remain valid after a loss of capacity to consent, and whether family members can override participant consents and request withdrawal samples and data.

de leur capacité à consentir. Cet article offre un portrait global et une mise à jour relative aux cadres règlementaires canadiens qui régissent la participation des adultes dont la capacité est diminuée à la recherche en santé. Ces cadres comprennent les lois et règlements provinciaux et territoriaux énumérant les parties autorisées à prendre des décisions liées à la recherche concernant des adultes incapables à consentir. Nous constatons plusieurs interdictions, conditions, divergences, et omissions règlementaires qui peuvent priver ces personnes des améliorations de la qualité des soins que la recherche serait en mesure de leur apporter, et affaiblir les droits de la personne concernant leur reconnaissance égale devant la loi et leur pleine participation au sein de la société. Nous comparons également les critères que doivent tenir en compte les représentants juridiques dans la prise de décisions concernant la recherche, y compris les instructions fournies dans les directives préalables; les volontés, valeurs, et croyances préalables; la consultation de la personne concernée; et son bien-être. Ces critères orientés vers le traitement se voient toutefois accorder une priorité différente à travers les provinces et s'appliquent parfois difficilement dans un contexte de recherche axée sur les données, ce qui peut décourager la participation des représentants légaux aux projets de recherche approuvés par les comités d'éthique. Puisant d'une étude de cas de l'Étude longitudinale canadienne sur le vieillissement, nous évaluons comment le consentement légal et les principes de capacité s'appliquent à cette étude pancanadienne. Nous examinons notamment si le consentement reste toujours valide après la perte de la capacité à consentir et si les membres d'une famille peuvent outrepasser le consentement d'un participant et demander le retrait des échantillons et des données.

Introduction

In 2016, 600,000 Canadians (about 1.6% of the overall population) were estimated to be living with dementia, costing $47,000 annually per patient.[1] The incidence of dementia is expected to significantly increase with the aging of the Canadian population. Alzheimer's disease is responsible for 60–80% of dementia cases.[2] Despite advances in understanding of the underlying pathology, treatments have been elusive and there have been a number of high-profile clinical trial failures.[3] The participation of persons with dementia in health research is necessary to evaluate the safety and efficacy of new drugs and therapies. Researchers also need access to biological samples and health information from persons with dementia and other neurodegenerative diseases for data-intensive discovery or observational research.

Under what conditions is it just to include persons with dementia in research or allow access to their health samples and data? On one hand, there is a need to protect persons with dementia from abuse and exploitation. On the other hand, protective exclusion can also exclude vulnerable populations from advancements in the standard of care.[4] Protective exclusion may also undermine the human rights of the elderly and disabled to equal recognition, non-discrimination, and full participation in society.

For regulatory frameworks to strike a balance between protection and inclusion, they must be responsive to the changing nature of biomedical research. Informatics, networking, molecular sequencing, and imaging technologies are leading a boom in data-intensive research. Research increas-

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1 See The Economist Intelligence Unit, *Assessing the Socioeconomic Impact of Alzheimer's Disease in Western Europe and Canada* (2017) at 32.

2 See *ibid* at 6.

3 See e.g. Pam Belluck, "Eli Lilly's Experimental Alzheimer's Drug Fails in Large Trial", *The New York Times* (23 November 2016), online: <www.nytimes.com/2016/11/23/health/eli-lillys-experimental-alzheimers-drug-failed-in-large-trial.html>.

4 See e.g. Nola M Ries, Katie A Thompson & Michael Lowe, "Including People with Dementia in Research: An Analysis of Australian Ethical and Legal Rules and Recommendations for Reform" (2017) 14:3 J Bioeth Inq 359 at 360; Beth Prusaczyk et al, "Informed Consent to Research with Cognitively Impaired Adults: Transdisciplinary Challenges and Opportunities" (2017) 40:1 Clin Gerontol 63 at 63, 66.

ingly involves collecting and linking a variety of molecular, clinical, and environmental data, analysed using big data techniques to reveal patterns and correlations. Access to and analysis of large numbers of biospecimens and associated data from both persons with dementia and healthy individuals can reveal the molecular basis of dementia and suggest new drug targets. Data-intensive research is also characterized by large infrastructure such as biobanks and databases of molecular and associated clinical data.[5] These infrastructures are often designed to serve as a resource for broad communities of researchers. Samples and rich individual-level data are collected, stored, used, and shared over long periods of time and across many jurisdictions. Moreover, researchers are increasingly encouraged or even required by funders, journals, and their peers to "share" rich individual-level data from their studies with the broader research community through research databases. Sharing data allows the research community to pool resources, avoid duplicative studies, and verify or refine results.[6] In turn, data sharing can accelerate the translation of new diagnostics, preventative interventions, and therapies.[7] In this paper, we take the position that it is ethical and appropriate to apply more permissive criteria for participation of persons with diminished capacity in *data-intensive* research, as long as appropriate safeguards are in place and international human rights principles are upheld.

This article begins by providing an up-to-date guide to the regulatory frameworks governing the involvement of adults with diminished capacity in research across Canadian provinces and territories (Parts I–III). These frameworks consist of a loosely coordinated web of international, national, and sub-national norms, including research laws and ethics policies, consent and capacity laws, and personal information protection laws. Our review reveals that Canadian regulatory frameworks do not sufficiently recognize the emerging ethical imperative to include vulnerable populations, namely adults with diminished or fluctuating capacity, in research. Some provinces prohibit, restrict, or fail to mention who is authorized to provide consent

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5 See Bartha Maria Knoppers, Ma'n H Zawati & Emily S Kirby, "Sampling Populations of Humans across the World: ELSI Issues" (2012) 13 Annu Rev Genomics Hum Genet 395 at 398.

6 See Darren B Taichman et al, "Sharing Clinical Trial Data: A Proposal from the International Committee of Medical Journal Editors", Editorial, (2016) 164:7 Ann Intern Med 505 at 506.

7 See Howard H Feldman et al, "Alzheimer's Disease Research and Development: A Call for a New Research Roadmap" (2014) 1313 Ann NY Acad Sci 1 at 4–6.

to research participation on behalf of adults who lack capacity. And even where a researcher can identify a legally authorized representative, the decision-making standard the representative must follow is often restrictive or unclear.

The regulatory balance between inclusion and protection is particularly tenuous for data-intensive research involving persons with dementia. In Part IV, we illustrate how regulatory barriers and uncertainties affect data-intensive research through a case study of the Canadian Longitudinal Study on Aging (CLSA), a pan-Canadian, data-intensive research platform (hereafter, the CLSA platform). Data-intensive research can present privacy risks, as genomic sequence and imaging data can be difficult to anonymize.[8] Such risks are especially difficult to assess where samples and data are stored over long periods of time and shared with researchers across institutions and jurisdictions. It can be hard to predict in advance who will access samples and data, how they might be used or misused, and how the benefits of research will ultimately be distributed.[9] Observational research does not typically benefit individual participants. Participants are even less likely to benefit (directly or indirectly) as they age or as their disease progresses. Uncertainty over the level and distribution of risks and benefits makes it difficult to determine if regulation permits, restricts, or prohibits participation of adults with diminishing capacity in data-intensive research. Legal tests that may apply clearly in health care and experimental research settings apply awkwardly to data-intensive research.

Legal barriers are compounded by practical ones. Unclear regulation can confuse researchers, research ethics boards, clinicians, family members, and carers,[10] leading to overprotective interpretations. The significant resources and effort needed to protect and support participants may also discourage researchers and gatekeepers from including persons with dementia. Regulation and consent processes, especially for data-intensive research,

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8 See Adrian Thorogood, Constance Deschênes St-Pierre & Bartha Maria Knoppers, "Substitute Consent to Data Sharing: A Way Forward for International Dementia Research?" (2017) 4:1 J Law Biosci 133 at 136.

9 See Graeme Laurie, "Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law" (2011) 130:3 Hum Genet 347 at 348.

10 See Victoria Shepherd, "Research Involving Adults Lacking Capacity to Consent: The Impact of Research Regulation on 'Evidence *Biased*' Medicine" (2016) 17:55 BMC Med Ethics 1 at 2.

need to strike a more explicit balance between supporting the involvement of persons with dementia in decisions about their participation in research, protecting them from exploitation and harm, and ensuring their responsible inclusion in research towards new methods of treatment and prevention.

Methodology

This work draws on three research resources developed for previous articles. First, we reviewed international, regional, and national norms across eight countries that govern if and when a representative may give substitute consent to research participation on behalf of an adult who lacks capacity.[11] We compared legally binding instruments and policies applicable to health research and personal information in Australia, Canada, Finland, France, Japan, Singapore, the United Kingdom, and the United States, and their constituent jurisdictions. This inventory of international norms was updated for this paper (see Appendix II). Second, we identified Canadian national and sub-national personal (health) information protection laws that apply to health research.[12] We revisit our inventory of Canadian privacy laws and policies here to identify provisions governing consent to the collection, use, and disclosure of personal information for incapable adults. Third, we carried out a scoping review of legal and ethical literature, identifying 116 articles published since 2007 which address the consent issues in dementia research that inform this discussion.[13] The novel research contribution made in this paper is a comprehensive review of provincial and territorial consent and capacity laws in Canada, in order to determine if and how they apply to research-related decisions (see Appendix I). Relevant statutes and case law were identified by searching on CanLII and provincial legislative websites. We focus on dementia not only because it presents a significant public health burden and attracts significant research interest, but also because this condition illustrates stark normative tensions between support for autonomy, protection, and inclusion. Our legal analysis is largely generalizable to

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[11] This was initially developed in Thorogood, Deschênes St-Pierre & Knoppers, *supra* note 8.

[12] This was initially developed in Adrian Thorogood et al, "Protecting the Privacy of Canadians' Health Information in the Cloud" (2016) 14:1 Can J Law Technol 173.

[13] This was initially developed in Adrian Thorogood et al, "Consent Recommendations for Research and International Data Sharing Involving Persons with Dementia" (2018) Alzheimer's & Dementia, DOI: <10.1016/j.jalz.2018.05.011>.

research on other neurodegenerative conditions in adults, such as traumatic brain injury or stroke.

I. Regulation of Research Involving Adults with Diminished Capacity

A number of international ethical norms apply to research and clinical trials in Canada. The World Medical Association's *Declaration of Helsinki* provides ethical principles primarily for physicians conducting human subjects research.[14] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Human Use's (ICH) *Guideline for Good Clinical Practice* is an international scientific and ethical standard for conducting clinical trials,[15] endorsed by Health Canada.[16] The Council for International Organizations of Medical Sciences established by the World Health Organization (CIOMS/WHO) also promulgates guidelines for the ethical conduct for research.[17] Nationally, the Tri-Council Policy Statement (TCPS) research ethics guidelines apply to researchers at institutions receiving research funding from Canada's three major public funding bodies.[18] In the province

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[14] World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 18th WMA General Assembly, June 1964, amended by the 64th WMA General Assembly, October 2013 [*Declaration of Helsinki*].

[15] International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline for Good Clinical Practice E6(R1),* Current Step 4 Version (10 June 1996) [*ICH Guideline E6(R1)*]; International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*, Current Step 4 Version (9 November 2016) [*ICH Guideline E6(R2)*].

[16] See Health Canada, *Good Clinical Practice: Integrated Addendum to E6(R1)*, *ICH Topic E6(R2)*, Guidance Document, adopted 9 November 2016 (Ottawa: HC, 2016) [Health Canada, *ICH Topic E6(R2)*].

[17] See Council for International Organizations of Medical Sciences & World Health Organization, *International Ethical Guidelines for Health-Related Research Involving Humans* (Geneva: CIOMS, 2016) [*CIOMS/WHO Guidelines*].

[18] Canadian Institutes of Health Research, Natural Sciences and Engineering Re-

of Québec, the *Civil Code of Québec* (*CCQ*) includes legal provisions concerning research.[19]

International ethical and legal principles contained in the *Declaration of Helsinki*, ICH Guidelines, and CIOMS/WHO Guidelines generally hold that research involving humans should be authorized by the consent of the participant,[20] overseen by a research ethics committee,[21] and should offer benefits that outweigh the risks while ensuring that risks are minimized.[22] Consent should be voluntary, informed (addressing purpose, benefits, and material risks of participation), and ongoing.[23] All of these international norms call for specific protections for research involving vulnerable persons.[24] They generally define vulnerable groups and individuals in research as those who may be particularly wronged, harmed, and coerced through research participation.[25] Each norm explicitly considers persons who lack the capacity to consent to be vulnerable and outlines related protections.

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search Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Secretariat on Responsible Conduct of Research, 2014) [*TCPS2*].

19 See e.g. art 20.

20 *Declaration of Helsinki*, *supra* note 14, arts 25–32; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 2.9; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 9.

21 *Declaration of Helsinki*, *supra* note 14, art 23; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 2.6; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 23.

22 *Declaration of Helsinki*, *supra* note 14, arts 16–18; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 2.2; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 4.

23 See *Declaration of Helsinki*, *supra* note 14, arts 25, 26, 32; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 4.8.10(s); *CIOMS/WHO Guidelines*, *supra* note 17, guideline 9.

24 See *Declaration of Helsinki*, *supra* note 14, art 19; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 3.1.1; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 15.

25 See *Declaration of Helsinki*, *supra* note 14, art 19; *ICH-GCP Guideline E6(R2)*, *supra* note 15, art 1.61; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 15.

A. Risk-benefit thresholds

The primary protection for persons who lack the capacity to consent is that researchers and research ethics committees are required to limit their participation according to restrictive risk-benefit thresholds. For research offering the prospect of individual benefit, the benefit must outweigh the risk. Research not offering the prospect of individual benefit (i.e., "non-therapeutic" research) must generally meet stricter requirements: (1) the participation of persons who lack the capacity to consent is necessary to answer the research question;[26] (2) the risks must be minimal[27] or low;[28] and (3) the research must offer the prospect of benefit to persons in a similar age or disease group.[29]

Similar limits are imposed by Québec's *CCQ*, which requires that research have either the potential to benefit the health of the subject or have the potential to produce benefits for "persons in the same age category or having the same disease or handicap."[30] The *CCQ* does not impose a strict therapeutic versus non-therapeutic distinction. Instead, it generally requires that the risk incurred is not disproportionate to the benefits anticipated.[31]

B. Informed consent

Another general protection for persons who lack the capacity to consent is the requirement that researchers instead seek consent from a "legally

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[26] See *ICH-GCP Guidelines E6(R2)*, *supra* note 15, art 4.8.14(a); *CIOMS/WHO Guidelines*, *supra* note 17, guideline 16; *TCPS2*, *supra* note 18, art 3.9.

[27] *CIOMS/WHO Guidelines*, *supra* note 17, guideline 16; *TCPS2*, *supra* note 18, art 3.9(d).

[28] *ICH-GCP Guidelines E6(R2)*, *supra* note 15, art. 4.8.14(b).

[29] See *ICH-GCP Guidelines E6(R2)*, *supra* note 15, art 4.8.14; *TCPS2*, *supra* note 18, art 3.9(d).

[30] Art 21, para 2.

[31] See *ibid*, para 1.

authorised representative,"[32] a "legally acceptable representative,"[33] or an "authorized third party."[34] These terms all similarly refer to an "LAR," a person or body with "the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent."[35] The CIOMS/WHO Guidelines require consent from an LAR, but provide an exception: where one "is not available to allow for timely enrolment, researchers may obtain the permission of a representative who is socially accepted but not formally recognized before the law."[36] The recently revised US *Federal Policy for the Protection of Human Subjects* (the *Common Rule*) provides a similar exception. The previous definition of an LAR had hindered health research in states where no applicable law provided legal authorization. In these jurisdictions, the *Common Rule* now considers LARs for research to include an individual recognized by institutional policy to provide consent in a non-research (e.g., clinical) context.[37] Canada's federalist system, however, means there is no clear way to provide more flexibility for representation through federal law. We discuss the lack of clarity and flexibility in provincial and territorial laws below.

One exception is Québec, which provides clear and flexible rules. The *CCQ* requires researchers to seek consent from an LAR and also defines who can act as an LAR. For research that could interfere with the integrity of the person, only formally designated or appointed LARs ("mandataries," "tutors," or "curators") may consent.[38] For "minimal risk" research, if the adult does not have a formally appointed representative, the *CCQ* exceptionally allows that "consent may be given by the person qualified to consent to any care required by the state of health of the person of full age."[39] We discuss this regime in detail in Parts II and III. In other provinces, how-

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32 *CIOMS/WHO Guidelines*, *supra* note 17, guideline 16; *Federal Policy for the Protection of Human Subjects*, 82 Fed Reg 7149 (2017) (to be codified at 6 CFR Part 46, § .102(i)) [*Common Rule*].

33 *ICH-GCP Guidelines E6(R2)*, *supra* note 15, arts 1.37, 4.8.12.

34 *TCPS2*, *supra* note 18, art 3.2.

35 *Ibid* at 25.

36 *Supra* note 17, guideline 16 commentary.

37 *Supra* note 32, §.102(i).

38 Art 21, para 6 CCQ.

39 *Ibid*.

ever, there are no statutory conditions defining when research may or may not be carried out with adults who lack capacity to consent.[40]

C. Assent and dissent

A third general protection requires that researchers ensure the person, even if they lack capacity, is involved in the decision to participate. The *Declaration of Helsinki*, CIOMS/WHO Guidelines, and TCPS all require researchers to seek "assent" from the person and to respect his or her "dissent" (objection).[41] Under the TCPS, researchers are expected to involve the person "to the greatest extent possible."[42] "Assent" means ascertaining the wishes of the individual with respect to participation, provided the individual can express them in a meaningful way.[43] Conversely, an "expression of dissent" or signs suggesting the person does not wish to participate must be respected.[44] Under the CIOMS/WHO Guidelines, researchers should take a participant's preferences and values into account "to the extent the person is capable" and respect a "refusal to enrol."[45] The ICH Guidelines require researchers to inform the subject about the trial to "the extent compatible with the subject's understanding" and to ask the subject to sign and personally date the written informed consent.[46] The ICH Guidelines also recommend close monitoring of the "subject's willingness to continue participation in the trial,"[47] and in the case a participant appears "unduly distressed,"[48] the person should be withdrawn. In Québec, the *CCQ* states that persons who lack the general capacity to consent to research may still *object* to research participation provided they "understand the nature and consequences of the

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40 We have reviewed only statutes and not case law.

41 *Declaration of Helsinki*, *supra* note 14, art 29; *CIOMS/WHO Guidelines*, *supra* note 17, guideline 16; *TCPS2*, *supra* note 18, art 3.10.

42 *Supra* note 18, art 3.9(a).

43 See *ibid*, art 3.10.

44 *Ibid*.

45 *Supra* note 17, guideline 16.

46 *Supra* note 15, art 4.8.12.

47 *Ibid*, art 4.8.10(p).

48 *Ibid*, art 4.8.14.

research."[49] This appears to mean that a lower capacity standard applies to objecting than consenting to research.

These various norms differ slightly with regard to whether or not a person who lacks capacity has a "veto" over research participation decisions and how informed that veto must be. Some appear to require researchers to respect an "uninformed" objection in certain circumstances. While encouraging the consultation of participants is admirable, researchers desire clarity over who has the authority to give or revoke consent.[50] The approach of the CIOMS/WHO Guidelines, by contrast, is to require researchers and research ethics committees *to ensure that the LAR* has consulted the person and considered his or her assent to the extent the person is capable.[51] As we discuss below, LARs typically have legal duties to consult with the person when making decisions.

D. Specific protections for adults with diminishing capacity

Only some of these norms have specific provisions for adults who were once capable but subsequently lose their capacity to consent. This population presents an additional ethical twist for consent: to what extent should researchers and representatives respect preferences the person previously expressed while capable? And what qualifies as a valid expressed preference? The *Declaration of Helsinki* and the ICH Guidelines do not address this specific population or mention previous instructions or wishes. The CIOMS/WHO Guidelines require researchers and research ethics committees to ensure that consent of the legally authorized representative "takes account of the participant's previously formed preferences and values (if any)."[52] These guidelines also state that an advance directive for participation in research should be respected, but do not define this instrument or how it should be interpreted.[53] The TCPS specifically recognizes the possibility of participants experiencing "diminishing and/or fluctuating decision-making capacity or degenerative conditions" and states that researchers and

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49 Art 21 [emphasis added].

50 See Shepherd, *supra* note 10 at 5.

51 *Supra* note 17, guideline 16.

52 *Ibid*.

53 *Ibid*.

LARs should be guided by "research directives."[54] (We critique the TCPS formulation of research directives in Part III.) The *CCQ* generally requires anyone who gives consent to care for another person to comply "as far as possible" with any wishes the person may have expressed.[55] Provincial consent and capacity laws in Canada also generally require LARs to respect previously expressed preferences, though, as we discuss below, what qualifies as a binding preference varies.

E. Human rights and the ethics of inclusion

International human rights law also merits consideration for dementia research. Canada has ratified the United Nations' *Convention on the Rights of Persons with Disabilities* (*UNCRPD*), committing to upholding the rights and interests of persons with physical and mental disabilities.[56] The general principles of the *UNCRPD* include respect for dignity (including individual autonomy to make one's own choices and independence), non-discrimination, and full and effective participation and inclusion in society.[57] According to the interpretation of the *UNCRPD* committee, "unsoundedness of the mind" is not a reason to deny persons the exercise of their legal capacity, though the stance of this committee is highly disputed.[58] Canada is also a signatory to the *United Nations Principles for Older Persons* (*UNPOP*), which promotes (1) independence, (2) participation (full and effective participation in the economic, political, and social life of society), (3) care, (4) self-fulfillment, and (5) dignity.[59] The *UNCRPD* and *UNPOP* call for equal

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54 *Supra* note 18, art 3.11.

55 Art 12 (given the hierarchical structure of the *CCQ*, this article presumably also applies to research).

56 *Convention on the Rights of Persons with Disabilities*, 13 December 2006, 2515 UNTS 3, art 1 (entered into force 3 May 2008) [*UNCRPD*]; Government of Canada, *Convention on the Rights of Persons with Disabilities: First Report of Canada* (2014) at 1.

57 *UNCRPD*, *supra* note 56, art 3.

58 Committee on the Rights of Persons with Disabilities, *General Comment No. 1*, 11th Sess, UN Doc CRPD/C/GC/1 (2014) at paras 13–14 [CRPD *General Comment*].

59 *United Nations Principles for Older Persons*, GA Res 46/91, UNGAOR, 46th Sess, Supp No 49 (1991) 160 [*UNPOP*].

recognition of persons with disabilities and older persons before the law and the elimination of all forms of discrimination. We consider the ramifications of these principles in the context of dementia research below.

The human rights principles of full participation and non-discrimination also align with an emerging ethics of inclusion in health research. It is increasingly considered unethical to exclude vulnerable populations from research because this effectively excludes these populations from advances in the standard of health care.[60] This principle is stated bluntly in guideline 16 of the CIOMS/WHO Guidelines: "Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion."[61] There must still, of course, be appropriate safeguards in place.[62] The Global Alliance for Genomics and Health (GA4GH), an international consortium with a mission to promote data sharing and accelerate improvements in human health, takes a similar stance. The GA4GH has established the "Framework for the Responsible Sharing of Genomic and Health-related Data," which aims to activate the human right of everyone to benefit from scientific progress, first articulated in article 27 of the UN *Universal Declaration of Human Rights*.[63] The framework emphasizes the benefits of science and in that sense differs from the traditional bioethical position that focuses on protecting participants' rights and interests.[64] Such an ethics of inclusion seeks to balance "society's interest in conducting important and promising research with the interests of the potential subject."[65] In this paper, we argue that adults with diminished capacity in Canada are both legally and practically excluded from partici-

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60 See Shepherd, *supra* note 10 at 3.

61 *Supra* note 17.

62 See *ibid*, guideline 15.

63 Global Alliance for Genomics & Health, "Framework for Responsible Sharing of Genomic and Health-Related Data" (9 December 2014), Preamble, online: <www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/>.

64 For an example of the traditional bioethical position, see *Declaration of Helsinki*, *supra* note 14, arts 8, 19.

65 George F Tomossy & David N Weisstub, "The Reform of Adult Guardianship Laws: The Case of Non-Therapeutic Experimentation" (1997) 20:1 Int J Law Psychiatry 113 at 118.

pating in research and, consequently, also from the health benefits that come to populations who participate in research.

F. Data-intensive research regulation

Data-intensive research generally presents particular challenges, though they are increasingly being explicitly addressed in regulation. First, the extent of potential privacy risks and benefits of research may not accrue to individuals or even populations for a long period of time and it is difficult to predict in advance how benefits will be shared. With global sample and data sharing, the trust relationship between researchers and participants contributing to biobanks and databases is changing: participants now "shake hands" with faceless researchers around the world.[66] Governance practices can help to mitigate privacy risks. These may include ethics review of biobanks or research projects, access review of the type of research or researcher who may access and use the biobank (e.g., academic versus commercial; local versus national versus international), and obligations imposed on researchers accessing the biobank.

Even where research involves identifiable samples or data, consent is not always required. Under Canada's TCPS, researchers may seek an exemption to the consent requirement for using identifiable data and samples from a research ethics board if the research necessitates identifiable resources, is unlikely to cause harm, involves adequate privacy safeguards, and if seeking consent from the person is impracticable or impossible.[67] Because of our focus on capacity, we limit our analysis to situations where researchers are seeking consent from participants or their representatives.

Second, it is not possible to specifically inform participants of numerous and future research purposes at the time of collection. In seeking to maximize the value of samples and data while still respecting autonomous decision making by individuals, many researchers have implemented "broad consent" processes. Broad consent is increasingly being explicitly recognized in research norms, in part because the use of samples and data for research over long periods of time makes it difficult to ensure consent is ongoing. This is especially true for participants with dementia, who are

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66 Jennifer Couzin-Frankel, "Trust Me, I'm a Medical Researcher" (2015) 347:6221 Science 501 at 502.

67 *Supra* note 18, arts 5.5A(a), (b), (c), (e).

likely to experience diminished capacity over time. The CIOMS/WHO Guidelines allow for broad consent "for unspecified future use" of specimens and data that is ethically acceptable, as long as it is combined with "proper governance."[68] Proper governance includes appropriate privacy, security, and access safeguards, transparency about future access and uses, and a right to withdraw at any time. The US *Common Rule* considers broad consent acceptable for "storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens."[69] The *Common Rule* specifies that broad consent requires a general description of the research conducted, samples and data to be shared, the type of institutions involved, and statements that the subject may not be informed on any specific use of their data and samples and about derived research results.[70]

The ICH draft *Guideline on Genomic Sampling and Management of Genomic Data* (ICH E18 Guideline) is largely deferent to local regulatory frameworks, but suggests that "informed consent … should permit broad analysis of the samples … regardless of the timing of analysis."[71] In Canada, the TCPS recognizes that identifiable data and human biological materials may be collected "for research or medical or diagnostic purposes with some expectation that they may, or will, also be used in future research, although the precise research project(s) may not be known at the time."[72] Researchers are required to inform research participants and the research ethics committee about "the full life cycle of information: its collection, use, dissemination, retention and/or disposal."[73] Not all research norms explicitly allow broad consent. In the context of research using identifiable human data and samples, the *Declaration of Helsinki* still requires research-

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68 *Supra* note 17, guideline 11.

69 *Supra* note 32 at 7150.

70 *Ibid* at 7221; US, Council on Governmental Relations, "Common Rule Overview" (1 February 2017) at § ll.116 (d), online: <www.cogr.edu/sites/default/files/Summary%20of%20Changes%20to%20the%20Common%20Rule_COGR.pdf>.

71 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, *Guideline on Genomic Sampling and Management of Genomic Data, E18*, Current Step 4 Version (3 August 2017), art 5 [*ICH-E18 Guideline*].

72 *Supra* note 18, Chapter 12, Part B.

73 *Ibid*, art 5.3.

ers to seek informed consent for "collection, storage *and/or reuse*."[74] The ICH E18 Guideline also calls for specific considerations for "subjects who can only be enrolled in the study with the consent of the subjects' legal representatives."[75]

The longitudinal, shared nature of these resources fulfills the traditional requirement that consent be ongoing – that is, that a participant can withdraw at any time, if participants are constantly updated via recontact.[76] Like all studies, once data has been analysed, published, or shared (downloaded) it can be impractical or impossible to withdraw an individual's data. We consider the complex, overlooked intersection of broad consent and capacity issues in the case study in Part IV.

II. Who Can Act as the LAR for Research?

In Canada, decision making about property, financial matters, health care, organ donation, and research participation generally requires legal capacity. Where a person lacks the capacity to consent, regulatory frameworks typically authorize a representative or proxy to make decisions on the person's behalf.[77] Indeed, as we discussed above, researchers are required to seek consent from an LAR. Health research on persons with dementia often takes place in health care institutions, so the research community naturally looks to health care consent and capacity laws for guidance. Under these frameworks, there are generally three categories of representatives authorized to make substitute decisions. First, a court may appoint a *guardian* to make decisions on behalf of a person. Second, a capable adult may appoint an *agent* to represent them in advance of a loss of a capacity by means of an *advance directive*. (We provide a definition and brief overview of advance directives across jurisdictions in Box 1.) Third, if no guardian or agent is available, a *surrogate* may be temporarily authorized by statute to make a

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74 *Supra* note 14, art 32 [emphasis added].

75 *Supra* note 71 at 8.

76 See *CIOMS/WHO Guidelines*, *supra* note 17, guidelines 11, 16; *Declaration of Helsinki*, *supra* note 14, arts 31, 32.

77 For a detailed, international comparative legal study of proxy decision making in research, see Thorogood, Deschênes St-Pierre & Knoppers, *supra* note 8.

specific decision (e.g., to consent to or refuse a specific health care treatment). Surrogates are typically selected from a hierarchical list of family members, relatives, or others close to the person.

Unfortunately, statutory consent and capacity frameworks in many Canadian jurisdictions do not (clearly) extend to decisions about research participation. Indeed, many jurisdictions prohibit, fail to address, or significantly restrict who may consent to research on behalf of an adult with diminished capacity. We identify three distinct legislative approaches across Canada, including those that (1) do not authorize health care LARs to make research decisions; (2) exclude research from the authority of LARs by default, unless an express override is provided by advance directive or court order; or (3) include research in the default authority of health care agents or guardians, if the research is approved and overseen by a research ethics committee. We limit our analysis to a review of consent and capacity statutes, as common law on the issue is uncertain.

Box 1. Key Definitions and Overview of Advance Directives

Legally Authorized Representative: A person authorized by statute or court appointment to make decisions for another.[78]

Guardian: A person appointed by the court to represent the best interests of a person with diminished capacity.[79]

Surrogate: A person that provides direction in decision making for someone else who is unable to make decisions.[80]

Agent: A person named in an advance directive to make decisions on behalf of the maker of the advance directive.[81]

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78 See JC Segen, ed, *Concise Dictionary of Modern Medicine*, 2nd ed (New York: McGraw-Hill, 2006) *sub verbo* "legally authorized representative".

79 See *ibid*, *sub verbo* "guardian".

80 See Charles Sabatino, "Default Surrogate Decision Making", *MSD Manual*, online: <www.msdmanuals.com/home/fundamentals/legal-and-ethical-issues/default-surrogate-decision-making>.

81 Adapted from Health Canada, *Implementation Guide to Advance Care Planning in Canada: A Case Study of Two Health Authorities* (March 2008) at 26, 38, online: <www.canada.ca/content/dam/hc-sc/migration/hc-sc/hcs-sss/alt_

Capacity: In the biomedical context, functional capacity is defined as a person's ability to understand relevant information, to appreciate consequences, to reason, and to express a decision.[82]

Advance Directive: A formal statement with legal authority used by a capable adult to plan for after a loss of capacity.[83] Advance directives are also known as "living wills" or "power of attorney for health care."[84] A directive comes into effect upon the loss of capacity. While advance directives can address a range of topics, they are commonly used in the health care context. Numerous provincial statutes enable health care advance directives and may in some cases extend to research. Courts have also recognized at common law that advance directives for refusal of treatment must be respected.[85] Advance directives may have two components. First, a person may legally appoint an agent to make decisions on their behalf (a "proxy directive"). Second, a person may provide instructions (an "in-

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formats/pdf/pubs/palliat/2008-acp-guide-pps/acp-guide-pps-eng.pdf> [Health Canada, *Advance Care Planning*]. Other equivalent terms used in different provinces are proxy, attorney of personal care, mandatary, representative, substitute decision maker, and guardian.

82 See *Starson v Swayze*, 2003 SCC 32 at para 78, [2003] 1 SCR 72:

> Capacity involves two criteria. First, a person must be able to understand the information that is relevant to making a treatment decision. This requires the cognitive ability to process, retain and understand the relevant information. […] Second, a person must be able to appreciate the reasonably foreseeable consequences of the decision or lack of one. This requires the patient to be able to apply the relevant information to his or her circumstances, and to be able to weigh the foreseeable risks and benefits of a decision or lack thereof.

See also Tom Archibald & Trudo Lemmens, "Data Collection from Legally Incompetent Subjects: A Paradigm Legal and Ethical Challenge for Population Databanks" (2008) Suppl Special Ed Health LJ 145 at 167: "The common law test for capacity asks whether the individual understands the nature of the proposed treatment and the consequences of the decision."

83 Janet Dunbrack, *Advance Care Planning: The Glossary Project, Final Report* (Health Canada, 2006), online: <www.canada.ca/content/dam/hc-sc/migration/hc-sc/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2006-proj-glos/2006-proj-gloss-eng.pdf>.

84 Health Canada, *Advance Care Planning*, *supra* note 81 at 28.

85 See *Malette v Shulman* (1990), 72 OR (2d) 417 at 426, 67 DLR (4th) 321 (CA) [Malette]; *Fleming v Reid* (1991), 4 OR (3d) 74 at 75, 82 DLR (4th) 298 (CA).

struction directive"). These instructions are typically directed to the agent, but in some contexts and provinces they may also be directed to other LARs.

A central challenge with advance directives in health care and research contexts is whether they satisfy the requirements of informed consent. Some provincial statutes affirm that competent adults can provide informed consent to treatment by means of an advance directive.[86] In Québec, health care professionals are required to follow "clearly expressed instructions relating to care that are recorded in the advance medical directives register or filed in the person's record." These have the "same weight as wishes expressed by a person capable of giving consent to care."[87] By contrast, Ontario allows for advance care plans to be prepared to guide care, but informed consent must ultimately be provided the patient's LAR (with the exception of emergency care).[88] Canadian common law and research ethics impose a high standard of informed consent in research contexts. It is therefore unlikely that a research advance directive would be sufficiently clear and informed, so consent to research is almost always provided by the LAR.

A. Research is expressly excluded from authority of LARs

In Ontario, research is expressly excluded from the statutory authority of health care LARs[89] and is not addressed in any other legislation. The *Health Care Consent Act* (*HCCA*) authorizes LARs to consent to "treatment," defined as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose."[90] LARs may be "powers of attorney for personal care" appointed by advance directive under the *Substitute Decisions Act*.[91] Neither act affects the state of the common law as it relates to "[a] procedure whose primary purpose is research."[92] In

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86 See e.g. *Representation Agreement Act*, RSBC 1996, c 405, ss 7, 9 [BC *RAA*]; *Act respecting end-of-life care*, c S-32.0001, s51 [Qc *ARELC*]; *Advance Health Care Directives Act*, SNL 1995, c A-41, s 3(1) [NL *AHCDA*].

87 Qc *ARELC*, *supra* note 86, s 58.

88 See *Health Care Consent Act*, SO 1996, c 2, Schedule A, ss 21(1), 25(2) [Ont *HCCA*].

89 See *ibid,* s 6(1).

90 *Ibid*, s 2(1), *sub verbo* "treatment".

91 SO 1992, c 30, s 46 [Ont *SDA*].

92 *Ibid*, s 66(13); Ont *HCCA*, *supra* note 88, s 6(1).

Nova Scotia and Saskatchewan, statute law is silent on research.[93] In New Brunswick, the law is also silent on research, with the exception of research interviews or examinations within nursing homes.[94]

In these four provinces, the common law governs research activities involving adults deemed to lack decision-making capacity. Case law is limited.[95] One commentator has suggested that, in Ontario, "it is likely that a family member or court-appointed guardian cannot consent to research which does not have a therapeutic benefit for the adult."[96] In *E (MRS) v Eve*, the court rejected a mother's authority to pursue non-therapeutic sterilization.[97] If interpreted broadly, this case might bar substitute decisions for participating in non-therapeutic research. In *Malette v Shulman*, the court recognized the validity of a written advance refusal to receive a blood transfusion.[98] This suggests that, at common law, courts may recognize an advance instruction to participate in non-therapeutic experimental research, although the instruction would have to meet the high common law standard of consent for such research.[99] In *Bentley v Maplewood Seniors Care Society*, the British Columbia Supreme Court considered whether or not a past statement of wishes of a person with dementia could constitute a bind-

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93 See *Personal Directives Act*, RSNS 2008, c 8 [NS *PDA*]; *Personal Directives Regulations*, NS Reg 31/2010 [NS *PDR*]; *Human Organ and Tissue Donation Act*, RSNS 2010, c 36; *The Adult Guardianship and Co-decision-making Act*, RSS 2000, c A-5.3 [Sask *AGCD*]; *The Representation Act, 2013*, SS 2013, c R-20.5 [Sask *Representation Act, 2013*].

94 See *Nursing Homes Act*, RSNB 2014, c 125, s 13(c) [NB *NHA*].

95 See e.g. Sheila Wildeman et al, "Substitute Decision Making About Research: Identifying the Legally Authorized Representative in Four Canadian Provinces" (2012) 6:1 McGill JL & Health 189 at 193; Archibald & Lemmens, *supra* note 82 at 167.

96 Lauri Ann Fenlon, "Clinical Trials Involving Children and Adults with Mental Disabilities" (April 2005), online: *Fasken Martineau* <http://www.fasken.com/files/Publication/12716880-6b19-4e5f-8ff7-a3946b72d65a/Presentation/PublicationAttachment/0e49b5ef-7ccd-4986-bc4c-0ead9fa406fb/CLINICAL_TRIALS.pdf>.

97 [1986] 2 SCR 388 at 431, 31 DLR (4th) 1.

98 *Supra* note 85 at 426.

99 See e.g. *Weiss c Solomon*, [1989] RJQ 731 at 742, [1989] RRA 374 (Sup Ct); *Halushka v University of Saskatchewan* (1965), 53 DLR (2d) 436 at 443–44, 52 WWR 608 (CA).

ing refusal to oral feeding and hydration.[100] The Court found this was not the case because the individual was still capable of accepting nutrition and because the health care consent and capacity provisions did not apply to personal care decisions. The Court found that refusal could only be respected with clear instruction and that withdrawal could otherwise constitute neglect.[101] This case raises the importance of whether or not different types of research qualify as health care in different jurisdictions. The result would be that statutory health care advance directive and substitute decision making provisions would not apply. While the case indicates that clear instructions may be broadly binding at common law, it also indicates the challenge of stating wishes in a manner that satisfies high informed consent standards, especially those in research. Given the current confusion at common law, statutory clarity on representation for research is imperative.

B. Research is excluded from default powers of LARs

Other provinces and territories exclude LAR authority over research by default, but allow a capable adult to override this restriction by express instruction in an advance directive (Alberta, Manitoba, Prince Edward Island, Newfoundland and Labrador, and the Northwest Territories).[102] In Alberta, for example, the *Personal Directives Act* enables a person to appoint an "agent" in a "personal directive" to make personal decisions on his or her behalf after a loss of capacity. The scope of this act is broad: a personal directive may include instructions about any "personal matter" including, but not limited to, health care decisions.[103] Agents must follow clear instructions provided in the personal directive.[104] By default, agents are prohibited from providing consent to participation in research if no potential benefits can be

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100 *(Litigation guardian of)*, 2014 BCSC 165 at para 3, 62 BCLR (5th) 352 [*Bentley*], aff'd 2015 BCCA 91, [2015] 6 WWR 252.

101 *Ibid* at para 145.

102 See *Personal Directives Act*, RSA 2000, c P-6, ss 7, 15 [Alta *PDA*]; *The Health Care Directives Act, Manitoba,* 1993 CCSM c H27, ss 5, 14 [Man *HCDA*]; *Consent to Treatment and Health Care Directives Act,* RSPEI 1996, c 10, ss 12, 20 [PEI *CTHCDA*]; NL *AHCDA*, *supra* note 86, ss 3, 5 (courts may also have the authority to do so by express court order); *Health Care Regulations*, NWT Reg 050-97, ss 1(c), (d) [NWT *HCR*].

103 Alta *PDA*, *supra* note 102, s 1.

104 See *ibid*, s 14.

expected for the participant or if the research involves the removal of tissue.[105] A capable adult can override these restrictions in a personal directive. Surrogates are also prohibited from making decisions in respect to research which offers little or no potential benefit to the participant or involves tissue removal,[106] though they may consent to research which is approved by a research ethics committee and poses no harm to the adult.[107] Court orders may grant a guardian authority over health care or any other personal matters the court considers necessary, though presumably courts would tend to follow the default exclusion of research that applies to agents and surrogates.[108] Similarly, the Northwest Territories prohibits guardians from consenting to "experimental treatment" or tissue removal for research, unless specifically authorized to do so in a guardianship order.[109]

C. Research is included in default powers of LARs

Three jurisdictions – British Columbia, Québec, and Yukon – authorize health care LARs to consent to research approved by a research ethics committee. In British Columbia, research is included in the definition of health care under the *Health Care (Consent) and Care Facility (Admission) Act*, meaning LARs for health care are generally authorized to consent to research.[110] The research must be approved by a research ethics committee designated by regulation.[111] LARs include agents designated by advance directives under the *Representation Agreement Act*,[112] but "temporary sub-

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105 See *ibid*, s 15.

106 See *Adult Guardianship and Trusteeship Act*, SA 2008, c A-4.2, ss 88(2)(d), 88(2)(c)(ii) [Alta *AGTA*].

107 See *Adult Guardianship and Trusteeship Regulation*, Alta Reg 219/2009, s 24(5) [Alta *AGTR*].

108 See Alta *AGTA*, *supra* note 106, ss 33(2)(a), (h). While we focus here on guardianship, Alberta has a range of additional regimes to reflect the spectrum of incapacity, including supported decision-making and co-decision-making.

109 NWT *HCR*, *supra* note 102.

110 RSBC 1996, c 181, s 1, *sub verbo* "health care" [BC *HCCFA*].

111 See *ibid.*

112 *Supra* note 86, s 2, 5.

stitute decision makers" (surrogates) cannot consent to non-therapeutic research or the removal of tissue for research.[113]

Québec has specific provisions that allow a mandatary (i.e., agent), tutor, and curator (i.e., types of guardians) to consent on behalf of an adult who lacks capacity to research that could interfere with the integrity of the person.[114] The *CCQ* provides an advance directive instrument called a "protection mandate."[115] The mandatary has powers to carry out instructions in the protection mandate and anything necessary to accomplish them, but not more.[116] Situations falling outside a mandate are dealt with under rules for tutorship (supporters) or curatorship (guardians). In the absence of a formal LAR, a spouse or close relative able to give consent to care (surrogate) may consent to minimal risk research.[117] The *CCQ* also includes general limits on acceptable research for this population (discussed in Part I) which technically also apply to LAR authority (e.g., the benefits must outweigh the risks, the research must benefit the individual or their age/disease group, and the research must be approved by an ethics committee).

In Yukon, all three types of LARs (agents, guardians, and surrogates) may give substitute consent to medical research approved by a recognized research ethics committee.[118] In effect, these jurisdictions achieve a balanced and flexible approach by allowing research ethics committees to de-

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113 *Health Care Consent Regulation*, BC Reg 20/2000, s 5 [BC *HCCR*]. In British Columbia, a temporary decision maker cannot authorize the following treatment: removal of tissue from a living human body for implantation in another human body or for medical education or research, experimental health care involving a foreseeable risk to the adult for whom the health care is proposed that is not outweighed by the expected therapeutic benefit, participation in a health care or medical research program that has not been approved by a committee (*ibid*).

114 See art 21 CCQ (provided the risk is not disproportionate to the benefit, the potential benefit is for the research subject or for a group of similar subjects, and the research is approved by a research ethics committee).

115 Arts 2130, 2166 (this is a contract whereby one person, the mandator, designates another person, the mandatary, to act in their name for matters involving property or care, in the event that the mandator loses capacity).

116 See art 2136 CCQ.

117 See arts 15, 21 CCQ.

118 See *Care Consent Regulation*, YOIC 2005/80, s 13 [Yk *CCR*].

termine the scope of acceptable research and, by extension, the scope of LAR authority to consent to research.

D. Problematic legal categories: "therapeutic research" and "minimal risk research"

A number of provincial regimes prohibit or restrict proxy consent for procedures "whose primary purpose is research", i.e., non-therapeutic research. Prince Edward Island and Newfoundland and Labrador prohibit proxy consent to such procedures unless explicitly authorized by advance directive.[119] Manitoba limits participation of adults who lack capacity "in an activity or project whose primary purpose is research."[120] Ontario's *HCCA* does not provide a statutory proxy consent mechanism for procedures "whose primary purpose is research."[121] The Northwest Territories uses a slightly different formulation, prohibiting court-appointed guardians from consenting to "experimental treatment" without specific authorization in a guardianship order.[122] New Brunswick only provides a statutory proxy consent mechanism for research that involves interviewing or examining a resident or resident records in a nursing home.[123] In provinces silent on whether or not health care includes research (New Brunswick, Nova Scotia, and Saskatchewan), the availability of proxy consent for research is an uncertain matter of statutory interpretation.[124] Restrictions on proxy consent to non-therapeutic research tend to exclude individuals with dementia from ethically acceptable forms of research, including data-intensive studies where privacy and security risks are managed.

Other proxy consent restrictions fixate on the prospect of direct benefit to the adult. The Northwest Territories and Nunavut do not allow agents to

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119 See PEI *CTHCDA*, *supra* note 102, s 12(a) ("except where the research is likely to be beneficial to the well-being of the patient"); NL *AHCDA*, *supra* note 86, s 5(3)(a).

120 *The Vulnerable Persons Living with a Mental Disability Act*, SM 1993, c 29, s 61(f) [Man *VPLMDA*].

121 *Supra* note 88, s 6(1).

122 NWT *HCR*, *supra* note 102, s 1(c).

123 See NB *NHA*, *supra* note 93, s 13(c).

124 See *ibid,* s 13.

consent to research "unless there is a reasonable likelihood of benefit to the [adult]."[125] In Prince Edward Island, agents and surrogates can only consent to a procedure with a primary research purpose where it is "likely to be beneficial to ... well-being."[126] In Alberta, surrogates cannot give one-time consent to research that offers "little or no potential benefit to the maker," though an exception is made for minimal risk research approved by a research ethics committee.[127] If LARs are only authorized to consent to research with direct benefit, persons with dementia would be excluded from participation in ethically acceptable research that benefits an age or disease group.

A handful of jurisdictions delegate the assessment of acceptable risk and benefit ratios to research ethics committees. In Yukon, health care LARs generally have the authority to consent to research that is "approved by a recognized ethics committee."[128] British Columbia allows health care LARs to consent to a "research program approved by an ethics committee designated by regulation."[129] In Québec, the *CCQ* allows only designated agents or court-appointed guardians to consent to research that "could interfere with the integrity of the individual," but additionally allows surrogates to consent to research that "involves minimal risk."[130] Québec has the most coordination between its legal conditions for research and its legal conditions for LAR authority because both sets of provisions are found in the *CCQ* and must be read together. In other words, an LAR does not have the authority to consent to research that is not approved by a research ethics committee in Québec.

Premising LAR authority on a minimal risk threshold, as we see in Québec and Alberta, may also be problematic, especially for data-intensive re-

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125 *Personal Directives Act*, Northwest Territories, SNWT 2005, c 16, s 13(2)(d), as duplicated for Nunavut by s 29 of the *Nunavut Act*, SC 1993, c 28 [NWT *PDA*]. There is also a restriction on the removal of tissue for scientific research (NWT *PDA,* s 13(2)(b)).

126 PEI *CTHCDA*, *supra* note 102, s 12(a).

127 Alta *PDA*, *supra* note 102, s 15(d); Alta *AGTA*, *supra* note 106, s 88(2); Alta *AGTR*, *supra* note 108, s 24(5).

128 Yk *CCR*, *supra* note 118, s 13.

129 BC *HCCFA*, *supra* note 110, s 1.

130 Art 21.

search where privacy risks may be subjective. We do not believe that LAR authority to consent to research should be directly prohibited or restricted based on legal risk-benefit thresholds. The assessment of risks and benefits should instead be left to research ethics committees.

E. Additional restrictions on tissue removal

Many consent and capacity laws in Canada place additional prohibitions or restrictions on proxy consent to removal of tissue for research purposes. Though Yukon allows proxy consent to ethically approved research, it prohibits such consent to tissue removal for research.[131] Though British Columbia allows surrogates to consent to research approved by a research ethics committee, it does not allow them to consent to the removal of tissues for research.[132] In Alberta, Manitoba, and Newfoundland and Labrador, only an agent, expressly authorized by clear instructions in an advance directive, can consent to the removal of tissue from the living body for research purposes.[133] Contradictions could arise where an advance directive expressly authorizes research but not tissue removal for research. Moreover, Alberta allows surrogates to consent to minimal risk research approved by a research ethics committee.[134] It is not clear whether this exception extends to minimal risk tissue removal. In the Northwest Territories and Nunavut, the same restriction applies to guardians without express court authority.[135]

It is unlikely that the legislators who created these provisions predicted the central importance of biospecimens – namely saliva, blood, and tissue biopsies – in modern research. While the spirit of tissue removal provisions to prevent exploitative organ removal is admirable, research regulation should avoid tissue exceptionalism.

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131 See Yk *CCR*, *supra* note 118, s 11(b).

132 See BC *HCCFA*, *supra* note 110, s 18(1); BC *HCCR*, *supra* note 113, s 5(1)(d).

133 See Alta *PDA*, *supra* note 102, s 15(c)(ii); Man *HCDA*, *supra* note 102, s 14(c)(ii); *The Mental Health Act*, CCSM c M110, s 93(c) [Man *MHA*]; Man *VPLMDA*, *supra* note 120, s 61(c); NL *AHCDA*, *supra* note 86, s 5(3)(c).

134 See Alta *AGTR*, *supra* note 107, s 24(5).

135 See NWT *HCR*, *supra* note 102, s 1(d); *Guardianship and Trusteeship Act*, SNWT 1994, c 29, s 11(2)(j), as duplicated for Nunavut by s 29 of the *Nunavut Act*, SC 1993, c 28 [NWT *GTA*].

F. Consent to the collection, use, and sharing of research data

The collection, use, and sharing of identifiable data from adults who lack capacity to consent may also pose problems. Federal and provincial personal information protection statutes generally require "custodians" (e.g., health care institutions) to seek consent for the collection, use, and disclosure of personal (health) information.[136] Legislation in many provinces allows researchers to access identifiable data about persons without additional consent for research purposes "consistent" with the purposes set out in an original consent.[137] For example, identifiable data collected with consent for a research project may be used to answer related research questions. Some provinces also allow researchers to access identifiable health data without consent under certain conditions. British Columbia's *Personal Information Protection Act*, for example, allows researchers to access data without consent if (a) the inclusion of identifiable information is necessary to the research purpose, (b) no attempt is made to contact participants, (c) the linkage of personal information to other information is not harmful to the individuals and is clearly in the public interest, (d) the recipient organization signs an agreement to ensure appropriate confidentiality and security, and (e) it is "impracticable" to seek consent from the individual.[138] The TCPS provides a consent waiver for research involving access to identifiable data or biospecimens under similar conditions.[139] In Québec, public bodies must

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136 See *Health Information Act*, RSA 2000, c H-5, s 104(1) [Alta *HIA*]; *Personal Health Information Act*, CCSM 2013, c P335, s 60 [Man *PHIA*]; *Access to Information and Protection of Privacy Act*, SNL 2015, c 12, s 68(1) [NL *AIPPA*]; *Freedom of Information and Protection of Privacy Act*, SNS 1993, c 5, s 43 [*NS FOIPPA*]; *Personal Health Information Protection Act*, SO 2004, c 3, s 26 [*ON PHIPA*]; *Personal Health Information Privacy and Access Act*, SNB 2009, c P-705, s 25 [NB *PHIPAA*]; *Freedom of Information and Protection of Privacy Act*, RSPEI 1988, c F-1501, s 71 [PEI *FOIPPA*]; *The Health Information Protection Act*, SS 1999, c H-0021, s 56 [Sask *HIPA*]; *Access to Information and Protection of Privacy Act*, SNWT 1994, c 20, s 52 [NWT *AIPPA*]; *Access to Information and Protection of Privacy Act*, RSY 2002, c 1, s 62 [Yk *AIPPA*]; *Act respecting health services and social services*, CQLR 2016, c S-4.2, s 22 [Qc *ARHSSS*]; *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5.

137 Archibald & Lemmens, *supra* note 82 at 161.

138 SBC 2003, c 63, s 21(1).

139 *TCPS2*, *supra* note 18, arts 5.5A, 12.3A.

seek written permission from a government commission before allowing researchers to access personal information without consent.[140]

Where these conditions are not met, consent from an individual or from an LAR is needed. Common categories of LARs who can consent to the collection, use, and disclosure of personal information generally include guardians, agents (both health care and non-health care-related), as well as other persons with "written authorization."[141] Ontario has stricter requirements which require consent from only health care LARs,[142] while New Brunswick has the broadest formulation which includes "parents" and "other representatives" in "appropriate circumstances."[143] Both the *categories* and the *priority* of LARs tend to be less strict for personal information than for health care decisions. Manitoba provides a hybrid example where any LAR (proxy, substitute decisions maker, guardian, person with written authorization), without priority, may access, use, and disclose personal health information on behalf of an individual they represent. If none of these LARs are available, a family member on a priority list may provide consent.[144] In summary, the conditions of who may act as an LAR are generally broader and more flexible for personal information than for health care.

G. Additional sources of complexity

There are discrepancies in different Canadian jurisdictions with regard to terminology, procedural requirements around advance directives, and divided authority which creates confusion in the research context. Termin-

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140 See *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR 2016, c A-2.1, s 125 [Qc *PBPA*] (the intended use cannot be "frivolous" and the personal information must be used in a manner that will ensure its confidentiality).

141 See e.g. *ibid*, s 59; Alta *HIA*, *supra* note 136, s 104(1)(i); Man *PHIA*, *supra* note 136, s 60; NS *FOIPPA*, *supra* note 136, s 71; Ont *PHIPA*, *supra* note 136, s 5(2); NL *AIPPA*, *supra* note 136, s 65; PEI *FOIPPA*, *supra* note 136, s 71; *SK HIPA*, *supra* note 136, s 56; NWT *AIPPA*, *supra* note 136, s 52; Yk *AIPPA*, *supra* note 136, s 62; NB *PHIPAA*, *supra* note 136, s 25. See also Archibald & Lemmens, *supra* note 82 at 163.

142 See Ont *PHIPA*, *supra* note 136, s 5(2).

143 NB *PHIPAA*, *supra* note 136, s 25(1).

144 See Man *PHIA*, *supra* note 136, ss 60(1), (2).

ology varies considerably across Canadian statutes. For example, terms for agent[145] include representative,[146] enduring power of attorney,[147] attorney of personal care,[148] proxy,[149] mandatary,[150] delegate,[151] and substitute decision maker.[152] This terminological variation adds to confusion and complicates efforts to develop pan-Canadian guidance on legally authorized representation.

Procedural requirements also differ for making or triggering an advance directive. In Québec, advance directives (mandates) must be notarized or made in the presence of two witnesses. Formal court authorization (homologation) is required to trigger the authority of a mandatary, rather than just professional assessment.[153] In Alberta, a maker of a personal directive may empower the proxy to assess capacity, in consultation with a physician or psychologist.[154] If the maker has not designated a proxy to assess capacity, the personal directive is activated with a declaration by two service providers that the maker lacks capacity.[155] Infrastructure that enables access to advance directives also differs. Some provinces put in place a registry of ad-

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145 See Alta *PDA*, *supra* note 102, s 1; NWT *PDA*, *supra* note 125, s 1.

146 See BC *RAA*, *supra* note 86, s 5; *Decision Making, Support and Protection to Adults Act*, SY 2003, c 21, Sch A, s 1 [Yk *DMSPAA*].

147 See *Power of Attorney Act*, RSBC 1996, c 370, s 10 [BC *PAA*] .

148 See Ont *SDA*, *supra* note 91, s 46.

149 See Man *HCDA*, *supra* note 102, s 1; *The Health Care Directives and Substitute Health Care Decision Makers Act*, SS 2015, c H-0.002, s 2(1)(g) [*SK HCDSHCDMA*]; *Advance Health Care Directives Act*, SNB 2016, c A-46, s 1 [NB *AHCDA*]; PEI *CTHCDA*, *supra* note 102, s 1; *Care Consent Act*, SY 2003, c 21, s 1 [Yk *CCA*].

150 See art 2130 CCQ.

151 See NS *PDA*, *supra* note 93, s 2.

152 See NL *AHCDA*, *supra* note 86, s 2.

153 See art 2166 CCQ.

154 See Alta *PDA*, *supra* note 102, s 9(2)(a).

155 See *ibid,* s 9(2)(b) (at least one of the service providers must be a physician or psychologist).

vance directives[156] or require clinicians to store them in medical records[157] in order for health care practitioners to easily verify the existence of advance care directives. However, the process of accessing such registries containing stored advance medical directives varies across provinces, which can hinder their usefulness.[158]

Identifying the LAR is complicated by a number of other factors. First, in line with the *UNCRPD*, consent and capacity laws in Canada increasingly include "supported decision-making" and "co-decision-making regimes" in addition to traditional substitute decision-making regimes.[159] Under supported or co-decision-making frameworks, representatives *share* authority with the adult.[160] These regimes are admirable in that they do not treat capacity as a black and white issue. However, they create uncertainty for researchers, who may be unsure whether they need to seek consent from the adult, from the LAR, or both. Second, the principle of limited intrusion has led to a tendency of courts to limit the authority granted to guardians. In other words, it is increasingly likely that even if a guardian can be identified, the authority of that guardian may be significantly restricted by the court order. This limitation may also come from the wording of the legislation

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156 See e.g. Nidus Personal Planning Resource Centre and Registry, online: <www.nidus.ca/?page_id=238> (for representation agreement in British Columbia).

157 See e.g. Qc *ARELC*, *supra* note 86, s 55.

158 See Jeremy McDonald & Diana Swain, "Do-Not-Resuscitate Requests Rarely Tracked in Canada", *CBC News* (15 September 2017), online: <www.cbc.ca/news/health/do-not-resuscitate-ontario-canada-1.4288481>.

159 Supported decision making generally means that the individual is the decision maker and the support person should enable the individual to exercise their legal capacity to the greatest extent possible, based on the wishes of the individual. Support includes consulting the individual to determine their wishes and translating their intention. This is more than just a one-time consultation: the process must be entrenched within both the daily process of decision making and in specific formal decisions. See generally Malcolm Parker, "Getting the Balance Right: Conceptual Considerations Concerning Legal Capacity and Supported Decision-Making" (2016) 13:3 J Bioethical Inq 381 at 386; Nina A Kohn & Jeremy A Blumenthal, "A Critical Assessment of Supported Decision-Making for Persons Aging with Intellectual Disabilities" (2014) 7:1 Supplement Disabil Health J S40 at 3; Tim Stainton, "Supported Decision-Making in Canada: Principles, Policy, and Practice" (2016) 3:1 Res Pract Intellect Dev Disabil 1 at 3, 6.

160 See e.g. Alta *AGTA*, *supra* note 106, s 17.

or the judicial court order, which may imply a lack of authority.[161] Third, some laws allow makers of advance directives great flexibility to determine who can act on their behalf. Makers can divide authority over specific areas between numerous agents. This makes it more difficult for a researcher to presume that, for example, the agent for care is the same as the agent for research. Makers can also appoint multiple representatives to share authority over research decisions.[162]

In summary, it is commonly understood that researchers should seek consent from an LAR on behalf of an adult who lacks capacity. Unfortunately, Canadian provincial and territorial laws often prohibit, fail to address, or considerably restrict who may provide consent. Discrepancies across jurisdictions in terminology, definitions of research, risk-benefit thresholds, and restrictions on tissue removal add confusion. The sheer complexity of interpreting the uncoordinated layers of research norms, consent and capacity laws, and their related regulations surely discourages research involving adults with diminished capacity, especially for projects spanning multiple jurisdictions. Variation can be healthy in a federation, by allowing for cultural and systemic differences, and legal experimentation. As health research is increasingly funded and carried out nationally (if not internationally), there is a practical need in this area for legal harmonization.

III. What Must the LAR Consider?

Consent and capacity statutes also prescribe how LARs are to make decisions on behalf of the adult they represent. LARs are generally required to factor certain considerations into their decisions and they typically also have obligations to consult the adult, or others close to the adult. This legal decision-making standard for LARs is relatively uniform across provinces and territories. The United States Uniform Law Commission offers a succinct summary that applies equally to Canada:

> The individual is always the dominant source for decision-making. Even if another assumes the decision-making role as agent, guardian, or surrogate, the decision-maker must always follow the individual's instructions. Without instructions, the

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161 See Gina Bravo et al, "Comparison of Provincial and Territorial Legislation Governing Substitute Consent for Research" (2005) 24:3 Can J Aging 237 at 244.

162 See Alta *PDA*, *supra* note 102, s 16.

> agent, guardian, or surrogate must make the decision in the best interests of the individual.[163]

Indeed, wishes expressed while an adult is capable, particularly written instructions in an advance directive, are given special status across Canada. Generally speaking, if wishes are unknown, consideration is given to the adult's values and beliefs. If values and beliefs are unknown, the LAR must consider the person's well-being (in the personal care context, this involves considering the benefits versus the risks of treatment and the availability of less restrictive or intrusive care). Recognizing that capacity is not black and white, LARs are also typically required to *consult* with the adult they represent and to consider the adult's *current wishes*.

There are, however, important jurisdictional differences in the priority given by LARs to various considerations, summarized in Table 1. Depending on the province or territory, highest priority is given to (1) written instructions in an advance directive, (2) any previously expressed wishes, or (3) consultation with and respect for the current wishes of the adult. Definitions of instructions, wishes, best interests, and the duty to consult the adult also vary across jurisdictions.

Table 1. LAR Decision-Making Standards

A. Special status given to written instructions in an advance directive	
Jurisdiction	**Priority of Considerations**
Alberta (agent)[164]	1. "Clear" instructions in personal directives 2. Wishes, values, and beliefs 3. Best interests (welfare) 4. Overarching duty to consult the person
Alberta (guardian)[165]	1. "Clear" instructions in personal directives 2. Best interests (expressed wishes, values, and beliefs)

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163 The National Conference of Commissioners on Uniform State Laws, "Health-Care Decisions Act Summary", online: <http://uniformlaws.org/ActSummary.aspx?title=Health-Care%20Decisions%20Act>.

164 Alta *PDA*, *supra* note 102, ss 13–14.

165 Alta *AGTA*, *supra* note 106, ss 2(d), 35(1)(2).

Alberta (surrogate)[166]	1. Best interests (condition, benefit/risk, and whether less restrictive treatment available)
Manitoba (all LARs)[167]	1. Instructions in a directive 2. Expressed wishes (except those that "would endanger the physical or mental health or the safety of the patient or another person") 3. Best interests (condition, benefit/risk, and whether less restrictive treatment available)
Prince Edward Island (all LARs)[168]	1. Instructions in a directive 2. Other oral or written wishes "applicable to the circumstances" 3. Best interests (values and beliefs, current wishes if they can be ascertained, and well-being) 4. Involve the adult in the decision "so far as is practicable"
New Brunswick (all LARs)[169]	1. Any decisions and statements of values, beliefs, and wishes expressed in a healthcare directive 2. Any other wishes 3. Best interests (condition, benefit/risk, and whether less restrictive treatment available)
Newfoundland and Labrador (all LARs)[170]	1. Instructions in a directive 2. Previous wishes 3. Best interests
Québec (all LARs)[171]	1. Anyone "who gives consent to or refuses care for another person is bound to act in the sole interest of that person, complying, as far as possible, with any wishes the latter may have expressed"
Québec (agent)[172]	1. What is "expressed in the mandate, but also to anything that may be inferred therefrom"

166 *Mental Health Act*, RSA 2000, c M-13, ss 28(3), (4) [Alta *MHA*].

167 Man *HCDA*, *supra* note 102, s 13; Man *MHA*, *supra* note 133, ss 28(1), (4), (5); Man *VPLMDA*, *supra* note 120, s 76(2).

168 PEI *CTHCDA*, *supra* note 102, ss 13(1)–(2)(b). See also Ont *SDA*, *supra* note 91, s 66(4)(b).

169 NB *AHCDA*, *supra* note 149, s 11; *Mental Health Act*, RSNB 1973, c M-10, ss 8.6(2), (8), (9) [NB *MHA*].

170 NL *AHCDA*, *supra* note 86, s 12.

171 Art 12 CCQ.

172 Qc *ARELC*, *supra* note 86, ss 51, 61 ("[a] person of full age who is capable

Nova Scotia (agent / surrogate)[173]	1. Written instructions in a directive, unless a. the maker expressed a more recent wish, b. "technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the maker," or c. the delegate believes the person would have given different instructions had he or she known the circumstances 2. Values, beliefs, and other written or oral instructions 3. Best interests (condition and well-being, benefit, and treatment's restrictiveness and intrusiveness)
B. No special status given to written instructions in an advance directive	
Jurisdiction	**Priority of Considerations**
Ontario (all LARs)[174]	1. Any known wish "applicable to the circumstances" 2. Best interests (giving equal consideration to values and beliefs, other wishes, and condition and well-being)
Northwest Territories (agent)[175]	1. Duty to consult with the maker or any person that can assist the agent 2. Instructions relevant to the decision 3. Wishes, beliefs, and values 4. Best interests
Northwest Territories (guardian)[176]	1. Expressed wishes 2. Best interests (values and beliefs, and current wishes "if they can be ascertained") 3. Encourage the maker to participate, "to the best of his or her ability," in the decision making

of giving consent to care may, by means of advance medical directives, specify whether or not they consent to care that may be required by their state of health, in the event they become incapable of giving consent"). See also art 2139 CCQ (care instructions are formally outlined in an "advance medical directive," which has a narrower statutory scope than mandates and do not include research; a court can override an advance medical directive on an application by a person or physician, if the court determines it does not reflect the maker's wishes).

173 NS *PDA*, *supra* note 93, ss 14(1), 15; NS *PDR*, *supra* note 93, s 6.

174 Ont *HCCA*, *supra* note 88, ss 20, 21; Ont *SDA*, *supra* note 91, s 66(4).

175 NWT *PDA*, *supra* note 125, s 15.

176 NWT *GTA*, *supra* note 135, ss 12(6), (7)(b), (8), (9), (10).

	4. Consult "from time to time" with supportive family members and friends
Saskatchewan (agent)[177]	1. Expressed wishes 2. Best interests
Saskatchewan (surrogate, ecclesiastical authority)[178]	1. If no clear instructions relating to treatment and if the maker has no proxy or guardian: a. expressed wishes b. best interests
C. Respect for current wishes prioritized	
Jurisdiction	**Priority of Considerations**
British Columbia (agent)[179]	1. Consult with the adult "to the extent reasonable," and comply with current wishes "if it is reasonable to do so" 2. Any instructions or wishes the adult expressed while capable 3. Values and beliefs 4. Best interests (condition, benefit/risk, and whether less restrictive treatment available) British Columbia also provides a non-standard advance directive, which can instruct a representative not to consider current wishes.[181]
British Columbia (surrogate)[180]	1. Consult with the adult "to the greatest extent possible" (though there is no suggestion they are required to follow current wishes) 2. Comply with any instructions or wishes the adult expressed while he or she was capable 3. Act in adult's best interests
Yukon (guardian)[182]	1. "Consult, to the extent reasonable, with the adult to determine their current wishes" and comply with those wishes if reasonable to do so, unless exempted by a court 2. Previously expressed wishes 3. Beliefs and values

177 Sask *HCDSHCDMA*, *supra* note 149, s 12.

178 *Ibid*, s 16.

179 BC *RAA*, *supra* note 86, s 16.

180 BC *HCCFA*, *supra* note 110, s 19.

181 See *ibid*.

182 Yk *DMSPAA*, *supra* note 146, s 44.

	4. Best interests
Yukon (agent)[183]	1. Consult "to the extent reasonable" to determine current wishes and comply with those 2. Instructions and wishes the adults expressed in directive 3. Beliefs and values 4. Best interests
Yukon (surrogate)[184]	1. Consult "to the extent reasonable" to determine current wishes and comply with those 2. Consult with "any friend or relative of the care recipient who asks to assist" 3. Consult with anyone who may reasonably have relevant information 4. Previously expressed wishes (with similar exceptions to Nova Scotia) 5. Beliefs and values (along with wishes that do not "clearly anticipate the specific circumstances") 6. Best interests (current wishes, condition, and well-being)

A. LAR decision-making standards for collection, use, and disclosure of personal information

Most personal information protection laws in Canada simply include a bare empowering provision enabling LARs to exercise any of the adult's rights over the collection, use, and disclosure of personal information.[185] Sometimes, the empowering provision specifies that rights must be exercised in relation to the authority of the LAR. Ontario, New Brunswick, and Nova Scotia each articulate a detailed standard for proxy decisions about personal information. These exceptions are described in Table 2.

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183 *Ibid*, s 23.

184 Yk *CCA*, *supra* note 149, ss 1–20.

185 See Archibald & Lemmens, *supra* note 82 at 162.

TABLE 2. LAR DECISION-MAKING STANDARDS (PERSONAL INFORMATION)

Statute	Decision-Making Standard
Ontario *Personal Health Information Protection Act*[186]	1. Wishes, values, and beliefs the adult held when capable, whether benefits outweigh risks, whether exercising the right is necessary to achieve the purpose or to satisfy a legal obligation (*no duty to consult the incapable adult or take into account his or her current wishes*)
New Brunswick *Personal Health Information Privacy and Access Act*[187]	1. Any written instruction in a directive 2. Wishes, values, and beliefs held when capable, whether benefits outweigh risks, whether exercising the right is necessary to achieve the purpose or to satisfy a legal obligation (*no priority is given to these considerations*)
Nova Scotia *Personal Health Information Act*[188]	1. Prior express requests 2. Values, beliefs, and other written or oral instructions 3. Best interests

B. Research ethics guidelines for LAR decision making

The TCPS also addresses ethical decision making by LARs. It contemplates the use of "research directives," defined as "[w]ritten instructions used to express an individual's preferences for participation in future research, in the event that the individual loses decision-making capacity" intended to guide the person's LAR.[189] The TCPS notes that the use of directives in the research context is not fully developed and their legal status is not yet recognized.[190] This section of the TCPS creates additional confusion over terminology, as it redefines an ethical concept (respect for previously expressed wishes) using a legal term (directive). The statement that research directives have no legal status is likely not correct in all jurisdictions. In some Canadian provinces (British Columbia, Québec, and Alberta), a directive could apply to research. The TCPS also insists that research directives be as specific as possible and that they be interpreted narrowly.[191] This may

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186 *Supra* note 136, s 24(1).

187 *Supra* note 136, s 26.

188 SNS 2010, c 41, s 22.

189 *TCPS2*, *supra* note 18 at 209 ("Glossary").

190 *Ibid* at 44.

191 *Ibid* at 46.

be in part to uphold a high standard of informed consent for research, but contradicts the legal guidance for LARs to follow broad wishes, values, and beliefs. The TCPS further states that "family members and friends may also provide information to the authorized third party about the interests and previous wishes of prospective participants."[192] If expressed wishes are unavailable, the TCPS instructs that the researcher "seeks and maintains consent" from the representative in accordance with the "best interests" of the represented adult.[193]

C. Formal instructions versus informal wishes

In some circumstances, LARs may find it difficult to resolve the tension in their decision-making process between the formal wishes of the represented person expressed through legally recognized advance directives and the expression of wishes, sometimes more recent ones, through informal documents and procedures with less authority (e.g., living will).

The *UNCRPD* emphasizes the "respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons."[194] The *UNCRPD* encourages the recognition of persons with disabilities as persons who should be at the center of decision making. It highlights the importance of providing support to persons with disabilities so that they can make their own decisions, and respect for advance instructions and wishes. But should instructions in an advance directive be given special status? On one hand, the formalities of advance directives provide reliable evidence of an individual's will and preferences. They safeguard against LARs substituting their own preferences for those of the adult. On the other hand, formalities discourage adults from expressing or updating their preferences. Advance directives may also fail to predict the context of future treatment or research decisions, raising concerns that instructions are not fully informed. In light of these weaknesses, jurisdictions give LARs interpretive wiggle room – to different degrees – where there are doubts about the clarity, applicability, or currency of instructions (see Table 1). From a legal standpoint, Canadian research LARs should generally first determine if research participation has been addressed in an advance directive. Unfortu-

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192 *Ibid* at 44 (art 3.9, "Application").

193 *Ibid* at 43 (art 3.9).

194 *Supra* note 56, art 3(1).

nately, advance directives do not commonly address research participation. Unless practices change, perhaps by introducing research participation onto standard advance directive forms, this important legal consideration will not be of much practical use to LARs.

D. Past versus current wishes

The *General Comment No. 1 on the CRPD* warns against the tyranny of previously expressed wishes. It proposes that persons should be entitled to respect for the "best interpretation of their rights, will, and preferences,"[195] and gives no clear priority to either previous or current wishes. The ethical tension between past and present wishes is highlighted by the Dworkin-Dresser debate. Dworkin proposes that a person's goals and life plans that are determined while the individual is capable constitute critical interests, while experiential interests relate to a state of the mind. He argues that critical interest decisions taken while the person has decision-making capacity should prevail over experiential interest wishes expressed when the individual has lost capacity.[196] In contrast, Dresser contends that people with dementia might remain cognizant of their experiential interests and retain some capacity to value their current activities and experiences.[197] In such cases, current experiences may primarily guide the best interpretation of their will and preferences.

This ethical tension is reflected in legal discrepancies across Canada (see Table 1). The majority of Canadian jurisdictions give priority to previously expressed wishes, while encouraging representatives to involve persons in decision making and consider current wishes. Other jurisdictions are more in line with the *General Comment No. 1*, which is critical of substitute consent and over emphasis of previously expressed wishes.[198] To address this uncertainty, research projects need clear protocols for when a capacity

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195 CRPD *General Comment*, *supra* note 58 at 5.

196 Ronald Dworkin, "Autonomy and the Demented Self" (1986) 64 Milbank Q 4 at 11. See also Marike E de Boer et al, "Advance Directives in Dementia: Issues of Validity and Effectiveness" (2010) 22:2 Int Psychogeriatr 201 at 204.

197 Rebecca Dresser, "Dworkin on Dementia: Elegant Theory, Questionable Policy" (1995) 25:6 Hastings Center Report 32 at 34–35. See also de Boer et al, *supra* note 196 at 204.

198 CRPD *General Comment*, *supra* note 58 at para 14.

assessment will be initiated (or re-initiated during a study), how capacity will be assessed, how researchers will seek assent from participants, how LARs will be encouraged to consult with participants, and what expressions or actions could qualify as an objection.

E. Applying the clinical "best interests" test in the research context

The legal "best interests" test applicable to health treatment decisions in the absence of instructions or wishes may also apply to research. This is problematic because LARs often lack guidance from instructions or wishes about research participation. First, the high standard of informed consent in the biomedical, and especially research, context raises questions about the applicability of past wishes. The unpredictable, complex, and rapidly evolving nature of research also makes it difficult for individuals to express informed preferences in advance. Second, few people currently express their wishes about research in advance directives, or otherwise. Most are already caught up trying to clarify their wishes about personal care and property. Standard forms do not typically direct people to fill out research preferences. Efforts by health care professionals or researchers to promote communication of wishes may be avoided for fear of provoking anxiety about worsening of symptoms. Third, adults with advanced dementia often cannot participate without practical support from their family members or carers. In the absence of instructions or wishes applicable to research, LARs are often left to apply a vague best interests test that is typically designed for treatment decisions.

Recall that research norms allow for the inclusion of adults with diminished capacity in research that does not offer a prospect of individual benefit. Does the legal "best interests" test, however, encompass benefit to others? Best interests are often equated with consideration for the individual's condition or well-being The best interests test is arguably an ethically weak basis for decision making in medical research for those lacking capacity as, while there may be a future benefit from the medical knowledge obtained, there may be no direct benefit to the participant.[199] Indeed, it has been suggested that health research "can never be primarily in a patient's

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[199] See JT Berger, "Is Best Interests a Relevant Decision Making Standard for Enrolling Non-Capacitated Subjects into Clinical Research?" (2011) 37:1 J Med Ethics 45 at 47–48.

best interests";[200] rather, it is intended to benefit both future persons and the common good.[201] However, as we have discussed throughout, enrolment of persons with diminished capacity in such research can be ethically grounded on societal benefits and the human right principles of a full and effective participation and non-discrimination in society, as well as an emerging ethics of inclusion in the context of data-intensive health research.

Mark Yarborough argues that the question of "[w]hen and how [we can] justifiably use cognitively impaired adults to benefit other people" remains largely unsettled.[202] There is a notable lack of consistency between research ethics norms, consent and capacity laws, research ethics board decisions, and presumably also LAR decisions. Arthur Derse and Ryan Spellecy suggest that the following safeguards be considered: "(1) the adult, while decisional, expressed or exhibited values of altruism, (2) the individual was not known to be unwilling to participate in research, and (3) there is documentation of these requirements by the LAR."[203]

An alternative approach could be to only include such persons in research if this would not be *against* their best interests.[204] In Alberta, for example, a trustee can make a gift out of the adult's property if it is not required to meet the needs of the adult or their dependants and there are "rea-

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200 Oonagh P Corrigan & Bryn Williams-Jones, "Consent Is Not Enough: Putting Incompetent Patients First in Clinical Trials" (2003) 361:9375 The Lancet 2096 at 2096.

201 See Berger, *supra* note 199 at 45.

202 "Inconsistent Approaches to Research Involving Cognitively Impaired Adults: Why the Broad View of Substituted Judgment Is Our Best Guide" (2015) 15:10 Am J Bioeth 66 at 66.

203 "Ethical and Regulatory Considerations Regarding Enrollment of Incompetent Adults in More Than Minimal Risk Research as Compared With Children" (2015) 15:10 Am J Bioeth 68 at 68.

204 See e.g. Ries, Thompson & Lowe, *supra* note 4 (in Australia, the province of Victoria's *Guardianship and Administration Act* (Vic), 1986/58, s 42(e) already incorporates this principle). See also Australia, National Health and Medical Research Council, "National Statement on Ethical Conduct in Human Research (2007)" (updated 2018) at 18, art 2.2.12, online: <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>.

sonable grounds to believe" the adult would make the gift.[205] On a practical level, LARs should not be left alone to wrestle with this legal uncertainty. Researchers should provide information and support to LARs about their ethical and legal obligations. To do so, the research community must engage with the difficult interpretative challenge of reconciling the tension between research ethics norms and consent and capacity laws. Multi-jurisdictional research projects, like the one in our case study below, also need to establish guidance and consent processes that handle discrepancies in the definition of best interests across jurisdictions.

Our primary aim in this paper was to provide an overview of legal principles applicable to consent to data-intensive research involving persons with diminished capacity. We have seen that there is considerable uncertainty both over what legal rules *do* apply to consent and capacity in data-intensive research, and over what rules *should* apply. We do not propose an overhaul of Canadian law. Instead, we have indicated our preferences for certain provincial legislative approaches over others and we have highlighted the value of working towards harmonized regulatory and research governance approaches across the country.

IV. Case Study: The Canadian Longitudinal Study on Aging

Against this legislative and policy backdrop, we now consider the efforts of the Canadian Longitudinal Study on Aging (CLSA) to establish a governance framework for a Canada-wide, data-intensive research platform. The CLSA recruited more than 50,000 participants aged 45 to 85 years old who will be followed until 2033 or death.[206] 20,000 will participate in a telephone interview protocol and 30,000 will undergo in-home interviews, physical examinations, and biological specimen collection. The overall goal is to "improve the health and quality of life of Canadians by better understanding the processes and dimensions of aging."[207] Considering participants' age and the duration of the study, it can be expected that a significant proportion will lose the capacity to consent or will die in the course of the study.

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205 Alta *AGTA*, *supra* note 106, s 60(2).

206 See Canadian Longitudinal Study on Aging, "About Us", online: <www.clsa-elcv.ca/about-us>.

207 Canadian Longitudinal Study on Aging, "CLSA Scientific Executive Summary (2015)" at 2, online: <https://clsa-elcv.ca/doc/1090>.

The CLSA employs an innovative advance planning approach. Starting at age 70, the CLSA asks participants upon re-contact to name a proxy to make study-related decisions on their behalf if they lose capacity.[208] If participants have already designated "a person to look after [their] affairs,"[209] they are encouraged to name that person as proxy. Proxies are informed that acceptance of the role is voluntary.[210] Participants can also specify the aspects of the study they wish to continue participating in (data collection, physical measurements, and/or donations of specimens). The biobank communicates these wishes to the proxy when he or she is first contacted. Similar to advance directives, the biobank consent process enables participants to designate a representative to make decisions on their behalf and to articulate their preferences about the extent of their future participation. These preferences are then communicated to and carried out by the proxy. This advance planning approach supports the precedent autonomy of participants. It also provides a practical mechanism for identifying a representative if a participant loses capacity.

The CLSA's approach appears to be bespoke. The Canadian Tissue Repository Network has not addressed this issue in its standards and we were unable to identify any other Canadian research biobanks or databanks that have integrated advance planning for incapacity into their consent process.[211] One limitation of using the CLSA as a general consent model is that it begins with a community dwelling cohort with or without cognitive impairment at baseline. Only those able to provide informed consent at recruitment are eligible to participate. Disease-specific biobanks recruiting persons with diminished capacity will need to confront the difficult challenge of determining who (if anyone) can legally provide the original consent to sample and data collection. Tissue laws or tissue-specific provisions may prohibit or restrict proxy consent to tissue removal for research (e.g., require an explicit authorization in an advance directive). Moreover, even

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208 See Canadian Longitudinal Study on Aging, "Combined Protocol" at 53–54, online: <https://clsa-elcv.ca/doc/511> [CLSA, "Combined Protocol"].

209 Canadian Longitudinal Study on Aging, "Participant Information Package for Proxy Decision Maker and Proxy Information Provider Contact" at 1, online: <www.clsa-elcv.ca/doc/416>.

210 See Canadian Longitudinal Study on Aging, "Consent Form for Proxy Decision Maker" at 3, online: <www.clsa-elcv.ca/doc/1275>.

211 See Canadian Tissue Repository Network, "Standard Operating Procedures" (2017), online: <www.ctrnet.ca/resources/operating-procedures>.

if an LAR is available, they will not have the benefit of being guided by an original consent.

Where proxies are not appointed, cannot be contacted, or are unable or refuse to be involved, the question of durable consent arises. Should participants be able to give consent that endures beyond a loss of capacity? In such cases, the CLSA protocol states that samples and data already collected will continue to be used.[212] On one hand, ongoing transparency and the ability to withdraw are considered key to the legitimacy of a broad consent.[213] On the other hand, the legal and practical challenges of finding a representative could seriously undermine the long-term value of a biobank. Moreover, advance planning is considered an important decision-making support in other areas of life. Many biobanks tacitly presume that sharing and use of samples and data will continue beyond a loss of capacity. Especially where biobanks have no ongoing contact with participants, it is impracticable to maintain an up-to-date knowledge of every participant's capacity. To improve the legitimacy of durable consent, biobanks could be explicit in the original consent that samples will continue to be used after a loss of capacity. Additionally, individuals could be offered choices about what they want or do not want to happen with their samples and data, should they lose capacity.

Biobanks may also encounter the issue of "family override": should a family member be able to withdraw consent to ongoing use of samples and data on behalf of an adult who lacks capacity? What about an informally appointed proxy? Or an LAR? One approach may be to consider broad consent as an "advance directive" to future uses of data. Under an advance consent paradigm, the biobank directly carries out the legally binding instructions of the participant. Family members or representatives have no say in the matter. It is not clear, however, that biobanks in Canada would have a legal basis to refuse to respect withdrawal requests from LARs. As a practical matter, they may also be unwilling to contest withdrawal requests from family members, even if the family member has no clear legal authority. Indeed, health care professionals often let family members "illegally" override informed consents to organ donation.[214] An ethical issue with an

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212 CLSA, "Combined Protocol", *supra* note 208 at 54.

213 See Jorge L Contreras & Bartha M Knoppers, "The Genomic Commons" 19 Annu Rev Genomics Hum Genet 14 [forthcoming in 2018].

214 See Samantha J Anthony et al, "Family Veto in Organ Donation in Canada: Framing within English-Language Newspaper Articles" (2017) 5:4 CMAJ Open E768 at E770.

advanced consent approach is that the biobank essentially acts as the proxy decision maker. Beyond the original consent, the preferences, values, and beliefs of the person are largely unknown to the biobank. Biobanks also prioritize maximizing access to and use of samples and data. They may face a conflict of interest if also required to be the representative of participants' welfare.

While many biobanks provide participants with a mechanism to withdraw consent to future sharing and use, few biobanks have considered or developed policies for handling withdrawal requests from LARs. Withdrawal processes should ideally specify how to determine that the participant has indeed lost capacity and, if so, who may (legally) act as a proxy. Family members may mistakenly believe that they have rights over the adult's samples and data (as is the case with organ donation), when in fact another individual has been legally appointed to exercise such decisions through an advance directive or court order. In the context of withdrawal, the biobank should also encourage the proxy to follow the applicable decision-making standard. Legally, or at least ethically, proxies should respect the known wishes of the person. The original consent is evidence of the person's wish to participate. Biobanks might even consider requiring a proxy to produce evidence of more recent, contrary wishes before allowing withdrawal, although taking on such an arbitration role may require extensive resources and resolve. Finally, proxies should also be encouraged to consider other factors when requesting withdrawal, such as the person's values, beliefs, and welfare, and should be encouraged to consult with the adult. All of these procedures must be carried out without breaching the privacy of the participant.

Legal uncertainty and variation complicates questions of durable consent and proxy withdrawal. It is uncertain if the CLSA's process for appointing an informal representative aligns with the law in all Canadian provinces and territories. If health care consent and capacity laws apply (as they might in British Columbia and Québec), these laws would seem to preclude an informal designation process. The proxy designated in the consent would only have authority if they were also the LAR (e.g., agent appointed by an advance directive). Order of priority may need to be respected. If only personal information protection laws apply, a person with "written authorization" is legally authorized to exercise rights relating to personal information in most, but not all, provinces. Again, other LARs (agents or guardians) may still have priority. The challenge is even greater for pan-Canadian biobanks like the CLSA, which must contend with multiple, discrepant frameworks.

Indeed, as the CLSA's protocol notes, "the requirements for a proxy for research purposes may differ by province."[215]

Others have considered ethical issues concerning the return of individual genomic results to relatives of incapable adults participating in biobanks or research studies. Wolf et al recommend that representatives respect the participant's expressed preferences about sharing their data with family members.[216] In the absence of preferences, they should weigh the individual's privacy interest with the family member's health interest.[217] Biobanks handling withdrawal or return of results should also be sensitive to potential conflicts of interest.[218] Genetic data, for example, may have privacy or health implications for family members.[219] Biological family members may seek to withdraw consent on behalf of an adult who has lost capacity over concerns for their own privacy. Family members may also *insist* on an adult's participation with the hopes that analysis will reveal important insights about their own health, or even to investigate paternity. An analogous clinical situation is genetic testing on an adult who lacks capacity to inform a family member's health risk. Clinicians may object to such testing if it is not in the adult's best interests.

Conclusion

We have identified a number of coordination failures between health research regulations and consent and capacity laws in Canada. Human rights and health research norms call for the inclusion of adults with diminished capacity in research, on their own terms, to ensure vulnerable populations share in improvements to health care. Yet provincial and territorial laws

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215 CLSA, "Combined Protocol", *supra* note 208 at 54.

216 See e.g. Susan M Wolf et al, "Returning a Research Participant's Genomic Results to Relatives: Analysis and Recommendations" (2015) 43:3 J Law Med Ethics 440, 448.

217 See *ibid* at 448.

218 See *ibid* at 451; Thorogood, Deschênes St-Pierre & Knoppers, *supra* note 8 at 18.

219 See Søren Holm, "Me, Myself, I: Against Narcissism in the Governance of Genetic Information" in Heather Widdows & Caroline Mullen, eds, *The Governance of Genetic Information* (Cambridge: Cambridge University Press, 2009) 37.

often restrict or obscure *who* may consent to ethically sound research. They also require LARs to consider treatment-centric "best interests" criteria that apply awkwardly to research, especially data-driven research. Legal and practical difficulties finding representatives who are authorized or willing to provide consent hinder research that advances the prevention, detection, and treatment of dementia. Following the lead of other jurisdictions, Canadian provinces and territories should expand, or at least clarify, who may act as a representative for adults who lack the capacity to make research-related decisions.

Data-intensive research promises to accelerate research with little risk to individual privacy, if accompanied by appropriate oversight. Most provinces and territories, however, equate research with human experimentation and in turn impose strict limits on non-therapeutic research or tissue removal for research purposes. Only a handful of jurisdictions provide clear statutory authorization for data-intensive research. Operating in a legal grey zone, dementia researchers and research biobanks must establish consent and governance processes that draw on the legal and human rights principles surveyed in this article. The principle of advance planning lends support for durable consent models, where consent to future storage and use continues to be respected after a loss of capacity. The principle of respect for past wishes points to the need for safeguards to limit when family members or other representatives can withdraw consent given by a person before a loss of capacity. When handling samples and data from persons with dementia, researchers must always seek to balance their tri-partite obligations: to protect, to include, and to involve individuals in decisions about their participation.

Appendix I. Consent and Capacity Statutes in Canada

British Columbia

- *Representation Agreement Act*, RSBC 1996, c 405 [BC *RAA*]
- *Health Care (Consent) and Care Facility (Admission) Act*, RSBC 1996, c 181 [BC *HCCFA*]
- *Power of Attorney Act*, RSBC 1996, c 370 [BC *PAA*]

Alberta

- *Personal Directives Act*, RSA 2000, c P-6 [Alta *PDA*]
- *Adult Guardianship and Trusteeship Act*, SA 2008, c A-42 [Alta *AGTA*]
- *Adult Guardianship and Trusteeship Regulation*, Alta Reg 219/2009 [Alta *AGTR*]

Saskatchewan

- *The Health Care Directives and Substitute Health Care Decision Makers Act*, SS 2015, c H-0002 [Sask *HCDSHCDMA*]
- *The Health Care Directives and Substitute Health Care Decision Makers Regulations*, 2017, RRS c H-0002 Reg 1 [Sask *HCDSHCDMR*]

Manitoba

- *The Health Care Directives Act*, 1993 CCSM c H27 [Man *HCDA*]
- *Mental Health Act*, 2014 CCSM c M110 [Man *MHA*]

Ontario

- *Health Care Consent Act*, SO 1996, c 2, Sch A [Ont *HCCA*]
- *Substitute Decisions Act*, SO 1992, c 30 [Ont *SDA*]
- *Consent to Treatment Act*, SO 1992, c 31 [Ont *CTA*]

Québec

- *Civil Code of Québec*
- *Act respecting end-of-life care, RSQ 2016, c S-320001* [Qc ARELC]

New Brunswick

- *Advance Health Care Directives Act*, SNB 2016, c 46 [NB *AHCDA*]
- *Infirm Persons Act*, RSNB 1973, c I-8 [NB *IPA*]
- *Personal Health Information Privacy and Access Act*, SNB 2009, c P-705 [NB *PHIPAA*]
- *Mental Health Act*, RSNB 1973, c M-10 [NB *MHA*]
- *Nursing Homes Act*, SNB 1982, c N-11 [NB *NHA*]

Prince Edward Island

- *Consent to Treatment and Health Care Directives Act*, RSPEI 1988, c C-172 [PEI *CTHCDA*]
- *General Regulations*, 2010, PEI Reg EC356/00 [PEI *GR*]

Nova Scotia

- *Personal Directives Act*, SNS 2008, c 8 [NS *PDA*]
- *Personal Directives Regulations*, NS Reg 31/2010 [NS *PDR*]

Newfoundland & Labrador

- *Advance Health Care Directives Act*, SNL 1995, c A-41 [NL *AHCDA*]

Yukon

- *Decision-Making Support and Protection to Adults Act*, SY 2003, c 21 [Yk *DMSPAA*]
- *Care Consent Act*, SY 2003, c 21 [Yk *CCA*]

Northwest Territories

- *Personal Directives Act*, SNWT 2005, c 16 [NWT *PDA*]
- *Guardianship and Trusteeship Act*, SNWT 1994, c 29 [NWT *GTA*]

Nunavut

- *Personal Directives Act*, SNWT 2005, c 16, s 13(2)(d), as duplicated for Nunavut by s 29 of the *Nunavut Act*, SC 1993, c 28 [NWT *PDA*]
- *Guardianship and Trusteeship Act*, SNWT 1994, c 29, as duplicated for Nunavut by s 29 of the *Nunavut Act*, SC 1993, c 28 [NWT *GTA*]

Appendix II. National, Regional, and International Research Regulations

National Regulation

- *Federal Policy for the Protection of Human Subjects*, 82 Fed Reg 7149 (2017) (to be codified at 6 CFR Part 46)

Regional Regulations

- Alzheimer Europe, "Informed Consent to Dementia Research" (29 March 2012), online: <www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2011-Ethics-of-dementia-research/Informed-consent-to-dementia-research?#fragment1>
- Council of Europe, Committee of Ministers, *Principles Concerning the Legal Protection of Incapable Adults, Recommendation* (99)4, (1999)
- Council of Europe, *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*, 4 April 1997, ETS 164, arts 6(3), 17
- Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms*, ETS 005 (1950), arts 5, 8
- EC, *Regulation 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use*, *and repealing Directive 2001/20*, [2014] OJ L 158/1
- EC, *Regulation 679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*, [2016] OJ L 119/1
- OECD, *Addressing Dementia: The OECD Response*, OECD Health Policy Series, (Paris: OECD, 2015)
- OECD, "*Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Sata"*, Annex of the *Recommendation of the Council Concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data* (C(80)58/FINAL, as amended on 11 July 2013 by C(2013)79) (2013), online: <www.oecd.org/sti/ieconomy/2013-oecd-privacy-guidelines.pdf>

- OECD, *Recommendation of the OECD Council on Health Data Governance*: *The Next Generation of Health Reforms* (OECD Health Ministerial Meeting: January 2017), online: <www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf>

International Regulations

- *Convention on the Rights of Persons with Disabilities*, 13 December 2006, 2515 UNTS 3, art 1 (entered into force 3 May 2008)
- Council for International Organizations of Medical Sciences & World Health Organization, *International Ethical Guidelines for Health-Related Research Involving Humans*, (Geneva: CIOMS, 2016)
- Global Alliance for Genomics & Health, "Consent Policy" (27 May 2015), online: <www.ga4gh.org/wp-content/uploads/Consent-Policy-Final-27-May-2015.pdf>
- Global Alliance for Genomics & Health, "Framework for Responsible Sharing of Genomic and Health-Related Data" (9 December 2014), Preamble, online: <www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/>
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, *Guideline on Genomic Sampling and Management of Genomic Data, E18*, Current Step 4 Version (3 August 2017)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline for Good Clinical Practice E6(R1),* Current Step 4 Version (10 June 1996)
- *International Covenant on Civil and Political Rights*, 19 December 1966, 999 UNTS 171 arts 9, 17 (entered into force 23 March 1976)
- *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 UNTS 3, art 15(1)(b) (entered into force 3 January 1976)
- *Universal Declaration of Human Rights*, GA Res 217A (III), UNGAOR, 3rd Sess, Supp No 13, UN Doc A/810 (1948) 71
- *Universal Declaration on Bioethics and Human Rights*, GA Res 24, UNESCOR, 33rd Sess (2005) 74
- *Universal Declaration on the Human Genome and Human Rights*, UNESCO General Conference, 29th Sess, 11 November 1997 (endorsed by GA Res 152, UNGAOR, 53rd Sess, UN Doc A/53/625/Add 2 (1998))

- *United Nations Principles for Older Persons*, GA Res 46/91, UNGAOR, 46th Sess, Supp No 49 (1991) 160
- World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 18th WMA General Assembly, June 1964, amended by the 64th WMA General Assembly, October 2013