THE RIGHT TO CONTROL AND ACCESS GENETIC RESEARCH INFORMATION: DOES *MCINERNEY* OFFER A WAY OUT OF THE CONSENT/WITHDRAWAL CONUNDRUM?

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I. INTRODUCTION

A highly contentious policy challenge facing genetic and cell-based research today relates to whether individuals who donate biological materials for research purposes can withdraw consent to the use of their donations at any stage in the research lifecycle.[1] Debate on this issue has generally been approached from the perspective of consent law. Proponents of traditional

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1 See generally Stefan Eriksson & Gert Helgesson, "Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research" (2005) 13:9 European Journal of Human Genetics 1071; Kristina Hug, Göran Hermerén & Mats Johansson, "Withdrawal from Biobank Research: Considerations and the Way Forward" (2012) 8:4 Stem Cell Reviews and Reports 1056.

or established consent norms argue that the right to withdraw consent at any time and for any reason is legally and ethically required and appropriate.[2] Challengers contend that unrestricted withdrawal would disrupt research activities and impose significant financial burdens on the research enterprise.[3] This debate reflects broader policy questions concerning the nature of the legal interest in and rights of control over human biological materials, as well as tensions between vital public interests in protecting research participants and facilitating beneficial, cutting-edge biomedical research.

As investment and interest in the storage and use of tissues for research continue to grow,[4] resolving the withdrawal dilemma has become a pressing issue. But while the consent debate has generated significant academic and policy reflection[5] (and in some cases, policies favouring a limited right of withdrawal),[6] consensus, or at a minimum, a widely accepted policy

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2 See Timothy Caulfield et al, "Research Ethics Recommendations for Whole-Genome Research: Consensus Statement" (2008) 6:3 PLoS Biology 0430 at 0432 [Caulfield et al, "Research Ethics"]; Gert Helgesson & Linus Johnsson, "The Right to Withdraw Consent to Research on Biobank Samples" (2005) 8:3 Medicine, Health Care and Philosophy 315 at 318–321.

3 Søren Holm, "Withdrawing from Research: A Rethink in the Context of Research Biobanks" (2011) 19:3 Health Care Analysis 269 at 276–77.

4 See "Everyone 'to be research patient', says David Cameron", *BBC News* (5 December 2011), online: <http://www.bbc.co.uk/news/uk-16026827>; Ian Sample, "UK Biobank puts medical records of half a million Britons online", *The Guardian* (30 March 2012), online: <http://www.guardian.co.uk/science/2012/mar/30/uk-biobank-medical- records-britons-online>; Jamie Doward, "Plans for NHS database of patients' DNA angers privacy campaigners", *The Guardian* (8 December 2012), online: <http://www.guardian.co.uk/science/2012/mar/30/uk-biobank-medical-records-britons-online>.

5 See Margaret FA Otlowski, "Tackling Legal Challenges Posed by Population Biobanks: Reconceptualising Consent Requirements" (2012) 20:2 Medical Law Review 191; B Hofmann, "Broadening Consent—and Diluting Ethics?" (2009) 35:2 Journal of Medical Ethics 125; Jane Kaye & Mark Stranger, eds, *Principles and Practice in Biobank Governance* (Farnham, UK: Ashgate, 2009).

6 See Timothy Caulfield, Ubaka Ogbogu & Rosario M Isasi, "Informed Consent in Embryonic Stem Cell Research: Are We Following Basic Principles?" (2007) 176:12 Canadian Medical Association Journal 1722 at 1723; *Assisted Human Reproduction (Section 8 Consent) Regulations*, SOR/2007-137, s 14(2)(e)(iii).

framework, remains elusive.[7] At the same time, recent empirical studies suggest public preference for meaningful and ongoing control of tissues donated to research, including an ongoing right of withdrawal.[8] In light of the latter trend, the continuing search for answers in the consent debate might well have obscured reflection on other relevant legal interests that allow tissue donors to exercise effective control, such as rights of privacy and access to health information.

Indeed, challenging privacy and access to information issues have emerged in relation to the collection and use of human tissue for genetic and cell-based research.[9] These include technological innovations that make it increasingly possible to uncover or extract "a great deal of hidden personal information of an intimate nature"[10] directly from human biological

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7 See Zubin Master et al, "Biobanks, Consent and Claims of Consensus" (2012) 9:9 Nature Methods 885 at 885. While consensus "facilitate[s] policy development", it is not necessary (or, in some cases, even desirable) for policymaking, especially where rights claims are involved.

8 See Timothy Caulfield, Christen Rachul & Erin Nelson, "Biobanking, Consent, and Control: A Survey of Albertans on Key Research Ethics Issues" (2012) 10:5 Biopreservation and Biobanking 433 at 434–35; Juli Murphy et al, "Public Perspectives on Informed Consent for Biobanking" (2009) 99:12 American Journal of Public Health 2128.

9 See Trudo Lemmens & Lisa Austin, "The End of Individual Control Over Health Information: Promoting Fair Information Practices and the Governance of Biobank Research" in Kaye & Stranger, *supra* note 5 at 243–66. In this article, references to genetic and cell-based research are limited to studies involving uses of human biological materials or derivatives that are genetically linked to an identifiable individual. For instance, induced pluripotent stem cells are presently considered to be genetically linked to the individual from whom the altered somatic cell was derived. Marina V Pryzhkova, "Stem Cells: Will They Ever Be the Same?" (2013) 8:2 Regenerative Medicine 97; Alexej Abyzov et al, "Somatic Copy Number Mosaicism in Human Skin Revealed by Induced Pluripotent Stem Cells" (2012), online: Nature <http://www.nature.com/nature/ journal/vaop/ncurrent/full/nature11629.html>. Therefore, research on induced pluripotent stem cells raises privacy issues that are within the scope of this paper.

10 Jessica Wright et al, "Regulating Tissue Research: Do We Need Additional Rules to Protect Research Participants?" (2010) 17:5 European Journal of Health Law 455 at 457.

materials,[11] and policies that truncate individuals' rights of access to and control over the research use and disclosure of sensitive genetic information; for example, broad consent rules, and limitations on the individual's right to withdraw consent to the use of his or her biological material for research purposes.[12] To date, Canadian privacy and access to information statutes have not directly addressed these concerns.

In this brief commentary, we explore whether Canadian jurisprudence provides any guidance on the nature and scope of an individual's legal right to access, and control the use and disclosure of, information derived from human biological materials donated for research purposes. Specifically, we rely on the Supreme Court of Canada's seminal decision in *McInerney v MacDonald*[13] to argue that Canadian case law, in the absence of directly applicable statutory rules, embraces a robust and ongoing right of access to and control over genetic information that is grounded in the nature and character of genetic information, personal autonomy, and fiduciary law. We contend further that this right of access and control includes a meaningful and enduring right to withdraw consent to research use of biological materials and associated genetic information. We chose to focus on *McInerney* because, though decided in 1992, the principles established in the decision remain prevalent, and have been codified in access-to-information statutes throughout Canada.

II. *MCINERNEY* AND THE ENDURING RIGHT OF ACCESS AND CONTROL

McInerney is a leading Canadian Supreme Court decision that sets out the nature and scope of common-law rights of access to health information. While the case deals with issues that emerged in the clinical context, the Court's pronouncements reflect principles of general application in relation to health information.

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[11] See Zhen Lin, Art B Owen & Russ B Altman, "Genomic Research and Human Subject Privacy", *Science* 305:5681 (9 July 2004) 183; William W Lowrance & Francis S Collins, "Identifiability in Genomic Research", *Science* 317:5838 (3 August 2007) 600.

[12] See Caulfield et al, "Research Ethics", *supra* note 2; Helgesson & Johnsson, *supra* note 2.

[13] [1992] 2 SCR 138, 93 DLR (4th) 415 [*McInerney* cited to SCR].

The facts of the case are straightforward: Mrs. MacDonald requested a copy of her medical records from her physician, Dr. McInerney, who provided copies of all notes she had made during the course of Mrs. MacDonald's treatment, but refused to provide reports received from other physicians because it would be unethical for her to release them.[14] Mrs. MacDonald sought a court order to compel Dr. McInerney to produce a copy of her entire medical record.[15] At the time of trial, New Brunswick, where the case arose, had no legislation governing access to health information.[16] The trial judge granted the order on the basis that the patient possesses a proprietary interest over health information in a physician's custody, and is therefore entitled to a right of access to this information upon request.[17]

Dr. McInerney appealed the decision to the New Brunswick Court of Appeal, which upheld the order, but for different reasons. The majority of the Court found that the issue was not one of ownership, but rather whether a patient has a right to access his or her medical record.[18] In the majority's view, this right of access is grounded in the contractual relationship between physician and patient, which gives rise to an implied

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14 See *ibid* at 142; Elaine Gibson, "Health Information: Confidentiality and Access" in Jocelyn Downie, Timothy Caulfield & Coleen Flood, eds, *Canadian Health Law and Policy*, 4d ed (Toronto: Lexis Nexis Canada, 2007) 253 at 256–58.

15 See *McInerney*, *supra* note 13 at 142; Gibson, *ibid* at 256-57.

16 See *McInerney*, *supra* note 13 at 143. The right of patients to access their health information is now codified by legislation in every province in Canada. See *Health Information Act*, RSA 2000, c H-5, s 7(1); *E-Health (Personal Health Information Access and Protection of Privacy) Act*, SBC 2008, c 38, s 18(1)(d); *Personal Health Information Act*, CCSM c P33.5, s 5(1); *Personal Health Information Privacy and Access Act*, SNB 2009, c P-7.05, s 7(1); *Personal Health Information Act*, SNL 2008, c P-7.01, s 52(1); *Personal Health Information Protection Act, 2004*, SO 2004, c 3, Schedule A, s 52(1); *An Act Respecting Health Services and Social Services*, RSQ, c S-4.2, s 17; *The Health Information Protection Act*, SS 1999, c H-0.021, ss 12, 32; *Freedom of Information and Protection of Privacy Act*, RSPEI 1988, c F-15.01, s 6(1); *Personal Health Information Act*, SNS 2010, c 41, s 71.

17 See Gibson, *supra* note 14 at 257; *McInerney*, *supra* note 13 at 143.

18 See *McInerney v MacDonald* (1990), 103 NBR (2d) 423, 66 DLR (4th) 736 at 738 (NB CA) [*McInerney 1990*]. See also Gibson, *supra* note 14.

term that a patient has a right to access information in his or her record if it "relates in any way to the treatment or advice provided by the physician to the patient".[19]

A further appeal to the Supreme Court of Canada was also unsuccessful. However, the Court unanimously rejected both the proprietary and contractual reasoning of the lower courts.[20] Confirming that the patient does have a right to access her medical records, the Court based its decision on two elements, namely the nature of the information in "medical records" and the fiduciary relationship between the physician and patient. On the first element, the Court stated:

> [M]edical records contain information about the patient revealed by the patient, and information that is acquired and recorded on behalf of the patient. Of primary significance is the fact that the records consist of information that is highly private and personal to the individual. It is information that goes to the personal integrity and autonomy of the patient.... [S]uch information remains in a fundamental sense one's own, for the individual to *communicate or retain* as he or she sees fit .... [I]nformation about oneself revealed to a doctor acting in a professional capacity remains, in a fundamental sense, one's own.[21]

Having found that a patient possesses a "vital interest"[22] in his or her health information by virtue of its "highly private and personal"[23] nature, the Court concluded that individuals have a "continuing interest in what happens to this information, and in controlling access to it".[24] According to the Court, personal health information relates to "sensitive [and] ... personal aspects of [an individual's] life",[25] and as such, individuals should have ongoing control and access to such information, even after it is shared with others. Regarding the second element, the Court held that, subject to

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19 *McInerney 1990, supra* note 18 at 744. Rice JA, dissenting (held that Mrs. MacDonald had no right to obtain the record: *ibid* at 739–40).

20 Gibson, *supra* note 14 at 257.

21 *McInerney, supra* note 13 at 148, 150 [emphasis added].

22 *Ibid* at 146.

23 *Ibid* at 148.

24 *Ibid.*

25 *Ibid.*

rare exceptions,[26] the physician had a fiduciary obligation to disclose the information requested because it was entrusted to a physician by the patient in the context of a relationship of "trust and confidence".[27]

In our view, the Court's strong endorsement of the character of, and interests in, personal health information disclosed during the clinical encounter applies with equal force to genetic information, even if it is contained in a cell line or tissue sample. Genetic information, like clinical-care information, is "in a fundamental sense, one's own"[28] as well as "highly private and personal to the individual."[29] It seems very unlikely that the Court's view would be different if genetic information were implicated in the case, especially in light of the fact that many, including a significant percentage of the general public,[30] view genetic information as being particularly sensitive.[31] Genetic information is also viewed as being relevant not only to the research participant, but to his or her biologically related kin.

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26 *Ibid* at 158 (chiefly, where there is "significant likelihood of a substantial adverse effect on the physical, mental or emotional health of the patient or harm to a third party").

27 *Ibid* at 154.

28 *Ibid* at 150.

29 *Ibid* at 148.

30 See Pollara Research & Earnscliffe Research and Communications, "Public Opinion Research into Genetic Privacy Issues", Presented to the Biotechnology Assistant Deputy Minister Coordinating Committee, Government of Canada (March 2003), online: <http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/industry_canada/2002/2002-513/index.html> at 9 (58% of respondents surveyed expressed the view that genetic information should receive heightened protection); David J Kaufman et al, "Public Opinion about the Importance of Privacy in Biobank Research" (2009) 85:5 American Journal of Human Genetics 643 at 649 (15% of surveyed Americans agreed that genetic test results warranted extra privacy protections).

31 The view that genetic information is unique or exceptional is contested in the literature. See e.g. Ken M Gatter, "Genetic Information and the Importance of Context: Implications for the Social Meaning of Genetic Information and Individual Identity" (2003) 47:2 St Louis U LJ 423; Péter Kakuk, "Genetic Information in the Age of Genohype" (2006) 9:3 Medicine, Health Care & Philosophy 325; Mark A Rothstein, "Genetic Exceptionalism and Legislative Pragmatism" (2007) 35:2, Supplement 2, JL Med & Ethics 59.

Indeed, the Supreme Court has expressed the view that there is "undoubtedly the highest level of personal and private information contained in an individual's DNA."[32] It follows therefore that the donors of biological materials will likely be viewed as having a similar "vital interest" in the genetic information derived from their materials, and, as outlined in *McInerney*, should, subject to a limited number of exceptions, be able to exercise any rights of access or control flowing from it. There seems no logical reason this conclusion should be altered by the mere fact that the health information is contained within a cell or a tissue sample. As a side note, this conclusion also suggests that donors may be legally entitled to request return of any incidental findings from research on donated materials, or even return of the research results—two issues which have generated considerable policy debate and attention.[33]

There is of course one important distinction between the clinical and research contexts. In the former, a patient provides personal health information in order to receive medical treatment, which is not the case for research projects that rely on donations of human biological materials. Indeed, research participants are specifically informed that they will not receive any direct benefits from their involvement at the time of consent.[34] Regardless, as *McInerney* makes clear, it is the sensitive nature of health information that informs an individual's "vital interest" in it, not the context of care or involvement. Thus, it would seem that individuals hold a vital interest in their biological materials and genetic information,

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32 *R v SAB*, 2003 SCC 60 at para 48, [2003] 2 SCR 678; See further *R v Dyment*, [1988] 2 SCR 417 at 429, 55 DLR (4th) 503.

33 Kristien Hens et al, "The Return of Individual Research Findings in Paediatric Genetic Research" (2011) 37:3 Journal of Medical Ethics 179; Susan M Wolf et al, "Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets" (2012) 14:4 Genetics in Medicine 361; Gina Johnson, Frances Lawrenz & Mao Thao, "An Empirical Examination of the Management of Return of Individual Research Results and Incidental Findings in Genomic Biobanks" (2012) 14:4 Genetics in Medicine 444; Jasper Bovenberg et al, "Biobank Research: Reporting Results to Individual Participants" (2009) 16:3 European Journal of Health Law 229.

34 Julie A Burger, "What is Owed Participants in Biotechnology Research" (2009) 84:1 Chicago-Kent L Rev 55 at 60; Donna M Gitter, "Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material" (2004) 61:1 Wash & Lee L Rev 257 at 284.

regardless of whether it is donated or disclosed for research purposes or in clinical settings. However, context does matter in determining whether, similar to the physician–patient relationship, the relationship between the researcher and donor/participant[35] gives rise to a fiduciary obligation to facilitate donor access to, and control over, information derived from donations of human biological materials. This claim is addressed fully in the next section of this paper.

The Court's ruling also suggests a clear distinction between medical records and the information contained therein. While the Court refused to endorse the view that patients have a proprietary interest in either their medical records or the information contained in the records,[36] it held that the "physician, institution or clinic compiling the medical records owns the physical records."[37] This view implies that ownership of the physical records is vested in the person who created or compiled them. But what happens when the physical record in question is biological material? Is human biological material, which contains "personal and private" genetic information about an individual, analogous to physical medical records, and, if yes, who owns the "records"? While it is not certain whether the Court's view of physical medical records can be applied to human biological materials, the ruling does make clear that medical records, in physical form, constitute property.

This conclusion leads to two related observations. First, if a researcher alters biological material or invents a new biological product from it—as often happens in, for example, the derivation of induced pluripotent stem cells from human tissue[38]—one could argue that the researcher has a property-like interest in the altered material or invention. But an

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35 Both terms are used interchangeably throughout.

36 *McInerney*, supra note 13 at 151–52.

37 *Ibid* at 146.

38 Induced pluripotent stem cells are created by using genes to reprogram adult non-pluripotent cells. The resulting cells have characteristics similar to pluripotent stem cells such as embryonic stem cells. See generally Kazutoshi Takahashi & Shinya Yamanaka, "Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors" (2006) 126:4 Cell 663; Gaoyang Liang & Yi Zhang, "Embryonic Stem Cell and Induced Pluripotent Stem Cell: An Epigenetic Perspective" (2013) 23:1 Cell Research 49.

application of the principles set out in *McInerney* would suggest that the donor retains a right of control over his or her health information (i.e., the genetic information) within the altered material or invention. Given that this information cannot be separated from the material or invention, the question arises as to whose interests should prevail: the researcher's "property-like interest" in the alteration or invention, or the donor's "vital interest" in the genetic information contained in the end product? The Supreme Court's reasoning in *McInerney*, current research ethics guidelines,[39] and judicial opinion in influential US cases such as *Moore v the Regents of the University of California*[40] and *Washington University v Catalona*,[41] suggest that the donor's interest ought to prevail, at least with respect to certain privacy and autonomy-based rights and interests.

By way of example, in *Moore*, the California Supreme Court held that, although a patient has no ownership interest in tissue removed from the human body under California law, there "may be ... some limited right to control the use of excised cells",[42] including the right to be informed of, and to refuse consent (for privacy and other reasons) to, future research uses of the excised cells.[43] Similarly, in *Catalona*, a US Court of Appeal held that, although patients do not retain an ownership interest in tissues voluntarily donated for research purposes, such as would grant them the right to transfer the tissues to a third party, they do have the right to request that their tissues should no longer be used for research or to have them identified and destroyed.[44] The latter point further suggests that a tissue donor's "limited right of control" remains when products derived from

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39 See Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010, Chapter 5 [Tri-Council Policy Statement].

40 51 Cal 3d 120 (Sup Ct 1990) [*Moore*].

41 490 F 3d 667 (8th Cir 2007) [*Catalona*].

42 *Moore, supra* note 40 at 141. See also Mosk J.'s dissenting opinion, where he held that the patient retains "valuable rights" of control over the uses of excised tissues: (*ibid* at 166–67).

43 *Ibid* at 141.

44 *Catalona, supra* note 41 at 675.

research use of donated tissue retain identifiable information about the donor. This is so regardless of the researcher's exclusive right to benefits accruing from financial exploitation of the tissue-derived products. Indeed, it is a somewhat settled view that certain products derived from human tissues, such as cell lines, must remain linked to the donor or patient's clinical information for research or clinical follow-up or regulatory purposes.[45] The donor's limited right of control is, arguably, further strengthened, as the *Moore* ruling suggests, where the inventive steps or products were achieved or derived in circumstances that violate or injure the donor's privacy or autonomy-based rights.[46]

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[45] See Amy Zarzeczny et al, "iPS Cells: Mapping the Policy Issues" (2009) 139:6 Cell 1032; Caulfield, Ogbogu & Isasi, *supra* note 6.

[46] The recently announced agreement between the US National Institutes of Health (NIH) and relatives of Henrietta Lacks highlights the possible scope of this limited right of control, even with regard to dead donors. See Carl Zimmer, "A Family Consents to a Medical Gift, 62 Years Later", *The New York Times* (7 August 2013), online: <http://www.nytimes.com/2013/08/08/science/after-decades-of-research-henrietta-lacks-family-is-asked-for-consent.html?pagewanted=all>; Kathy L Hudson & Francis S Collins, "Biospecimen Policy: Family Matters" (2013) 500 Nature 141; National Institutes of Health, News Release, "NIH, Lacks family reach understanding to share genomic data of HeLa cells" (7 August 2013), online: <http://www.nih.gov/news/health/aug2013/nih-07.htm>; National Institutes of Health, *HeLa Genome Data Use Agreement* (6 August 2013), online: <https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?page=DUC&view_pdf&stacc=phs000640.v1.p> [HeLa Agreement]. Henrietta Lacks is the parent of HeLa, the first and most widely used cell line in human history. The HeLa cell line was derived from a tumor biopsy removed from Ms. Lacks's body without her knowledge or consent while she was being treated for cervical cancer at the Johns Hopkins University Hospital in 1951. For a definitive history of Henrietta Lacks and the HeLa cell line, see Rebecca Skloot, *The Immortal Life of Henrietta Lacks* (New York: Crown Publishers, 2010). Under the terms of the agreement, NIH will facilitate placement of genomic sequence data derived from the foundational (and extensively commercialized) HeLa cell line in a controlled-access database, and allow access only to researchers who agree to comply with terms of use monitored by a committee that includes members of the Lacks family. See also Hudson & Collins, *supra* note 46; HeLa Agreement, *supra* note 46. The terms of use require researchers to implement safeguards to prevent security breaches and unauthorized uses of HeLa genome data, and to respect the privacy of the family members. The (first of its kind) agreement seeks to address privacy concerns and widespread criticism that arose when a German research team sequenced the genome of the HeLa cell line and posted the genome data in a publicly accessible database. See (*ibid*); Jonathan JM Landry et al,

Second, the finding that the medical record, in its physical form, belongs to the physician who created it implies that *medical records belong to whoever created or compiled them.* If this is the case, could it not be argued, by analogy, that tissue, which is "created", in a biological sense, by the individual (through actions such as eating, sleeping or simply staying alive) equally *belongs* to that individual?[47] On this view, tissues donated to research, and which are stored or remain unaltered in the research process, *belong* to the donor. While this view amounts to a radical interpretation of the *McInerney* decision (which did not deal with human tissues or with the property-law issues surrounding collection and use of tissues for research purposes), it raises interesting questions about how a Canadian court might characterize the legal interests in human tissue.

Finally, our contention that *McInerney* supports the view that research donors, like patients, have a right of continuing access to, and control over, genetic information contained in donated human biological materials calls for an examination of the scope of such a right. Does the right entitle the participant to withdraw his or her material or information from research? In *McInerney*, the Supreme Court found that the right of continued access and control entitles the patient to view and acquire copies of the health information contained in his or her medical record. Though not addressed

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"The Genomic and Transcriptomic Landscape of a HeLa Cell Line" (2013) 3:8 G3 1213; Andrew Adey et al, "The Haplotype-Resolved Genome and Epigenome of the Aneuploid HeLa Cancer Cell Line" (2013) 500 Nature 207. It also marks the first instance of granting some control over decisions regarding research uses and disclosure of products and information derived from donated tissue to persons who do not possess any identifiable or supportable legal interest over such tissue.

47 For discussions regarding whether individuals have a property interest in their bodies, see Michelle Bourianoff Bray, "Personalizing Personality: Toward a Property Right in Human Bodies" (1990) 69:1 Tex L Rev 209 at 211–20; Margaret Jane Radin, "Property and Personhood" (1982) 34:5 Stan L Rev 957; Remigius N Nwabueze, "Biotechnology and the New Property Regime in Human Bodies and Body Parts" (2002) 24:1 Loy LA Int'l & Comp L Rev 19 at 39–46; Rohan Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control* (Portland: Hart Publishing, 2007); *Doodeward v Spence* (1908) 6 CLR 406 (HCA) at 414; *Yearworth v North Bristol NHS Trust*, [2009] EWCA Civ 37; Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research* (2011), online: Nuffield Council on Bioethics <http://www.nuffieldbioethics.org/ sites/default/files/Donation_full_report.pdf>.

in the case, it is doubtful that the reasoning in *McInerney* can be extended to situations where the patient requests withdrawal of personal health information from, or destruction of, their medical records, as this would defeat or negate the physician's proprietary interest in the records. However, we see no reason why this limitation on withdrawal should apply to the research context, especially in situations where donated materials remain unaltered or where the genetic or other health information derived from biological materials remain linked to the donor. There is some support for this view in *Catalona*, where the court rejected the tissue donors' property claim but upheld their continuing right to request their biological materials no longer be used for research purposes.[48]

III. RIGHTS OF ACCESS TO AND CONTROL OVER GENETIC INFORMATION: THE FIDUCIARY-LAW ANGLE

In *McInerney*, the Supreme Court ruled that the individual's right to access and control personal health information is also grounded in fiduciary law. According to the Court, physicians have a fiduciary obligation to provide patients with access to their medical records that is "ultimately grounded in the nature of the patient's interest in his or her records."[49] While the Court felt it was not necessary to address the question of whether the patient's interest extended to ownership of the records themselves, it made clear that the interest was broad enough to encompass a continuing right of access and control. As the Court puts it, "[t]he confiding of the information to the physician for medical purposes gives rise to *an expectation that the patient's interest in and control of the information will continue.*"[50] The fiduciary obligation, which is based on the duty to act with "utmost good faith and loyalty"[51] toward patients and the "trust-like 'beneficial interest'"[52] patients have in information contained in their medical records, binds the

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48 *Catalona, supra* note 41 at 675.

49 *McInerney, supra* note 13 at 150.

50 *Ibid* at 151 [emphasis added].

51 *Ibid* at 152.

52 *Ibid* at 152.

physicians to facilitate and provide access to health information upon request, or to "justify an exception to the general rule of access."[53]

The implications of this ruling for access to and control of genetic information are clear and significant. Even putting aside questions of ownership of human biological materials or genetic information discussed earlier, the Court's reasoning indicates that an individual who makes his or her genetic information available to a fiduciary may be entitled to expect that his or her interest in and control of that information will continue for access purposes. Assuming that the relationship between researcher and participant is viewed as having characteristics similar to the physician–patient relationship, this expectation of continued control and access should arguably negate (or at a minimum, raise questions about the legitimacy of) policies that limit donor control, such as limitations on the right to withdraw participation from research. It should be noted that this expectation also raises challenges for policies that ask donors to consent to future, unspecified research use of their biological materials.

The foregoing view is subject to three possible challenges: First, from a fiduciary-law perspective, it remains unclear whether the researcher–participant relationship has the "fiducial qualities"[54] of the physician–patient relationship. As the Supreme Court makes clear in *McInerney*, "not all fiduciary relationships and not all fiduciary obligations are the same",[55] and the finding that the relationship or obligation exists is "shaped by the demands of the situation."[56] Indeed, in *McInerney*, the Supreme Court specifically identified a feature of the fiduciary relationship between physicians and patients that may not exist in the researcher–participant relationship, namely that the patient's interest in unimpeded access to his or her medical records derives from the fact that the patient must disclose information to the physician in order to obtain treatment. By contrast, research participants generally do not derive any direct benefit from research conducted on donated tissues or biological material. However, this distinction, though significant, does not end the matter, especially in light

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[53] *Ibid* at 155.

[54] *Ibid* at 150.

[55] *Ibid* at 149.

[56] *Ibid.*

of other factors, discussed next, that suggest analytical similarities between both sets of relationships.

While there is no Canadian case law on point, there is some support in the literature for the view that the researcher–participant and physician–patient relationships share similar fiduciary qualities.[57] For example, one commentator has observed that when individuals disclose health information to a researcher, they trust that the researcher will not misuse it, mirroring the trust patients place in their physicians when disclosing health information.[58] Indeed, similar to the clinical context, "trust is a key feature of research and research participation."[59] Also, as Litman notes, the common indicia of fiduciary relationships set out by Justice Wilson in *Frame v Smith*,[60] which have since found acceptance in Canadian law, include the ability of fiduciaries to "unilaterally exercise . . . power or discretion so as to affect the . . . legal or practical interests"[61] of beneficiaries who are vulnerable to their influence.[62] The latter criterion is likely applicable to the researcher–participant relationship, which is characterized by an imbalance of power and knowledge between the researcher, who is familiar with the goals and risks of research, and the participant, who is vulnerable to harm if the researcher uses such power or knowledge to the participant's detriment.[63] This imbalance is heightened in the case of

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57 See e.g. Timothy Caulfield & Nola Ries, "Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context" (2004) 11 Health LJ Supplement 1 at 24–28; Paul B Miller & Charles Weijer, "Fiduciary Obligation in Clinical Research" (2006) 34:2 JL Med & Ethics 424; Josef A Mejido, "Personalized Genomics: A Need for a Fiduciary Duty Remains" (2011) 37:2 Rutgers Computer & Tech LJ 281 at 304–07.

58 Mejido, *supra* note 57 at 299, 311.

59 *Ibid* at 311.

60 [1987] 2 SCR 99, 42 DLR (4th) 81 Wilson J, dissenting [*Frame* cited to SCR].

61 *Ibid* at 136.

62 Moe Litman, "Fiduciary Law in the Hospital Context: The Prescriptive Duty of Protective Intervention" (2007) 15 Health LJ 295 at 300. See also *Frame*, *supra* note 60 at 135–36.

63 Mejido, *supra* note 57 at 306.

clinician-researchers who also provide primary care to their research subjects.[64]

A second objection is that the principle of autonomy supports limitations on continued access and control where research participants consent to such limitations. In other words, it is suggested that if participants are fully informed at the time they agreed to participate in the research, and if there is no significant change in the nature of the research, they should be bound by their initial consent and should not be able to withdraw their consent.[65] This is sometimes framed as a "waiver" of the right to withdraw.[66] While intuitively appealing,[67] such an approach cuts against the traditional view that consent is not a one-time contract but an ongoing process.[68] A waiver would need to be fully informed and, of course, this is nearly impossible where tissues are stored, in biobanks, for future "as-yet-unknown" research.[69] Also, it seems highly unlikely that the conditions of the research or the nature of the biobank itself will not evolve, thereby justifying a reconsideration of participation.[70] Finally, it should not be forgotten that, rightly or not, many biobanks use a broad consent approach.[71] This means that it is likely that research participants are not fully informed at the time of recruitment, at least not in the traditional

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64 Miller & Weijer, *supra* note 57 at 428–30.

65 Eric Chwang, "Against the Inalienable Right to Withdraw from Research" (2008) 22:7 Bioethics 370; Monique A Spillman & Robert M Sade, "Clinical Trials of Xenotransplantation: Waiver of the Right to Withdraw from a Clinical Trial Should Be Required" (2007) 35:2 J L Med & Ethics 265 at 268–70. *Contra* Terrance McConnell, "The Inalienable Right to Withdraw from Research" (2010) 38:4 J L Med & Ethics 840.

66 See generally *ibid.*

67 Some commentators have suggested that participants should be allowed to withdraw only if the reasons for withdrawal are "sufficient". See generally Holm, *supra* note 3. Such an approach seems inconsistent with the legally well-established right that participants have to withdraw without giving reasons.

68 Caulfield & Ries, *supra* note 57 at 28.

69 Hofmann, *supra* note 5 at 125–27. *Contra* Mark Sheehan, "Can Broad Consent Be Informed Consent?" (2011) 4:3 Public Health Ethics 226–35.

70 Monya Baker, "Big biotech buys iconic genetics firm", *Nature* (18 December 2012), online: <http://www.nature.com>.

71 Master et al, *supra* note 7.

sense of "informed". To sum up, issues with consent in this research context raise important questions about whether participants are truly "informed" enough to justify the application of a waiver theory.[72]

A third and final challenge is that limitations on access and control promote or facilitate the public interest in the benefits of tissue-based research, and as such, should supersede the fiduciary obligation to facilitate and provide continued access and control.[73] This objection correctly relies on the premise that the obligation to provide continued access is not absolute, and can be overridden on "reasonable grounds" or for "paramount reasons." However, as the Supreme Court points out in *McInerney*,

> the discretion to withhold information should not be exercised readily... [and] in situations that do not involve the interests of third parties, the court should demand compelling grounds before confirming a decision to deny access.[74]

Reasons for limiting access must also be compelling and consider the right to self-determination and general well being of the person seeking access.[75] Indeed, the Court concludes:

> In short, patients should have access to their medical records in all but a small number of circumstances. In the ordinary case, these records should be disclosed upon the request of the patient unless there is a significant

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[72] Indeed, those that favour reducing consent requirements for biobanks (e.g., allowing broad or general consent), note the requirement, as a counter balance, of a strong and ongoing right of withdrawal. Otlowski, *supra* note 5 at 220–21.

[73] For critiques of the use of the "public good" rationale to justify limitations on research-participant rights, see Timothy Caulfield, "Biobanks and Blanket Consent: The Proper Place of the Public Perception and Public Good Rationales" (2007) 18:2 King's Law Journal 209; Doward, *supra* note 4; Susan Watts, "Will Big Data DNA analysis herald new era in medicine?", *BBC News* (17 January 2013), online: <http://www.bbc.co.uk/news>; Alok Jha "500,000 people, a span of decades—and a waste of time and money?", *The Guardian* (23 February 2006), online: <http://www.guardian.co.uk/science/2006/feb/23/health.society>.

[74] *McInerney*, *supra* note 13 at 157.

[75] *Ibid.*

> likelihood of a substantial adverse effect on the physical, mental or emotional health of the patient or harm to a third party.[76]

The foregoing suggests that a very high legal threshold applies in this context. In our opinion, limitations on continued access designed to ease logistical barriers to research will likely not meet this threshold, especially if such limitations also negate fundamental, established consent principles that allow individuals full expression of self-determination and autonomy in relation to their biological materials.

IV. CONCLUSION

We have argued that the Supreme Court's decision in *McInerney* suggests that individuals have a continuing interest in the information derived from biological materials donated by them for genetic and cell-based research purposes. This continuing interest is founded in the nature and character of health/genetic information and in fiduciary law, and seems certain to encompass or include a meaningful right to withdraw consent to further research use of the information. It is also likely to include the right to access any incidental findings or results derived from research on donated human biological materials. Our conclusions sidestep the narrow focus on consent issues in debates about participants' rights in current tissue-based research, and highlight other legal avenues that allow donors to exercise effective control over human biological materials donated to research. In so concluding, we also hope to prompt a shift in scholarly reflection on this topic, from the undue focus on consent to other analytical lenses that offer valuable insights and arguments, such as fiduciary and access-to-information law.

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[76] *Ibid* at 158.