PRIVACY PROTECTION AND GENETIC RESEARCH: WHERE DOES THE PUBLIC INTEREST LIE?

1. Introduction

The collection, use and disclosure of personal health information for genetic research raise the possibility of conflicts between policies that promote or protect vital public interests in health research and in individual privacy. There is significant public interest in the outcomes of genetic research, which include diagnostic, therapeutic and preventative health methods and products, early detection of genetic susceptibility to disease and economic growth through job creation and product revenues.\(^1\) However, there is also a great deal of concern that genetic research and associated realms, such as cell therapy research and biobanking (collection and storage of human biological materials and related health information for research use) will foster the use and disclosure of personal health and genetic information in ways that implicate or undermine protected privacy interests.\(^2\) For example, the practice of allowing open access to genetic research data poses privacy risks for research participants and their genetically-linked kin,\(^3\) and research studies that depend on long-term storage of genetic

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\(^1\) See e.g. Timothy Caulfield, "Stem Cell Research and Economic Promises" (2010) 38 JL Med & Ethics 303 at 304-5, noting that economic benefits are often used in government documents to justify and promote genetic research funding, and that economic justifications may create intense expectations as to whether and when promised benefits will materialize.


\(^3\) See Genome Canada, Data Release and Resource Sharing Policy (18 September 2008), online: Genome Canada <http://www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf> [Genome Canada Policy]; National Human Genome Research Institute, Reaffirmation and
materials and information may compromise the privacy interests of donors who cannot (legally or practically) consent to or withdraw from future research use of their samples and information.4

As genetic research moves mainstream, a balance needs to be struck between legitimate public interests implicated in the collection, use and disclosure of genetic information for research purposes. Such balance should lie in clear and precise guidance on what constitutes appropriate public interest exceptions and considerations for use and disclosure of protected personal information in this context. While some guidance exists in legal doctrine,5 it is not clear whether legal rules fully address or anticipate the specific privacy issues associated with genetic research and related fields.

This paper examines the tension between the public interest in genetic research and in protection of individual privacy in relation to (1) policies requiring

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5 In Canada, for example, the question of how to strike an appropriate balance between privacy interests and access to information on grounds of public interests has received considerable attention in privacy and access to information law. See eg, Canada (Information Commissioner) v Canada (Minister of National Defence), 2011 SCC 25, [2011] 2 SCR 306; Criminal Lawyers’ Assn v Ontario (Ministry of Public Safety & Security), 2010 SCC 23, [2010] 1 SCR 815; Dagg v Canada (Minister of Finance), [1997] 2 SCR 403, 148 DLR (4th) 385. See also McInerney v MacDonald, [1992] 2 SCR 138, 93 DLR (4th) 415 (affirming that patients have a right to access their medical records); Frenette v. Metropolitan Life Insurance Co, [1992] 1 SCR 647, 89 DLR (4th) 653 (holding that patients may waive the right to confidentiality of their medical records).
open access to genetic research outputs, and (2) policies that ease logistical or practical impediments to research by limiting or varying the application of customary consent rules, such as broad or blanket consent\textsuperscript{6} policies and rules that preclude withdrawal of consent past a certain point in the research process. We review existing statutory rules, case law and administrative decisions on the public interest exception in Canadian privacy and access to information law. Through this review, we explore the legal framework for balancing competing public interests in the domain of genetic and tissue-based research. We conclude with a proposal for improving privacy protection outcomes in this research context.

2. Open access as a public interest

In the last decade, there has been a shift in many fields of scientific endeavour to policies favouring open access to research outputs.\textsuperscript{7} In an ethos

\textsuperscript{6} Broad or blanket consent models require participants to consent to the use of biological material for unforeseen research purposes, whereas specific consent models require researchers to seek and obtain participants’ consent for each new use of biological material: see e.g. Gert Helgesson, “In Defence of Broad Consent” (2012) 21:1 Camb Q Healthc Ethic 40; Zubin Master, Erin Nelson, Blake Murdoch & Timothy Caulfield, “Biobanks, Consent and Claims of Consensus” (2012) 9:9 Nature Methods 885. While both broad consent and blanket consent models permit participants to consent to future research uses of their biological material, they are in fact distinct concepts. Blanket consent models grant researchers the “unrestricted right to use the sample/information in any research without any other information”, whereas broad consent models provide participants with “enough information to understand the general nature” of the research (e.g. genetic research), though not the specific details of every research use made of their biological materials: Margaret FA Otlowski, “Tackling Legal Challenges Posed By Population Biobanks: Reconceptualising Consent Requirements” (2012) 20:2 Med Law Rev 191 at 212, 218.

that first emerged as part of the Human Genome Project (HGP) and is now firmly embedded in the genetic research context, “the free flow, access, and exchange of data” has long been encouraged as essential to ensure “the fair and equitable distribution of benefits” of this type of research.\(^8\) The HGP approach believes “human genomic databases are global public goods” and “a public resource”\(^9\), and as such, everyone deserves access to their benefits.

Many funding organizations and government policies mandate open access or data sharing as a condition for receipt of funding. For example, in the United Kingdom, both the Wellcome Trust and the Medical Research Council require funded research papers “be made freely available as soon as possible, and in any event within six months of publication.”\(^10\) In the United States, researchers supported by the National Institutes of Health (NIH) are required to make papers


publicly available within twelve months of publication.\(^{11}\) The NIH’s \textit{Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)} (the “GWAS Policy”) creates a centralized NIH data repository to enable sharing of de-identified data.\(^{12}\) Many other initiatives around the globe reflect this trend toward open access to and sharing of research data in the field of genetic research as well as other fields of scientific research.\(^{13}\)

In Canada, researchers in receipt of funding from the Canadian Institutes of Health Research (CIHR) “are required to ensure that their peer-reviewed publications are freely accessible through [either] the Publisher’s website…or an online repository…within 12 months of publication.”\(^{14}\) The new CIHR policy also


\(^{12}\) \textit{Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)}, Federal Register (Notice), Vol. 72, No. 166, P. 49290 (28 August 2007). Information or biological materials that have been “de-identified” have had identifying information (such as name or social insurance number) removed. We use the term “de-identified” throughout the paper, rather than “anonymized”, which bears an inconsistent meaning in academic literature and policy documents. It has been noted that inconsistent use of bioethical terms may undermine efforts to achieve harmonization in policy documents on an international scale. See generally B S Elger & A L Caplan, “Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework” (2006) 7 EMBO Rep 661.


\(^{14}\) Canadian Institutes of Health Research, *CIHR Open Access Policy* (1 January 2013), online: CIHR [http://www.cihr-irsc.gc.ca/e/46068.html] [2013 CIHR Policy].
requires researchers to deposit research data “into the appropriate public database...immediately upon publication of research results.”\textsuperscript{15} For example, all nucleic acid sequences must be deposited into GenBank, a NIH database containing “all publicly available DNA sequences”.\textsuperscript{16} Similarly, Genome Canada policies require researchers “to share data and resources as rapidly as possible...[and] no later than the original publication date of the [project’s] main findings.”\textsuperscript{17}

Why are open access policies so prevalent in genetic research? First, underlying these policies is the idea that research funded by the public should be accessible to that public.\textsuperscript{18} Second, open access, by promoting faster and wider dissemination of research results, may lead to better scientific outcomes.\textsuperscript{19} Researchers can cost-effectively re-use research data by comparing, contrasting, reusing, and mining data, resulting in new knowledge without the need to spend more money or time on data collection.\textsuperscript{20} Third, open access policies may

\textsuperscript{15} Ibid.
\textsuperscript{17} Genome Canada Policy, supra note 3. See also International Society for Stem Cell Research (ISSCR), Guidelines for the Conduct of Human Embryonic Stem Cell Research (21 December 2006), online: <http://www.forth.gr/_gfx/pdf/ISSCRhESCguidelines2006.pdf> at 4, which directs researchers “to share research materials, data and intellectual property (IP) rights necessary for published research to be validated and for other scientists to conduct further research”: P L Taylor, “Research Sharing, Ethics and Public Benefit” (2007) 25 Nature Biotechnology 398 at 398.
\textsuperscript{18} Bevin P Engelward & Richard J Roberts, “Open Access to Research Is in the Public Interest” (2007) 5:2 PLOS Biology 48 at 48. The 2013 CIHR Policy provides: “As a publicly funded organization, CIHR has a fundamental interest in ensuring that the findings that result from the research it funds, including research publications and publication-related data, are available to the widest possible audience, and at the earliest possible opportunity”: 2013 CIHR Policy, supra note 14 at para 1.
\textsuperscript{19} Engelward & Roberts, ibid at 48. The 2013 CIHR policy provides: “Advancements in science and health care are made possible through widespread and barrier-free access to cutting-edge research and knowledge enabling scientists, clinicians, policymakers and the public to use and build on this knowledge”: 2013 CIHR Policy, ibid at para 1.
\textsuperscript{20} Giglia & Swan, supra note 8 at 714.
increase, economic and societal opportunities.\textsuperscript{21} Evidence suggests that the “reduced costs and shortened development cycles [furthered] by greater access to…research outputs could generate” economic benefits to the tune of several million dollars while also enabling products to be brought to the market earlier.\textsuperscript{22} Data sharing enables “efficient use of resources funded by the public purse”,\textsuperscript{23} providing “greater returns from the public investment in research.”\textsuperscript{24} Finally, open access is promoted on the belief that it may result in more equal and just distribution of the benefits of research.\textsuperscript{25} Sharing research outputs and data facilitates just distribution of the benefits of scientific research among “economically and geographically diverse” scientists and publics.\textsuperscript{26} Open access is thus linked to the idea that genetic research is equally valuable and beneficial to everyone.\textsuperscript{27}

At the same time, open access and data sharing practices pose significant privacy concerns for individuals who contribute their biological materials to genetic research. One such concern is that placing sensitive genetic information or data derived from these materials in the public domain increases the possibility of misuse, especially for non-research purposes. Even when genetic information is de-identified, it remains unique to an individual and could potentially be linked to that person (or his or her genetic relatives) if used in

\textsuperscript{21} Taylor, \textit{supra} note 16.  
\textsuperscript{22} Carr & Kiley, \textit{supra} note 10; Giglia & Swan, \textit{supra} note 8 at 714.  
\textsuperscript{23} Kaye, \textit{supra} note 8 at 419.  
\textsuperscript{25} Taylor, \textit{supra} note 16 at 399.  
\textsuperscript{27} Ibid.  
\textsuperscript{27} Ibid.
conjunction with other personal health information or publicly available information.\textsuperscript{28} Indeed, recent studies have shown that it is possible to re-identify donors of biological material used in research by combining de-identified genetic data\textsuperscript{29} or DNA samples\textsuperscript{30} with demographic and/or genealogical information available in the public domain.

The privacy risks associated with genetic research data “are likely to become more frequent as increasingly diverse sources of data are linked” and databases expand.\textsuperscript{31} Under open access policies, data will also increasingly be used by researchers who were not involved in collecting the data, thus “sever[ing] the ties between” researchers and donors of biological material/research participants, which may have implications for the obligation to obtain informed consent.\textsuperscript{32} As one commentator has observed, “[t]he onward sharing of data raises questions about who is accountable not only to research ethics committees approving new research but also to the research participants

\textsuperscript{28} John Timmer, “Anonymized genetic research data still carries privacy risks”, \textit{ARS Technica} (6 October 2009), online: <http://arstechnica.com/science/2009/10/anonymized-genetic-research-data-still-carries-privacy-risks>; Matthew D Mailman et al, “The NCBI dbGaP Database of Genotypes and Phenotypes” (2007) 39:10 Nat Genet 1181. As one commentator has stated: “[T]he current methods for sharing genetic data pose a real privacy risk for those who have generously volunteered to allow their DNA to be used for medical research, and the degree of risk is likely to increase with the ever-expanding volume of genetic data available. Researchers not only have an ethical obligation to protect these volunteers; in many cases, they’re required to do so by law or federal policy, which set strict rules for the protection of privacy in regard to human samples.


\textsuperscript{30} See e.g. Lowrance & Collins, \textit{supra} note 2; McGuire & Gibbs, \textit{supra} note 2; B Malin et al, “Identifiability in Biobanks: Models, Measures, and Mitigation Strategies” (2011) 130 Hum Genet 383.

\textsuperscript{31} Kaye, \textit{supra} note 8 at 419. “As genealogy databases and other resources improve, “the reidentification of existing data sets will become easier”: John Bohannon “Genealogy Databases Enable Naming of Anonymous DNA Donors” (2013) 339 Science 262 at 262.

\textsuperscript{32} Kaye, \textit{ibid} at 420.
for the secondary uses of data in other studies.” Data sharing and open access approaches thus add “a new twist to the old questions of informed consent, protection of privacy and governance of medical research.”

Rationales and justifications used to support open access policies often appeal to public interest considerations. The endorsement of open access on the basis of “the public good” or “the public interest” abounds in policies promoting this research trend. The NIH policy states, for example, that the granting agency “encourages the sharing of ideas, data, and research findings to help accomplish its important public mission to uncover new knowledge that will lead to better health for everyone.”

Similarly, the CIHR’s policy provides:

Advancements in science and health care are made possible through widespread and barrier-free access to cutting-edge research and knowledge enabling scientists, clinicians, policymakers and the public to use and build on this knowledge…CIHR strongly supports unrestricted open access, which promotes the principle of scientific openness, an essential element of science.

Similarly, Genome Canada’s Policy on Data Release and Resource Sharing states that “data and resource sharing policy is intended to accelerate the translation of research for the benefit of humankind.” At the international level, a report by the Organisation for Economic Co-operation and Development (OECD) promotes open access to data generated from tax-payer supported research on the basis such research is “a public good, produced in the public

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33 Ibid.
34 Ibid.
35 NIH Public Access Policy, supra note 11.
36 2013 CIHR Policy, supra note 14.
37 Genome Canada Policy, supra note 3.
interest.\textsuperscript{39} This perspective is reflected in the Research Councils UK Common Principles on Data Policy, which provides that “[p]ublicly funded research data are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner that does not harm intellectual property.”\textsuperscript{39} Clearly, open access policies appeal to public interest considerations.

By contrast, privacy considerations have often been treated as an afterthought in the process of developing open access and data sharing policies. For example, CIHR’s open access policy initially failed to address adequately privacy issues.\textsuperscript{40} Following consultation with researchers who worried that the draft policy did not sufficiently take account of privacy norms—some even felt that the data sharing requirements in the draft “may violate provincial…privacy policies”\textsuperscript{41}—CIHR clarified that researchers must follow relevant privacy rules.\textsuperscript{42}

The NIH GWAS Policy followed a similar trajectory. The policy requires researchers to deposit findings in a central database intended to facilitate data-sharing (the database of Genotypes and Phenotypes or “dbGaP”).\textsuperscript{43} Access is two-tiered: the public may access “summary-level information and aggregate genotype data” (open access) while individual-level is available to approved


\textsuperscript{39} Research Councils UK, \textit{RCUK Common Principles on Data Policy}, online: RCUK <http://www.rcuk.ac.uk/research/Pages/DataPolicy.aspx> [RCUK Policy].

\textsuperscript{40} Canadian Institutes of Health Research, \textit{CIHR Consultation: Developing a CIHR Access to Research Outputs Policy} (4 April 2004), online: CIHR <http://www.cihr-irsc.gc.ca/e/33925.html>.

\textsuperscript{41} Ibid.

\textsuperscript{42} 2013 CIHR Policy, \textit{supra} note 14 at para 5.1.

\textsuperscript{43} A A Lemke et al, “Public and Biobank Participant Attitudes toward Genetic Research Participation and Data Sharing” (2010) 13:6 Public Health Genomics 368 at 368.
researchers (“controlled access”). Aggregate genotype data was publicly accessible until 2008, when researchers indicated this was sufficient to re-identify individuals, and, following this revelation, the NIH subsequently restricted public access to this data.

In both the CIHR and NIH examples, the original open access policy was drafted and implemented without due consideration of privacy concerns, but was later modified to take account of such concerns. Unlike discussions of rationales for open access and data sharing, mentions of privacy risks in current open access and data sharing policies are generally expressed in secondary terms, and there are no references to or discussions of a public interest in privacy protection. This dichotomy signals to those charged with implementing these policies that open access and privacy are not equally weighted public interest objectives, and may lead to a decisional bias in favour of data disclosure.


45 Nils Homer et al, “Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays” (2008) 4:8 PLoS Genet e1000167 (The authors note that “sharing only summary data does not completely mask identity.”); In 2013, researchers demonstrated they were able to re-identify individuals from de-identified genetic data available in publicly accessible databases: Gymrek et al, supra note 28. The NIH worked in consultation with the researchers to place publicly accessible data under a system of controlled access: Laura L Rodriguez, Lisa D Brooks, Judith H Greenberg & Eric D Green, “The Complexities of Genomic Identifiability” (2013) 339:18 Science 257.

46 By contrast, open access policies issued by UK’s Medical Research Council (MRC) and Research Councils UK appear to have adopted a “bottom up” approach to incorporating privacy considerations. Both refer to risks posed to personal privacy due to inappropriate release of data, and the MRC policy cross-references its guidance on the use and disclosure of personal information in medical research. See Medical Research Council, MRC Policy on Research Data-Sharing, online: MRC <http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/datasharing/Policy/index.htm>; RCUK Policy, supra note 38.
when resolving conflicts between both public interest objectives. This approach is also at odds with Canadian legal doctrine on what constitutes legitimate justifications for public interest override of protected privacy interests. We expand on the latter point in a later section of this paper.

Lastly, it is important to note that we are not suggesting that open access or data sharing should be discouraged in the genetic research context. Rather, our point is that privacy considerations ought to be accorded equal recognition in policies promoting these research goals, especially given technological innovations that have increased the risk and seriousness of potential privacy violations and the fact that such policies allow for practices that create and deepen privacy risks. As noted in a recent commentary:

We are at a crucial juncture brought about by the confluence of new technologies for data generation, bioinformatics, and information access on the one hand, which seem to create new risks to privacy, and the public’s desire to benefit from these advances for a variety of personal and health reasons on the other hand. In light of this changing landscape, it is time to re-examine how to balance the protection of research participants (individuals, families, and groups) with the societal benefits likely to be gained through the enhanced research that broad data sharing facilitates.  

2. Emerging consent policies and the public interest in genetic research

Consent has been called “the cornerstone of contemporary research ethics.” Legal and ethical principles require researchers to obtain consent to specific identifiable research studies from fully informed participants, including

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47 Rodriguez et al, supra note 45. The authors note further: “Although the research community must be realistic and mindful of identifiability concerns, there are also ethical responsibilities to ensure that data contributed by participants for research are maximally utilized and that public research funding stimulates the greatest public good.” Ibid.

individuals who donate biological material for research purposes, and generally allow participants to withdraw from research studies at any time and for any reason. While these principles are well established and faithfully applied in many research contexts, they pose significant practical and logistical challenges for certain research areas, such as future genetic research studies that rely on stored biological materials or genetic data. For example, obtaining specific consent from donors of biological material for research studies that arise after the time of collection is likely to be prohibitively expensive or even impractical, especially for studies involving large, diverse collections or populations. Given that potential research uses of stored biological materials are unknown at the time consent to donation and storage is obtained, donors must be re-contacted and re-consented prior to research use in accordance with legal and ethical norms.

Allowing participants to withdraw consent to use of their biological materials raises similar concerns; withdrawal may be expensive, impossible or futile if biological material or associated data have been widely shared, used to derive

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49 Ibid. The right to withdraw consent is “a basic tenet of research ethics” and an “almost unqualified right...found in guidelines throughout the world”: Timothy Caulfield, Ubaka Ogbovu & Rosario M Isasi, “Informed Consent in Embryonic Stem Cell Research: Are We Following Basic Principles?” (2007) 176:12 CMAJ 1722 at 1723. For example, the UNESCO policy provides “[w]hen a person withdraws consent, the person’s genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.” UNESCO International Declaration on Human Genetic Data (16 October 2003), Art 9(b).


51 Caulfield, supra note 49.

novel products such as stem cell lines, or published in the public domain.

Further, there may be concern that allowing withdrawal from genetic or tissue-based research projects may have a negative impact, resulting in a biased sample or a reduced pool of participants.53

In Canada and elsewhere, policymakers have responded to these challenges by adopting policies and practices that run counter to well-established legal and ethical norms, such as rules that allow broad or blanket consent for unknown, future research purposes,54 or policies that preclude withdrawal of consent past a certain point in the research process.55 While these policies and practices have been and remain hugely controversial,56 several biobanks and national and international research policies have adopted broad or blanket consent models,57 and rules that limit the right of withdrawal of consent have emerged in many policy contexts.58 For example, Canada’s Assisted Human Reproduction Act, SC 2004, c 2, which governs, inter alia, assisted procreation procedures such as fertility treatments and embryo research.

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53 Kristina Hug, Göran Hermerén & Mats Johansson, “Withdrawal from Biobank Research: Considerations and the Way Forward” (2012) 8:4 Stem Cell Rev and Rep 1056. The authors note empirical evidence is unclear regarding whether these consequences will in fact result if participants withdraw consent. Ibid.


55 See e.g. Assisted Human Reproduction (Section 8 Consent) Regulations, SOR/2007-137, s 14(2)(e)(iii) [Consent Regulations]. Enacted pursuant to the Assisted Human Reproduction Act, SC 2004, c 2, which governs, inter alia, assisted procreation procedures such as fertility treatments and embryo research.

56 Master, supra note 55.

57 For example, the OECD guidelines provide for “a consent that will permit human biological specimens and/or data to be used to address unforeseen research questions” so long as participants are “fully informed of the breadth of such consent and there [are] safeguards in place to ensure that participants are protected”. OECD Guidelines on Human Biobanks and Genetic Research Databases, Guideline 4.6. Similarly WHO guidelines state: “A blanket informed consent that would allow use of a sample for future genetic research in general, including future as yet unspecified projects, appears to be the most efficient and economical approach.” World Health Organization, Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (December 1997), online: <http://whqlibdoc.who.int/hq/1998/WHO_HGN_GL_ETH_98.1.pdf> at 13.

58 Caulfield, Ogbogu & Isasi, supra note 50.
Reproduction (Section 8 Consent) Regulations limits withdrawal of consent to research use of donated embryos to the time before a stem cell line is derived from the embryos.\footnote{\textit{Supra} note 56.}

Such variations to established consent norms are also very likely to compromise privacy protections, as it is doubtful whether, in the absence of an enduring legal or ethical right to consent or withdraw consent, donors and research participants can meaningfully exercise control over the use and disclosure of the “genetic health record” stored in their cells and tissues.\footnote{\textit{Ibid}, s 14(2)(e)(iii). This policy is in place presumably to address the practical problems associated with withdrawing consent to research use of donated biological material after a product, such as a cell line or other innovation, has been derived from that research. Such policies highlight the pressures on research ethics norms created and exacerbated by the unique nature of genetic and tissue-based research (as opposed to other types of human subject research). An exploration of whether the practical problems and ensuing pressures justify departures from research ethics norms is outside the scope of this paper. See e.g. Lawrence O Gostin, “Genetic Privacy” (1995) 23:4 JL Med Ethics 320.}

At the same time, de-identification of genetic data prior to research use and sharing is not a panacea for privacy risks, for two main reasons. First, there is an emerging policy preference for ongoing linkage between biological material and the donor’s health information to facilitate rescreening or access to the donor’s health status prior to clinical use or therapeutic application of products or data derived from donated biological material.\footnote{See e.g. Committee on Guidelines for Human Embryonic Stem Cell Research, \textit{Guidelines for Human Embryonic Stem Cell Research} (Washington: National Academies Press, 2005); \textit{Donor Eligibility}, 21 CFR §1271.55 (2005). See e.g. Committee on Guidelines for Human Embryonic Stem Cell Research, \textit{Guidelines for Human Embryonic Stem Cell Research} (Washington: National Academies Press, 2005); \textit{Donor Eligibility}, 21 CFR §1271.55 (2005).} Second, as previously discussed, studies have shown that it is possible to re-establish donor identity if de-identified data is combined with other publicly available data.\footnote{A\textit{my Zarzeczny et al, “iPS Cells: Mapping the Policy Issues” (2009) 139:6 Cell 1032 at 1032. See e.g. Committee on Guidelines for Human Embryonic Stem Cell Research, \textit{Guidelines for Human Embryonic Stem Cell Research} (Washington: National Academies Press, 2005); \textit{Donor Eligibility}, 21 CFR §1271.55 (2005).} Also, if research involves a
discrete group of donors/participants, de-identification is less likely to provide sufficient privacy protection. As Kaye neatly sums up, “the traditional focus of privacy protection in research on consent and anonymization cannot address the concerns raised by data sharing and whole-genome sequences.” Given that the individual’s ability to control the use and disclosure of his or her personal information under Canadian privacy and data protection laws and the law on medical research relies largely on specific consent and a robust right of withdrawal, limitations of these principles should at least attract policy reflection and analysis. However, to date, the privacy risks flowing from unique consent challenges posed by tissue-based research has not received much attention in policies promoting variations to consent norms (or ethical guidelines more generally) or in Canadian privacy and data protections laws and academic and policy discussions. As one commentator observes, “[g]enetic information is not afforded exceptional legal status [in Canada], and is for the most part treated the same way as other personal information in our general data protection regimes.” At the same time, Canadians appear to want greater control over and

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65 Kaye, supra note 8 at 424.
66 Halushka v University of Saskatchewan (1965), 53 DLR (2d) 436 (Sask CA); Weiss v Solomon (1989), 48 CCLT 280 (Que SC).
protection of their genetic information. For example, in a 2003 survey of 1,200 Canadians, 58% of respondents desired stricter regulation of genetic information compared to other health information.⁶⁹

Much like policies promoting open access and data sharing, variations or limitations of established consent norms in the genetic research context are often justified by reference to public interest considerations. Proponents claim that these non-customary consent and withdrawal policies facilitate or aid the realization of the public interest in genetic research, and that potential societal benefits arising from genetic research justify the minimal risk to the participant.⁷⁰ Erik Christensen has argued, for example, that biobank-based research is part of a good society and thus specific informed consent of individuals is not required, as long as the research promotes values and benefits the public can support.⁷¹ Such appeals to public interest considerations often ignore or fail to mention a possible corresponding public interest in the values flowing from robust consent and withdrawal policies, such as privacy protection and respect for individual autonomy. As we argued in relation to open access policies, this approach underplays or obscures privacy protections at the research policy development and implementation stages. It also begs for an examination of the legitimacy of

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applying public interest justifications to override or defeat privacy considerations in this context. For example, do public interest justifications for open access and consent variations fit within the definition of acceptable public interest considerations in Canadian privacy and data protection laws? Can policies and institutions promoting or implementing the public interest in genetic research legitimately ignore consideration of privacy issues and solutions? We address these questions in the next and final section of this paper by reviewing applicable Canadian legal principles.

3. Public interest considerations in Canadian privacy and access to information law

a) The legal scope of the public interest override

Statutory rules for public interest use and disclosure of protected personal information are fairly uniform throughout Canada.\(^\text{72}\) Applicable provisions generally mandate or permit information custodians (such as public officials) to disclose information that is in the public interest.\(^\text{73}\) Also, in most if not all cases,

\(^{72}\) See e.g. Privacy Act, RSC 1985, c P-21, s 8(2)(m); Freedom of Information and Protection of Privacy Act, RSA 2000, c F-25, s 32(1) [AB FIPPA]; Freedom of Information and Protection of Privacy Act, RSBC 1996, c 165, s 25(1) [BC FIPPA]; Right to Information and Protection of Privacy Act, SNB 2009, c R-10.6, ss 28(2), 47 [NB RIPPA]; Access to Information and Protection of Privacy Act, SNL 2002, c A-1.1, s 31(1) [NL AIPPA]; Freedom of Information and Protection of Privacy Act, SNS 1993, c 5, s 31(1) [NS FIPPA]; Freedom of Information and Protection of Privacy Act, RSO 1990, c F.31, s 11(1) [ON FIPPA]; Freedom of Information and Protection of Privacy Act, RSPEI 1998, c F-15.01, s 30(1) [PEI FIPPA]; Freedom of Information and Protection of Privacy Act, SS 1990-91, c F-22.01, s 29(2)(o) [SK FIPPA]; Freedom of Information and Protection of Privacy Act, CCSM c F-175, s 18(4) [MB FIPPA]. The provision in the Manitoba Act applies only as an exception to provisions requiring non-disclosure of information affecting the business interests of third parties. Similar public interest overrides over non-disclosure of third party business interests exist in other legislation. See e.g. Access to Information Act, RSC 1985, c A-1, s 20(6); SK FIPPA, ibid, s 19(3). Also, there are slight variations in wording among the statutes.

\(^{73}\) See generally ibid.
such disclosure operates as a statutory override of protected privacy rights and interests.

Depending on the jurisdiction and subject matter, the public interest can be invoked to allow the disclosure of information: (1) about risk of significant harm to public safety, public health or the environment;\(^\text{74}\) (2) for research purposes,\(^\text{75}\) and (3) where the information custodian determines that the public interest in disclosure outweighs a statutory access exemption or any invasions of privacy that would result from such disclosure.\(^\text{76}\) The federal *Privacy Act* and privacy and access to information statutes in Alberta, British Columbia, Nova Scotia and Prince Edward Island also allow responsible public officials the discretion to identify other reasons for public interest disclosure.\(^\text{77}\)

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\(\text{74}\) In Alberta, the latter provision has been interpreted as imposing "a statutory obligation on the head of a public body to release information of certain risks under 'emergency-like' circumstances (i.e., 'without delay')": Order 98-011 (1 September 1998) (AB IPC) [Order 98-011].

\(\text{75}\) Personal Information Protection and Electronic Documents Act, SC 2000, c 5, s 7(3)(f); Privacy Act, supra note 72, s 8(2)(j); AB FIPPA, supra note 72, s. 42; Health Information Act, RSA 2000, c H-5, ss 49-55 [AB HIA]; Personal Information Protection Act, SA 2003, c P-6.5, s 20 [AB PIPA]; E-Health (Personal Health Information Access and Protection of Privacy) Act, SBC 2008, c 38, s 15 [BC E-Health Act]; Personal Information Protection Act, SBC 2003, c 63, s 21 [BC PIPA]; BC FIPPA, supra note 72, s 35; Personal Health Information Act, CCSM, c P-33.5, s 24 [MB PHIA]; MB FIPPA, supra note 72, s 47; NB RIPPA, supra note 72, ss 46-7; Personal Health Information Privacy and Access Act, SNB 2009, c P-7.05, s 43 [NB PHIPAA]; NL AIPPA, supra note 72, s 41; Personal Health Information Act, SNL 2008, c P-7.01, s 44 [NL PHIA]; NS FIPPA, supra note 72, s 29; ON FIPPA, supra note 72, s 21; Personal Health Information Protection Act, SO 2004, c 3, s 44 [ON PHIPA]; PEI FIPPA, supra note 72, s 39; c s 29; Health Information Protection Act, SS 1999, c H-0.021, s 29 [SK HIPA].

\(\text{76}\) Alberta, British Columbia, Newfoundland and Labrador, Nova Scotia, Ontario, and Prince Edward Island are examples of jurisdictions that use the override model. The Saskatchewan statute and the federal *Privacy Act* simply provide that personal information may be disclosed where the "public interest in disclosure clearly outweighs any invasion of privacy that could result from the disclosure": see SK FIPPA, supra note 72, s 29(2)(o); *Privacy Act*, supra note 72, s 8(2)(m).

\(\text{77}\) *Privacy Act*, supra note 72, s 8(2)(m). The wording of the Ontario and Newfoundland provisions seem to restrict the scope of public interest only to risks posed to public health, public safety, or the environment. It is doubtful that information custodian in these jurisdictions possess any residual discretion to identify other public interest objectives. See ON FIPPA, supra note 72, s 11(1); NL AIPPA, supra note 729, s 31(1). In Alberta, the Privacy Commissioner has interpreted "other reason" in the AB FIPPA to include disclosure for "scientific monitoring and research": Order F2012-14 (29 June 2012) (AB IPC).
A review of provincial privacy adjudications reveals that the public interest override has been successfully invoked to justify disclosure of (1) matters of grave or immediate danger to the public or groups of persons, such as risks to public health, public safety, and the environment;78 (2) matters of substantial utility or benefit to members of the public, such as improvement of health and health care delivery services; and (3) matters which promote or preserve certain ideas and practices considered to be hallmarks of citizenry, political and social culture, or the democratic process, such as encouraging openness and accountability in government (see generally Table 1).

In relation to research purposes, the public interest override can be relied on to disclose identifying personal information for research purposes without the consent of the individual who is the subject of that information. However, such disclosure is generally only permitted if (1) any record linkage will not cause harm to the identified individual, it is clearly beneficial to the public interest, and efforts are made to remove or destroy individual identifiers at the earliest reasonable time,79 or (2) if the public interest in the research outweighs the public interest in privacy protection.80 These rules clearly indicate that data de-identification are

78 See generally supra notes 74, 76 and accompanying text. See also Clubb v Saanich (District), [1996] 35 Admin LR (2d) 309, [1996] 46 CR (4th) 253 at 264 (BCSC) [Clubb] where Melvin J states: “The public is, however, truly ‘interested’ in matters that may affect the health or safety of children.” See also RJR MacDonald Inc v Canada (Attorney General), [1994] 1 SCR 311 at 344, 111 DLR (4th) 385, where Sopinka and Cory JJ (interpreting the meaning and scope of the phrase “public interest” in the context of an interlocutory relief application) state: “‘Public interest’ includes both the concerns of society generally and the particular interests of identifiable groups.”

79 AB FIPPA, supra note 72, s 42; BC FIPPA, supra note 72, s 35; MB FIPPA, supra note 72, s 47(4); NS FIPPA, supra note 72, s 29; NL AIPPA, supra note 72, s 41; NB RIPPA, supra note 72, s 47(6); PEI FIPPA, supra note 72, s 39; Access to Information and Protection of Privacy Act, RSY 2002, c1, s 38; Access to Information and Protection of Privacy Act, SNWT 1994, c 20, s 49 [NWT AIPPA]; Nunavut Act, SC 1993, c 28, s 29.

80 See AB HIA, supra note 75, s 50(1); BC E-Health Act, supra note 75, s 14(2.1)(d); MB PHIA, supra note 75, s 24(3)(a); NB PHIPAA, supra note 75, s 43(3)(a); ON PHIPA, supra note 75, s
important concepts in the context of public interest determinations and privacy protections more broadly, especially in situations where the consent of the research subject or participant is not legally required prior to use or disclosure of personal information.

Provinces with health information protection legislation typically empower Research Ethics Boards (REB) to assess if and when the public interest override should apply to disclosure for health research purposes. Alberta’s Health Information Act, for example, mandates that REBs assess whether “the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy” of personal health information. The Act also contains a non-exhaustive list of factors that REBs should consider in making public interest determinations for health research disclosure purposes, including the degree to which the proposed research may aid “identification, prevention or treatment of illness or disease, scientific understanding relating to health, promotion and protection of the health of individuals and communities, improved

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44(3)(c); SK HIPA, supra note 75, s 29. The Ontario provision envisages a balancing of the “public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed”: ON PHIPA, ibid, s 44(3)(c). The statutes in Manitoba, New Brunswick and Saskatchewan do not mention “public interest”: the statutes in Manitoba and New Brunswick require instead that the research be “of sufficient importance to outweigh the intrusion into privacy that would result from the disclosure” of personal health information, and the Saskatchewan legislation provides that “the potential benefits of the research project clearly outweigh the potential risk to the privacy of the subject individual”: MB PHIA, ibid; NB PHIPAA, ibid; SK HIPA, ibid.

81 Alberta, Ontario, Saskatchewan, Manitoba, British Columbia, New Brunswick, and Newfoundland.

82 See generally supra, note 75. Recent personal health information access and privacy protection legislation in British Columbia vests the responsibility for review of research protocols requiring disclosure in a Data Stewardship Committee (DSC) made up of members drawn from a wider range of stakeholders than traditional research ethics review committees, and members will receive remuneration for their services. See generally BC E-Health Act, supra note 75, ss 14, 15.

83 AB HIA, supra note 75, s 50(1)(b).
delivery of health services, or improvements in health system management.\textsuperscript{84}

Other provinces do not provide similarly detailed criteria for interpreting public interest.

The public interest objective that provides the basis for a privacy override must also be “significant”, “compelling” or “of sufficient importance.”\textsuperscript{85} While the statutes provide no further explanation of these terms, interpretative clues abound in case law and privacy adjudications. Below, we highlight a few examples.

In Ontario Information and Privacy Commissioner (ON IPC) Order P-984,\textsuperscript{86} Adjudicator Holly Big Canoe considered the meaning of the phrase “compelling” in the wording of the public interest override provision in Ontario’s FIPPA, and concluded as follows:

‘Compelling’ is defined as ‘rousing strong interest or attention’... [T]he public interest in disclosure of a record should be measured in terms of the relationship of the record to the Act’s central purpose of shedding light on the operations of government. In order to find that there is a compelling public interest in disclosure, the information contained in a record must serve the purpose of informing the citizenry about the activities of their government, adding in some way to the information the public has to make effective use of the means of expressing public opinion or to make political choices.\textsuperscript{87}

To summarize, in the context of Ontario’s FIPPA, the public interest basis for a privacy override should reflect the aims of the governing legislation and relate to

\textsuperscript{84} Ibid, s 50(2).
\textsuperscript{85} Actual language or term used varies by province.
\textsuperscript{86} Order P-984 (28 August 1995).
\textsuperscript{87} Ibid. See also In the Matter of an adjudication under s 62, requested by [G.R.] on April 22, 1996 (20 June 1997) Adjudication Order No 3, online: BC IPC <http://www.oipc.bc.ca> [Adjudication Order No 3], where Madam Justice Levine found that the word “clearly” in s 25 of the BC FIPPA (the equivalent provision to s 23 of the ON FIPPA) meant “[o]bvious, beyond reasonable doubt; perspicuous; plain.”
matters that the general public would have a strong interest in knowing about.\textsuperscript{88}

For example, in Ontario IPC Order PO-2516,\textsuperscript{89} the parents of a suicide victim claimed there was a compelling public interest in the disclosure of police investigation reports (which included witnesses’ personal information) about the death of their son. According to the parents, the public interest basis lay in the public’s right to know the true circumstances of their son’s death, which allegedly occurred in the presence of four police officers. They also claimed the requested information was necessary to refute the public attribution of the cause of death to suicide, and that police opposition to disclosure created suspicion and was likely to hurt public confidence in the administration of justice. The Attorney General of Ontario opposed the claim, citing a public interest in non-disclosure that was necessary to protect the integrity of police operations and ensure an environment in which an independent investigative body could review the actions of the police officers involved. Adjudicator Holly Big Canoe found that the appellants’ interest in disclosure was of a purely private nature, and held that “[a] public interest does not exist where the interests being advanced are essentially private in nature.”\textsuperscript{90} She also noted that her decision would have been different if “a private interest in disclosure raises issues of more general application.”\textsuperscript{91}

Likewise, in the above-discussed ON IPC Order P-984, the adjudicator rejected a claim for public interest disclosure of records relating to hiring of a

\textsuperscript{88} Order P-984, supra note 86. See also Clubb, supra note 78 at 264, where Melvin J noted that the term “public interest” in s 25(1)(b) of the BC FIPPA “cannot be so broad as to encompass anything that the public may be interested in learning...[and] is not defined by the various levels of public curiosity.”

\textsuperscript{89} Order PO-2516 (30 October 2006) (ON IPC), online: ON IPC <http://www.ipc.on.ca>.

\textsuperscript{90} Ibid. at 7.

\textsuperscript{91} Ibid.
contractor to establish a Local Area Network because the requested records would not “contribute in any meaningful way to the public’s understanding of the activities of government.”

In British Columbia, the statutory provision that allows information custodians to disclose information in the public interest has also been interpreted as requiring disclosure of information that is of interest to “the public at large [or to] a group of individuals.” In one case, for example, the adjudicator refused to apply the public interest override to order disclosure of records that were shown to be of interest only to the parties involved in the application.

The Privacy Commissioner of Alberta reached a similar conclusion in a 1996 adjudication concerning an application for a fee waiver on grounds that the requested disclosure was in the public interest. Ruling on the application, the Commissioner stated:

It is possible to have the term “public” apply to everyone (“the public good”) and to anyone (John or Jane Public who are the objects of government programs and policies). Similarly “interest” can range between individual [curiosity] and the notion of interest as a benefit, as in a collective interest in something. The weight of public interest will depend on a balancing of the weights afforded “curiosity,” “benefit” and “broad” versus “narrow” publics. Where an access request relates to a matter that is of “interest” in both the sense of curiosity and benefit and the relevant “public” is broad, the case for removing all obstacles to access is very strong. So a matter that is the subject of curiosity to the larger public and also relates to a benefit to the broad public would present a very strong case for the waiver of fees. A matter which is of curiosity to many but affects no general benefit would present a less compelling case. Similarly, a matter that affects a benefit but in which few citizens are interested may present a less compelling case. In the less compelling cases, the importance of respecting the integrity of the legislated fee

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92 Order P-984, supra note 86.
93 Adjudication Order No 3, supra note 87.
94 Adjudication Order No 3, supra note 88.
structure could outweigh the public interest dimension.95

Subsequent orders from privacy adjudications in the Province of Alberta also provide useful guidance. For example, in Alberta IPC Order F2006-032,96 Adjudicator Christina Gauk outlined comprehensive criteria for assessing whether a record relates to a matter of public interest (see Box A),97 including factors such as the extent to which the records contribute to transparency and accountability in government and to public understanding and debate, and the applicant’s motivation for seeking public interest disclosure.

Lastly, the provision in Alberta’s FIPPA allowing disclosure of information about risk of significant harm to public safety, public health or the environment has been interpreted as imposing ”a statutory obligation on the head of a public body to release information of certain risks under ‘emergency-like’ circumstances (i.e., ‘without delay’).”98 Adjudicators have stated that the public interest override “must be defined narrowly”99 and can only apply to disclosure where there is “some actual risk…[or] some evidence that the harm in question is significant.”100

b) Public interest determinations and the balancing approach

Before granting access to protected information on public interest grounds, a custodian or designated decision-maker must balance the specific public interest consideration permitting disclosure with the general public interest in

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95 Order 96-002 (21 March 1996) (AB IPC) at 15-16.
97 This is a revision of earlier criteria formulated in Order 96-002, supra note 94. The revised criteria have been applied in Order F2010-004 (6 July 2010) (AB IPC), Order F2010-005 (13 July 2010) (AB IPC), and Order F2012-16 (11 July 2012) (AB IPC).
98 Order 98-011, supra note 74. See also Order F2012-14 (29 June 2012) (AB IPC), online: AB IPC <http://www.oipc.ab.ca>.
100 Ibid at 17-18.
protecting affected privacy interests. Applicable statutory rules,\textsuperscript{101} judicial precedents and administrative law rulings support this interpretation. In \textit{Dagg v. Canada (Minister of Finance)}, for example, Justice LaForest observed that “the \textit{Access to Information Act} and \textit{Privacy Act} have equal status”\textsuperscript{102} and that “Parliament did not intend access to be given preeminence over privacy.”\textsuperscript{103} He added further that “the collective purpose of...[access to information and privacy] legislation is to provide Canadians with access to information...without unduly infringing individual privacy.”\textsuperscript{104} This balancing approach has also been endorsed by dicta in lower court decisions\textsuperscript{105} and provincial privacy

\textsuperscript{101} Order PO-1779 (5 May 2000) (ON IPC): In all the circumstances, based on the very compelling nature of the public interests that are at stake, and subject to a number of exceptions to protect personal privacy, I am of the view that the compelling public interest in disclosure of the records at issue clearly outweighs the purpose of the section 21 exemption, including the important public policy basis for that exemption relating to the protection of individual privacy. See also Tom Mitchinson, “‘Public Interest’ and Ontario’s Freedom of Information and Protection of Privacy Act” (lecture to British Columbia Law Society’s Continuing Education Program, 16 February 2001), online: ON IPC <http://www.ipc.on.ca>.

\textsuperscript{102} Dagg, supra note 5 at para 55 (LaForest J, dissenting). The majority (per Cory J) concurred on this point. \textit{Ibid} at para 1.

\textsuperscript{103} \textit{Ibid} at para 51.

\textsuperscript{104} \textit{Ibid} at para 97. See also \textit{HJ Heinz Co of Canada v Canada (Attorney General)}, 2006 SCC 13, [2006] 1 SCR 441 at paras 26, 31, where the Supreme Court of Canada noted: The intimate connection between the right of access to information and privacy rights does not mean, however, that equal value should be accorded to all rights in all circumstances. The legislative scheme established by the \textit{Access Act} and the \textit{Privacy Act} clearly indicates that in a situation involving personal information about an individual, the right to privacy is paramount over the right of access to information, except as prescribed by the legislation.

... It is apparent from the scheme and legislative histories of the \textit{Access Act} and the \textit{Privacy Act} that the combined purpose of the two statutes is to strike a careful balance between privacy rights and the right of access to information. However, within this balanced scheme, the Acts afford greater protection to personal information. By imposing stringent restrictions on the disclosure of personal information, Parliament clearly intended that no violation of this aspect of the right to privacy should occur.

\textsuperscript{105} In \textit{Ontario Hydro v Mitchinson}, [1996] OJ No 4636 (Div Ct), leave to appeal refused [1997] OJ No 694 (CA), the Ontario Divisional Court noted that, in deciding whether there is a compelling
adjudications. In Ontario IPC Order P-1398,\textsuperscript{106} for example, a journalist relied on the public interest override in Ontario Freedom of Information and Protection of Privacy Act to challenge the refusal by the Minister of Finance to grant access to records relating to “all documents on the economic, social & Ontario budget impacts of Quebec independence compiled since January 1, 1995.” Ruling on the challenge, Inquiry Officer John Higgins stated:

If a compelling public interest is established, it must then be balanced against the purpose of any exemptions which have been found to apply. Section 23 recognizes that each of the exemptions listed, while serving to protect valid interests, must yield on occasion to the public interest in access to information which has been requested. An important consideration in this balance is the extent to which denying access to the information is consistent with the purpose of the exemption.\textsuperscript{107}

The public interest override in British Columbia’s FIPPA has similarly been interpreted as requiring “an assessment of the public interest in disclosure versus the public interest in nondisclosure.”\textsuperscript{108}

The foregoing review indicates that the legal threshold for the public interest override is generally high and will only permit disclosure of matters that address the aims of governing legislation and/or are of established relevance to a general or significant proportion of the public. Existing interpretations also emphasize a

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\item public interest, it is necessary to “take into account the public interest in protecting the confidentiality” of the information. \textit{Ibid} at para 1.
\item Order P-1398 (27 May 1997) (ON IPC), upheld on judicial review, \textit{Ontario (Ministry of Finance) v. Ontario (Information and Privacy Commissioner)} (1999), 118 OAC 108 (CA).
\item \textit{Ibid}. See also Order PO-2224 (9 January 2004) (ON IPC), where, the adjudicator, dealing with a refusal by Ontario’s Ministry of Health and Long-Term Care to disclose records relating to assessment of diagnostic clinics, held that the public interest override in the Ontario FIPPA requires a consideration of “both the existence of any compelling public interest in disclosing the records and any public interest in keeping them confidential.” See also Order P-984, \textit{supra} note 86, where the adjudicator held that, once a compelling public interest is established, “it must be balanced against the purpose of the exemption which has been found to apply”, keeping in mind “the principle of severability and the extent to which withholding the information is consistent with the purpose of the exemption.”
\item See Adjudication Order No 3, \textit{supra} note 87.
\end{itemize}
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narrow reading of relevant statutory provisions, invoking the override only in circumstances where the information sought will address actual or immediate rather than speculative concerns, and balancing its likely effects with the public interest in protecting privacy.109

While it seems clear that the open access and consent policies discussed above may legitimately be justified by reference to the public interest in facilitating research that is useful or beneficial to members of the public, our review of Canadian legal principles also makes clear that public interest justifications affecting privacy interests attract real legal obligations, and cannot be used merely as rhetorical flourish or without due consideration of protected privacy rights and interests. Where public interests that affect privacy concerns are invoked in policy development and implementation, a legal obligation exists to ensure that the public interest in research is truly compelling and of pressing relevance to established public aims, and that the corresponding public interest in privacy protection is addressed and given equal consideration. It is essential that privacy be viewed properly—as a public interest in its own right—rather than just a hurdle that must be overcome to promote other public interests (e.g., public benefits accruing from open access policies). Privacy considerations should be built into genetic research policies from the conception stages, rather than as an afterthought appended to an existing regulatory framework or as a response to privacy threats or violations. Additionally, the expansion of publicly accessible

109 Protection of individual privacy is not just a public interest objective, but also a fundamental value that is protected by the Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11, in the right to be free from unreasonable searches and seizures. See Hunter v Southam Inc, [1984] 2 SCR 145; 11 DLR (4th) 641.
databases containing identifying personal information means that “privacy risks
must be assessed in this broader context, not only within the narrow confines of
one [research] project.”

In promoting public interest objectives that ease logistical or practical
hurdles to genetic research, policy deliberations should also give equal or
corresponding consideration to the degree to which traditional consent norms
serve the public interest in privacy protection. The deliberative process, which is
likely to be based on case-by-case assessment of conflicts between research
practicalities and consent principles, should reflect appropriate balancing of the
public interest in privacy with the public interest in genetic research. Such
balancing should take into account the sensitive nature of genetic information
and the unique implications of inappropriate disclosure for both donors of
biological material and their genetic kin. Indeed, Canadian research ethics
guidelines currently require “researchers and REBs [to] ensure that an
appropriate plan is in place for managing information” revealed through genetic
research and its implications for participants and their biological relatives.
Similarly, evidence indicates that Canadians believe genetic information should
attract extra privacy protection. In assessing the public interest in this context,

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110 Kaye, supra note 8 at 424.
111 P A Roche & G J Annas, “Protecting Genetic Privacy” (2001) 2 Nat Rev Gen 392; Amy
112 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
113 Timothy Caulfield, “Biobanks and Blanket Consent: the Proper Place of the Public Good and
Public Perception Rationales” (2007) 18 King’s LJ 209 at 221-22.; Pollara Research and
Earnscliffe Research and Communications, supra note 69 at 9; D Kaufman et al, “Public Opinion
about the Importance of Privacy in Biobank Research” (2009) 85 Am J Hum Genet 643. However,
the notion that genetic information is “unique” or different from other personal or health
information is contested in the literature: see e.g. Ken M Gatter, “Genetic Information and the
the impact of the sensitive nature of this information on the expectations and behaviours of the public should also be considered. For example, many people are reluctant to undergo genetic testing, because they fear that the information may be disclosed to third parties, such as employers or insurance companies.114 Public trust in science and genetic research may be undermined by privacy violations, leading to a decrease in public participation and investment in this type of research.115 A final factor that should be taken into account in balancing public interests is the fact that the benefits served by genetic research have not fully materialized and are not likely to be realized in the near future.116 The foregoing observations indicate that public interest determinations in this context require a good working knowledge of applicable legal rules and of the unique and general privacy risks and challenges associated with the use, disclosure and sharing of genetic information. These matters, in turn, arguably demand dedicated mechanisms charged chiefly with responsibilities of balancing competing public interests in the health research arena, monitoring emerging privacy concerns flowing from technological advances and fashioning appropriate

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responses to such concerns.

Given that the responsibility for making public interest determinations in the context of health research currently falls to institutional REBs, one must inquire into whether they are properly placed to perform these roles.

c) The role of REBs in health-related public interest determinations

In Canada, the composition of biomedical research REBs does not specifically include a privacy law expert, but does include at least one member knowledgeable in law and ethics respectively. However, the mandated size and composition of the Boards are a minimum requirement. Institutions therefore have the flexibility to appoint additional members to fulfill capacities in specified areas, including law and ethics. While this approach allows REBs room for dedicated or as-needed expertise in privacy matters, it is doubtful that it will be employed in practice to retain a privacy expert to fill the mandatory law position or a gap in expertise, unless of course in the highly unlikely event that research protocols requiring such expertise are the central focus of a particular REB. More generally, the fact that REBs are primarily composed of members affiliated with the institution that appointed them and are sometimes involved in the research protocols they review raises questions about whether they are sufficiently at arm’s length to implement policies that may affect research progress.

Furthermore, REBs are notoriously overworked and chronically underfunded. Members usually serve on a volunteer basis, in addition to

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117 TCPS, supra note 111, art 6.4.
118 Ibid.
119 Kathleen C Glass, “Questions and Challenges in the Governance of Research Involving Humans: A Canadian Perspective” in Duff R Waring & Trudo Lemmens, eds, Law and Ethics in
various primary work responsibilities. The scope of their involvement in the REB also involves fairly extensive and ongoing familiarity with numerous research ethics, laws, policies, and guidance documents. In a sense, it takes “a jack of all trades” rather than a specialist to serve on an REB. These structural problems may also pose challenges to recruiting appropriate experts to address niche issues and concerns.

Lastly, REBs have also been criticized for having “ethical tunnel vision”, a term that describes a situation where ethics oversight bodies simply follow and apply the procedures and standards set out in ethical guidelines without reflecting on issues raised by and in their work. As one commentator explains, “the ethics review process by the REB has come to be, in the minds of the major institutional actors and their constituents, a surrogate for a comprehensive ethical approach to research involving human subjects.” A characteristic practice in this regard is when comprehensive ethical review is replaced by “bureaucratic process[es]” such as reviewing consent forms. As Michael McDonald notes:

[E]thics is funnelled into a bureaucratic process, and the process itself is reduced to a bare minimum. That bare minimum consists of the tangible parts – consent forms and other items, like adverse incident reports. Harms are reduced to simple measures of pain, morbidity and mortality. An important general result of this funnelling and narrowing down of ethical concerns is that important issues are missed at all levels and at all stages. For example, the

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121 Ibid.
123 Hirtle, *supra* note 117 at 144, 150; McDonald, *supra* note 121 at 296-97.
focus on consent forms tends to distract attention from the realities of consent – that for example, many subjects neither heed nor even read consent forms.\textsuperscript{124}

To summarize, these critiques raise doubts regarding whether REBs are well positioned to undertake substantive review functions, especially ones that involve significant application of and deliberation on statutory rules and areas of specialized knowledge, such as public interest determinations.

d) \textit{Data Access Committees as an alternative approach?}

Given the structural and capacity problems with REB involvement in making privacy-related decisions, an alternative strategy may be to establish data access committees specifically designed to tackle privacy matters in the context of health research. The composition of such committees should include experts in privacy and access to information law and in relevant areas of research, as well as independent members. The committees can also be positioned to tackle policy development and reform functions, including monitoring developments in health research and formulating model policy.

British Columbia adopted this approach in its recent health information legislation, which primarily governs the collection, use and disclosure of information held in “health information banks” (defined as any database containing “recorded information about an identifiable individual that is related to the individual's health or the provision of health services to the individual”

\textsuperscript{124} McDonald, \textit{ibid} at 299.
collected and used for a purpose identified in the Act).\textsuperscript{125} The Act, which was enacted in 2008, establishes and empowers a Data Stewardship Committee (DSC) to review requests for and authorize the disclosure of protected health information for health research purposes. The committee is also charged with broad powers to “establish policies and procedures respecting the disclosure of information” under the Act, and to make recommendations to the Minister against the issuance of disclosure directives which authorize a person or persons to disclose personal health information held in a health information bank.\textsuperscript{126} Most relevant to this paper, the DSC is empowered to make determinations regarding when it is in the public interest to disclose protected information for a health research purpose.

The composition of the DSC includes mandatory representation from relevant government ministries, regional health boards, provincial health services authority, professional medical, pharmacy and nursing colleges, as well as a health researcher, a pharmaceutical researcher and up to three public representatives.\textsuperscript{127} The Act also allows for the appointment of two more unspecified members. This membership structure allows flexibility in shaping and altering the composition of the Committee to include expertise in any area of pressing significance. Another noteworthy feature of the DSC is that unlike REBs, the Act authorizes the Minister to pay remuneration to its members for their service and to reimburse "reasonable and necessary travel and out of

\begin{footnotesize}
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\item[126] \textit{Ibid}, ss 11-13.
\item[127] \textit{Ibid}, s 12.
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pocket expenses”. A major criticism of this approach is that it will create another level of research oversight in an already largely bureaucratized governance system, thus burdening researchers with more paperwork and rules. Second, while a DSC model would likely apply to all personal health information, given the public’s heightened concern in ensuring genetic privacy, genetic information might receive extra scrutiny, thus giving the impression that issues and concerns emerging in this area deserve unique oversight and contributing to the “exceptionalization” of genetics, which may result in overly strict regulation of the field. While these criticisms do raise genuine concerns, we do not think regulatory inaction or leaving matters “as they are” offer any genuine solution to the issues raised in this paper. Besides, several strategies could be adopted to ease the concerns inherent in both criticisms. One such strategy is structural; a national data access committee, similar to the Stem Cell Oversight Committee, could be established to handle only research protocols identified by REBs as engaging unique privacy challenges. Another strategy is to set up provincial data access committees that monitor institutional data access policies and periodically review REB public interest determinations to ensure compliance and offer guidance for future determinations. Data access committees can also serve in a secondary oversight role by directing REB action in this area rather than direct involvement in the review of research protocols.

4. Conclusion

128 Ibid, s 12(4).
129 The Stem Cell Oversight Committee is a national body created to conduct ethical review of research funding applications dealing with human pluripotent stem cell research: Canadian Institutes of Health Research, Terms of Reference – Stem Cell Oversight Committee (11 November 2009), online: CIHR <http://www.cihr-irsc.gc.ca>.
Genetic research may result in significant health, economic and other societal benefits. Recognizing this potential, policy makers have sought, rightly so, to promote the research as a public good. In hopes of realizing these benefits, policies designed to encourage and advance this research, such as open access policies and the relaxation of traditional informed consent standards, have been embraced by both policymakers and the research community. While the view that it is in the public interest to promote and facilitate genetic research is supported by Canadian jurisprudence, there is corresponding support for and emphasis on promoting and protecting the public interest in individual privacy. However, the latter objective is not reflected or is understated in existing genetic research policies, a situation that minimizes both the value of robust privacy protections and the considerable risk of privacy invasions in this context.

As genetic research moves forward, constructive governance reforms, such as the inclusion of persons with appropriate privacy expertise in the research review and policy development process, are needed to ensure adequate privacy protection and to maintain the legally required balance between vital public interests in research and in privacy. Such reforms will also impact positively on the progress of and public trust in genetic research by ensuring that activities and developments in the field are not compromised by a lack of commitment to individual privacy, or a lack of attention to privacy issues and concerns.
Box A: Factors guiding public interest determinations in the context of Alberta privacy legislation.
The following is quoted from Order F2006-032 (2 March 2007) (AB IPC), online: AB IPC <http://www.oipc.ab.ca>.

1. Will the records contribute to the public understanding of, or to debate on or resolution of, a matter or issue that is of concern to the public or a sector of the public, or that would be, if the public knew about it? The following may be relevant:
   a. Have others besides the applicant sought or expressed an interest in the records?
   b. Are there other indicators that the public has or would have an interest in the records?

2. Is the applicant motivated by commercial or other private interests or purposes, or by a concern on behalf of the public, or a sector of the public? The following may be relevant:
   a. Do the records relate to a conflict between the applicant and government?
   b. What is the likelihood the applicant will disseminate the contents of the records?

3. If the records are about the process or functioning of government, will they contribute to open, transparent and accountable government? The following may be relevant:
   a. Do the records contain information that will show how the
| **a.** Government of Alberta or a public body reached or will reach a decision? |
| **b.** Are the records desirable for the purpose of subjecting the activities of the Government of Alberta or a public body to scrutiny? |
| **c.** Will the records shed light on an activity of the Government of Alberta or a public body that have been called into question? |
### Table 1: Examples of public interest objectives, by province

<table>
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<tr>
<th>Province</th>
<th>Example</th>
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<tbody>
<tr>
<td><strong>Ontario</strong></td>
<td>There is “compelling public interest” in information relating to:</td>
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<td>- “the integrity of the criminal justice system” (Order PO-1779);</td>
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<td>- public safety and nuclear facilities (Order P-1190, upheld on judicial review in <em>Ontario Hydro v. Ontario (Information and Privacy Commissioner)</em>, [1996] OJ No 4636 (Div Ct), leave to appeal refused [1997] OJ No 694 (CA); Order PO-1805);</td>
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<td>- “safe operation of petrochemical facilities” (Order P-1175) or “the province’s ability to prepare for a nuclear emergency” (Order P-901);</td>
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<td>- “contributions to candidates for [municipal] office” (<em>Gombu v Ontario (Assistant Information and Privacy Commissioner)</em> (2002), 59 OR (3d) 773);</td>
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<td>- “health or safety of children” (<em>Clubb v Saanich (District)</em>, [1996] 46 CR (4th) 253); and</td>
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<td>- “the integrity of the lottery”(Order PO-3017)</td>
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<td></td>
<td>No “compelling public interest” where:</td>
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<td>- “another public process or forum has been established to address public interest considerations” (Orders P-123/124, P-391, M-539, MO-1901);</td>
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<td>- the disclosure that has occurred sufficiently addresses public interest concerns (Orders P-532, P-568);</td>
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<td>- “a court process provides an alternative disclosure mechanism, and the reason for the request is to obtain records for a civil or criminal proceeding” (Orders M-249, M-317, MO-1901); and</td>
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<td>- “there has already been wide public coverage or debate of the issue, and the records would not shed further light on the matter” (Order P-613, MO-1901).</td>
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<td><strong>British Columbia</strong></td>
<td>A public interest exists where:</td>
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<td>- financial information “relates to a publicly funded institution that is clearly a public body within the meaning of the” <em>BC FIPPA</em> (<em>Tromp v. British Columbia (Information and Privacy Commissioner)</em>, 2000 BCSC 598); and</td>
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<td>- the information would permit a representative plaintiff to contact people with class action claims (<em>Dalhuisen (Guardian ad litem of) v. Maxim's Bakery Ltd.</em>, 2002 BCSC 580).</td>
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</table>
1146, 4 BCLR (4th) 196, leave to appeal granted 2002 BCCA 541).

**No public interest where:**
- information relates merely to a “shift in public policy” (Order 02-38);
- information “add[s] little or nothing…to that which is already known” (Order 02-38);
- there is “no urgent and compelling need” for disclosure or no “element of temporal urgency” (Order F12-04; Order 02-38; Order F07-04; Order F09-04);
- the information does not “facilitate effective use of various means of expressing public opinion and making political choices” (Order 02-38; Order F07-23); or
- the information is sought to “test[] the accuracy or truthfulness of statements made…by public figures”, which is not urgent or compelling (Order F07-04).

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<tr>
<th>Alberta</th>
<th>A public interest exists where:</th>
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<td>information relates to “accident reports concerning elevators and escalators” and thus public health and safety (Order 97-001).</td>
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**No public interest where:**
- “emergency-like circumstances” do not exist because the applicant is aware of the risk (Order 97-009);
- The information (regarding courthouse security) does not relate to the interests alleged (“the ability of Albertans to visit courthouses and to a risk to public safety”) (Order F2010-004);
- the applicant merely “asserts interest in the information” (Order 97-018); or
- the risk of harm has passed and suggestions that future incidents could pose a risk are “too speculative” (Order F2012-03).