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DATA SHARING, BIOBANKS AND INFORMED CONSENT: A RESEARCH PARADOX?

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Population biobanks are research facilities that store human biological material and health data of thousands of participants to facilitate research in the field of personalized medicine. To achieve this goal, biobanks usually collect samples and data from research participants through the process of broad consent. This type of research consent request permission to use data and biological samples collected from a wide range of research projects that are not specifically identified in the consent form (e.g. for genetic research). This article aims to determine if the trend supported by research funding agencies, to require broad consent from biobank participants, meets current Canadian legal and ethical standards. Based on our research, it appears of paramount importance that the requirements of funding agencies could be better harmonized with the current legal and ethical framework. The lack of synchronization identified could have negative impacts on research and the realization of legal objectives. Ideally, rules governing consent in this area of research will have

Les biobanques populationnelles sont des infrastructures de recherche qui conservent le matériel biologique humain et les données de santé de milliers de participants pour faciliter la conduite de la recherche dans le domaine de la médecine personnalisée. Pour atteindre leurs objectifs ces biobanques recueillent généralement des échantillons et des données sur les participants à la recherche par l'entremise d'un processus de consentement large. Ce type de consentement à la recherche requiert la permission d'utiliser les données et le matériel collectés dans un large ensemble de projets de recherche qui ne sont pas identifiés de façon spécifique dans le formulaire de consentement (ex. pour la recherche en génétique). Cet article a pour objectif d'identifier si la tendance soutenue par les organismes subventionnaires de la recherche à requérir un consentement large des participants aux projets de biobanques répond aux normes juridiques et éthiques en vigueur au Canada. À la lumière de nos recherches, il appert de toute première importance que les exigences des organis-

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to evolve in order to better respond to the objectives and challenges of contemporary biomedical research. Meanwhile, funding agencies involved in biobank research should make a greater effort to reconcile their scientific requirements with current ethics and legal rules.

mes subventionnaires soient mieux harmonisées avec le cadre juridique et éthique en vigueur. Le manque de synchronisation identifié pourrait nuire à la recherche et à l'atteinte d'objectifs légaux. Idéalement, les règles régissant le consentement dans ce domaine de recherche devront évoluer pour mieux répondre aux objectifs et enjeux de la recherche biomédicale contemporaine. En attendant, les organismes subventionnaires impliqués dans la recherche avec les biobanques devront faire un plus grand effort pour concilier leurs exigences scientifiques avec les règles de droit et d'éthique présentement en vigueur.

Introduction

Large-scale population biobanks, which store human biological material and link health data to environmental and demographic information for use in biomedical research, are emerging as a promising research tool in many countries around the world.[1] These biobanks promise to be of significant benefit to the development of personalized medicine, since genomic and phenotypic variation across populations must first be catalogued before the features of a given disease can be recognized in individuals.[2] The vast amounts of data currently being collected and generated by population biobank projects are enabling researchers to elucidate the relationships between environment, socioeconomic status, diet, education, access to healthcare, gender, ethnicity, genetics, and health that in many instances contribute to disease. With sufficient biospecimens and effective governance structures, these biobanks have the potential to serve as valuable resources facilitating research on health and disease for decades to come.[3]

Governments, funding bodies, and scientists have suggested that the more researchers have access to biobank data and materials, the more quickly the biomedical advances promised by biobanks can be achieved.[4] Accordingly, researchers often ask research participants contributing biological material and data to biobanks to provide broad consent to research. Subject to ongoing ethics review, broad consent grants the original researchers and sometimes future researchers as well permission to use individuals' materials and data in a wide range of future research projects that are unknown at the time of subject recruitment. While this practice maximizes the value of biobanks by making them accessible to a greater number of researchers for a greater number of projects, opponents of broad consent argue that it does not adequately inform subjects of the specific nature, risks, and benefits of the

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[1] See Timothy Caulfield & Bartha Maria Knoppers, "Consent, Privacy & Research Biobanks", Genome Canada GPS Policy Brief No 1 (26 January 2010), online: GC <www.genomecanada.ca/medias/pdf/en/GPS-Policy-Directions-Brief.pdf> at 1; Christopher Heaney et al, "The Perils of Taking Property Too Far" (2009) 1 Stanf Journal of Law, Science & Policy 46 at 47.

[2] See Krishanu Saha & J Benjamin Hurlbut, "Treat Donors as Partners in Biobank Research" (2011) 478 Nature 312 at 312.

[3] *Ibid*.

[4] See e.g. Wellcome Trust, "Sharing Research Data to Improve Public Health: Full Joint Statement by Funders of Health Research", online: WT <www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030690.htm>.

future research to which they are being asked to consent. Thus, according to these opponents, this type of broad consent meets neither the ethical nor legal requirements put forward to promote the respect of participants' autonomy.[5] The issue of whether broad consent is an ethically valid consent model to use in the context of biobank research has been widely debated in the academic literature in recent years, but no consensus has been reached.[6] Nor has there been a comprehensive review of relevant Canadian law to ascertain whether broad consent practices fulfill current legal requirements. Despite these issues, most active population biobanks in Canada seem to be acting on the presumption that broad consent is both a legally and ethically valid practice.[7]

In this paper, we seek to elucidate the legal and policy dimensions of consent in Canadian biobank research. By analyzing relevant legislation, jurisprudence, ethical guidelines, funding policies, and informed-consent documents from ongoing, large-scale Canadian population biobank projects, we determine that Canadian biobank researchers face a complex and often conflicting array of legal, ethical, and financial obligations. In particular, funding organizations that indirectly pressure biomedical researchers to adopt broad consent models through their "open-science" policies make it difficult for researchers to meet current legal and ethical requirements applicable to informed consent. Indeed, as we describe below, funders offer no practical advice on how to reconcile their data sharing and "open-science" policies with their informed consent requirements.

We will explore the issues raised by consent in Canadian large-scale population biobanks by first discussing the growing importance of data sharing in contemporary health research. In the context of biobanking, open data sharing is facilitated by obtaining broad consent from research participants who donate samples, so our discussion will segue into the notion of broad consent and how it differs from the traditional informed-consent model. Following this introduction to the benefits of data sharing and the debate around the ethical and legal status of broad consent, we will present the methodology and results of our review of relevant Canadian legislation and jurisprudence, research ethics guidelines, funding policies, and biobank consent

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[5] See Christian M Simon et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13:9 Genet Med 821 at 822.

[6] For a review of the literature on this topic, see Zubin Master et al, "Biobanks, Consent and Claims of Consensus" (2012) 9 Nat Methods 885.

[7] Refer to the section entitled "Consent Forms" for the evidence we have collected supporting this claim.

forms. In our discussion, we conclude that there is a tension between the current practice of large-scale population biobanks asking participants for broad consent (as required by funding policies) and the legal and ethical requirements of a more traditional informed consent. Though this tension can be lessened by mechanisms such as public engagement and more sophisticated biobank governance models, it will become apparent from our review that clarification of the legal and ethical thresholds for obtaining truly informed consent in the context of large-scale population biobanks, and in biomedical research in general, is needed.

I. Data Sharing

In recent years, the importance of data sharing to the advancement of health research has become increasingly well recognized. Since the late 1990s, several national and international statements have been made on behalf of a variety of stakeholders, including government representatives,[8] scientists[9], journal editors,[10] and research funders,[11] emphasizing a commitment to the rapid and open sharing of data in order to help maximize the public benefit to be gained from biomedical research. Though early statements focused on the pre-publication release of genomic data sets, stakeholders have since expanded their outlook to recommend that proteomic, metabolomic, chemical structure, and RNA interference data sets, as well as annotated clinical resources such as birth cohorts and tissue banks, be rapidly and openly shared in publicly accessible databases.[12] The recommendations made in these statements have subsequently been imposed on researchers by major health-research funding bodies, both public and private, including the Bill and Melinda Gates Foundation, Wellcome Trust, National Institute of

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[8] The White House, Office of the Press Secretary, Press Release, "Joint Statement by President Clinton and Prime Minister Tony Blair of the UK" (14 March 2000), online: National Archives <clinton4.nara.gov/WH/EOP/OSTP/html/00314. html>.

[9] Toronto International Data Release Workshop Authors, "Prepublication Data Sharing" (2009) 461 Nature 168.

[10] BioMed Central, "BioMed Central's Position Statement on Open Data (Draft)" (8 September 2010), online: BioMed Central <blogs.biomedcentral.com/bmcblog/files/2010/09/opendatastatementdraft.pdf>.

[11] Wellcome Trust, *supra* note 4.

[12] See e.g. Henry Rodriguez et al, "Recommendations from the 2008 International Summit on Proteomics Data Release and Sharing Policy: The Amsterdam Principles" (2009) 8:7 J Proteome Res 3689 at 3690.

Health, Canadian Institute of Health Research, UK Medical Research Council, and many others.[13]

The benefits of rapid, open data sharing in health research have been most clearly illustrated by the Human Genome Project. During the development of the entire draft human genome sequence, the data was shared on an ongoing basis, such that each sequence of 1000 base pairs was generally made public within 24 hours of being read. As a result of this rapid sharing, new information on 30 disease genes was published before the genome draft was even complete, representing many new insights and discoveries that were made much earlier than would otherwise have been achieved.[14]

In addition to the evident advantage of making fundamental research data and tools quickly available for general use, data-sharing models have been associated with a number of scientific, economic, and social benefits. With regard to science, open data sharing by its nature involves a significant degree of transparency. Consequently, it allows peer evaluation and validation of findings, thereby encouraging open, critical discussion of results and increasing the quality of scientific work overall.[15] In economic terms, open sharing of data reduces duplication, allowing researchers to share the financial burden of generating fundamental data and tools. Additionally, the standardization of sharing agreements arising from uniform data release policies reduces the need for costly and time-consuming case-by-case data-sharing negotiations.[16] Finally, open data sharing represents significant social benefits. Firstly, the transparency engendered by open access promotes public trust. This is particularly essential to projects such as biobanks, which rely on the altruistic participation of many thousands of individuals.[17] Secondly, it respects the normative claim that "research with human materials is valuable to all, … [and consequently] requires unhindered distribution of research materials to all qualified investigators… and the dissemination of its benefits to

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[13] See Jane Kaye et al, "Data Sharing in Genomics – Re-shaping Scientific Practice" (2009) 10 Nat Rev Genet 331 at 332; Wellcome Trust, "Signatories to the Joint Statement", online: WT <www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/Signatories-to-the-joint-statement/index.htm>.

[14] Toronto International Data Release Workshop Authors, *supra* note 9 at 168.

[15] Yann Joly, "Open Source Approaches in Biotechnology: Utopia Revisited" (2007) 59:2 Me L Rev 385 at 398.

[16] *Ibid* at 400-02.

[17] See Heaney et al, *supra* note 1 at 47.

humanity at large on just and reasonable terms."[18] The benefits of rapid, open data sharing are therefore substantial and may be key to ensuring the realization of the full clinical potential of the genomic revolution.

Data sharing can, however, create tensions for researchers, especially when it is required by funding organizations. Data sharing as an alternative to ownership and commercialization of research tools and genetic materials has received considerable attention in recent years.[19] Researchers need to be concerned with the ethical requirements imposed by various regulatory bodies. The fundamental normative obligation of respecting subject autonomy, as traditionally defined, is a particularly challenging issue in the context of data sharing.[20] Sharing data openly means that researchers cannot be aware, at the time they recruit subjects for research, of the full extent of future uses of the data those subjects provide, or of the psychosocial risks involved. This is particularly true in the context of biobanking, in which data and tissue samples are collected for the purpose of creating an accessible resource that any researcher may access. Given this indeterminacy, some argue that data sharing inhibits researchers from fully respecting subject autonomy, as it prevents the consent process – the primary locus of subject self-governance in the context of health research – from being sufficiently informed.[21] Thus, while broad consent supports a central purpose of biobanking insofar as it optimally allows for the open sharing of subject data and materials between researchers, there is a question as to whether it truly satisfies the current legal and ethical norms regarding consent. This is the issue with which we are primarily concerned.

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[18] Patrick L Taylor, "Research Sharing, Ethics and Public Benefit" (2007) 25:4 Nat Biotechnol 398 at 398, citing International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, version 1 (21 December 2006), online: ISSCR <www.isscr.org/docs/default-source/hesc-guidelines/isscrhescguidelines2006.pdf>.

[19] Jeremy de Beer, Richard Gold & Mauricio Guaranga, "Intellectual Property Management: Policy Issues and Options", Genome Canada GPS Policy Brief No 4 (August 2011), online: GC <www.genomecanada.ca/medias/pdf/en/Research_Policy-Directions-Brief.pdf> at 5-6.

[20] Timothy Caulfield, "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" (2007) 18 King's Law Journal 209 at 212-15.

[21] *Ibid*.

II. Consent

(For a description of different models of consent, see Table 1.)

In the context of biobanking, open data sharing is facilitated by broad consent. Broad consent describes a process in which subjects are asked to provide researchers with permission to use their data and biological samples for a wide range of research activities, such as genetic research. Though the terms are not uniformly defined in the literature, broad consent may be said to differ from blanket consent (also known as "open consent") in that there remains some minimal delimitation of what data and samples may be used for; for example, the consent may be limited to medical research on a particular condition such as cancer, or research on a particular population, such as children. Subjects are also often made aware that the specific future use(s) to which data and samples will be put must be approved by a designated oversight body or ethics committee, and must conform to the general principles governing the biobanking endeavor.[22] Under broad consent, biobankers are therefore free to maximize the utility of data and samples and can make them available to a variety of researchers, as long as the general aims and governing structure of the biobank, as described to subjects, are respected.

Broad consent appears to deviate from the hallmarks of informed consent as enshrined in case law, legislation, and research ethics.[23] Traditionally, respecting subject autonomy through consent is thought to require that decisions regarding whether or not to participate in research be informed by the relevant details of the specific research project, such as the identity of the researcher(s), the project objectives, the potential risks and benefits, the anticipated outcomes, and so on.[24] The concern with this traditional model, as alluded to above, is that it places significant limits on the realization of the benefits of data sharing that can otherwise be effectively achieved through biobanking. If biobanks are to serve as research platforms to be used over several decades for a variety of initiatives that are not fully known at the time of data and material collection, it is extremely difficult and impractical to provide subjects upon their enrolment with all the details needed to satisfy traditional consent norms. Recontacting subjects to provide information on each proposed study has been suggested as a way of respecting subjects' autonomy, but would likely be too expensive and time-consuming to provide a feasible solution to this chal-

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[22] Simon et al, *supra* note 5 at 822.

[23] Master et al, *supra* note 6 at 886.

[24] Mark Sheehan, "Can Broad Consent Be Informed Consent?" (2011) 4:3 Public Health Ethics 226 at 226.

lenge.[25] As an intermediate solution, several population biobanks have adopted ongoing consent mechanisms (e.x. CARTaGÈNE) that allow biobanks to re-contact the participants thus keeping the initial consent alive. These mechanisms can be used to ask new data/samples from the participants and to provide important updates regarding the biobank (thus making the participant's decision process more informed). The tension that exists between the significant scientific and social benefits to be gained from open data sharing, facilitated by broad consent, on one hand, and the requirements imposed by traditional informed consent, on the other, has engendered a growing body of academic literature arguing that the traditional informed-consent model is too restrictive and burdensome in the context of biobank research, and should therefore be amended.[26] However, even in the case of large-scale population biobanking, this proposal has not met with unanimous approval either in public opinion or among scholars.[27]

A recent literature review by Master et al (2012)[28] found that while there are many academic articles that favour a broad consent approach,[29] there is no consensus on the topic outside of the population biobank community. Those in favour of broad consent tend to argue that the great social utility and scientific value of biobanking and the absence of physical risks justify the alteration of consent norms they perceive as socially and technologically outdated. Seeking reconsent for each research project has been described as "extremely arduous or impossible,"[30] while the risks to donor subjects are ar-

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[25] Carlo Petrini, "'Broad Consent', Exceptions to Consent and the Question of Using Biological Samples for Research Purposes Different from the Initial Collection Purpose" (2010) 70:2 Soc Sci Med 217 at 217.

[26] Caulfield, *supra* note 20 at 213.

[27] Master et al, *supra* note 6 at 885, 887.

[28] *Ibid* at 887-88. It is important to note that a limitation of the study by Master et al is that they do not distinguish between different types of research in which broad consent is considered by the authors they cite. Nevertheless, their study provides a fairly comprehensive review of the debate around broad consent, which itself is not a uniformly used term. See also Bartha Maria Knoppers, Ma'n Zawati & Emily Kirby, "Sampling Populations of Humans Across the World: ELSI Issues" (2012) 13 Annu Rev Genomics Hum Genet 395.

[29] See e.g. Mats G Hansson, "Ethics and Biobanks" (2009) 100:1 Br J Cancer 8; Bartha M Knoppers & Rosario Isasi, "Stem Cell Banking: Between Traceablility and Identifiability" (2010) 2:73 Genome Med 1; Mats G Hansson et al, "Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?" (2006) 7:3 Lancet Oncol 266.

[30] Petrini, *supra* note 25 at 217

guably extremely small. In light of the analysis of benefits compared to burdens it would appear that broad consent might be justified. As long as privacy is protected and ethical oversight is in place, proponents argue that subjects should be allowed to consent to permitting biobanks to make future decisions for them regarding the data and samples they donate.[31]

On the other hand, those who argue against broad consent question whether consent that is not adequately informed can really be autonomous, and therefore legally and ethically acceptable.[32] Since, according to critics, consent by its nature presupposes the communication of complete and precise information, broad consent is said to undermine the meaning of this practice.[33] Allowing scientific goals to take precedence over individual rights is contrary to traditional bioethics norms, which developed in a context of human-subject research abuses.[34] These same opponents argue that even if public opinion data, which itself reflects a variety of preferences,[35] were to suggest a general acceptance of, or preference for, broad consent, this would not in itself justify overturning fundamental normative principles requiring that the interests of research subjects prevail over the interests of science and

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[31] Sheehan, *supra* note 24 at 231.

[32] See e.g. Timothy Caulfield, Ross EG Upshur & Abdallah Daar, "DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model" (2003) 4:1 BMC Med Ethics E1; Vilhjálmur Árnason, "Coding and Consent: Moral Challenges of the Database Project in Iceland" (2004) 18:1 Bioethics 27; B Hofmann, "Broadening Consent – and Diluting Ethics?" (2009) 35 J Med Ethics 125; David Hunter, "Letter: One-time General Consent for Research on Biological Samples: Autonomy and Majority Rules Have Been Misunderstood" (2006) 332 Brit Med J 665.

[33] Petrini, *supra* note 25 at 218.

[34] Caulfield, *supra* note 20 at 216.

[35] See e.g. David Wendler, "One-time Consent for Research on Biological Samples" (2006) 332 Brit Med J 544 at 546 (in favour of broad consent); Geraldine M McQuillan et al, "Consent for Genetic Research in a General Population: The NHANES Experience" (2003) 5 Genetics in Medicine 35 at 40 (in favour of specific consent); Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future* (30 November 2001), online: Ontario, Ministry of Health <www.health.gov.on.ca/en/common/ministry/publications/reports/geneticsrep01/genetic_report.pdf> (in a 2001 survey conducted in Ontario, "87% believed that consent must be given for each specific new research initiative for which a sample is to be used" at 17).

society.[36] The divergence of opinions surrounding this issue is reflected in international research ethics instruments, which also variably reject[37] or condone[38] a broad consent approach. Clearly, more in-depth investigations of what type of consent is ethically and socially acceptable in the context of biobanking, as well as a systematic analysis of legal requirements are needed.

III. Methodology

As there is no consensus in academic literature, public opinion data, or international research ethics instruments, the collection and analysis of additional empirical evidence can serve to advance the debate regarding consent in the large-scale population-biobanking context. To this end, we conducted a comparative, qualitative review of a variety of relevant documents, in order first to identify Canadian legal, ethical, and policy-imposed obligations of researchers in regard to consent for biobanking research and second, to compare these obligations to consent practices used by Canadian biobank researchers, as documented by their respective consent forms.

To identify Canadian legislation and jurisprudence relevant to the regulation of consent to health research and the use of personal health information, we searched legal resource databases such as Westlaw Canada, Quicklaw, HeinOnline, and HumGen, an international database of laws and policies concerning ethical, legal, and social issues in human genetics, using key terms such as "informed consent" and "medical research." We also searched provincial Ministry of Health websites for relevant legislation, and additionally consulted experts in medical and biotechnology law from various Canadian provinces. Finally, we referred to secondary sources, such as

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[36] World Medical Association, *WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Helsinki, Finland: WMA, 1964), online: WMA <www.wma.net/en/30publications/10policies/b3/> at para 6 [*Declaration of Helsinki*].

[37] See *Universal Declaration on Bioethics and Human Rights*, UNESCO General Conference Res 36, UNESCOOR, 32d Sess (2005), at art 6; Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Epidemiological Studies* (Geneva: CIOMS, 2008) at 2, guideline 5.

[38] Organization for Economic Co-operation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases* (OECD, 2009) at 10, best practices, section 4.6.

Halsbury's Laws of Canada[39] and *Canadian Health Law and Policy*[40] to ensure that relevant documents had been identified.

To research ethical guidelines discussing consent to health research, we again used HumGen, and also searched both the websites of Canadian federal and provincial governmental research oversight bodies, such as the Canadian Institutes of Health Research ("CIHR") and the Fonds de recherche du Québec – Santé ("FRQS"), and those of professional organizations, such as the Canadian College of Medical Geneticists () and the Réseau de médecine génétique appliquée. All documents providing ethical guidelines for obtaining consent for health research generally, and genetic research and/or biobanking specifically, were included. Similarly, to determine what requirements funding bodies impose on researchers in relation to data sharing, we searched the websites of major Canadian funding bodies such as CIHR and Genome Canada. Policies containing requirements imposed as a condition of funding that related to access or to sharing of research materials and data were included.

To gather data on how researchers are managing the various requirements imposed upon them in relation to consenting subjects, we collected informed-consent documents from major large-scale population biobanks in Canada. There are currently different categories of biobank projects in existence in Canada (eg. disease specific bioboanks, public health biobanks, collections of residual samples, the National DNA databank of Canada) each raising its own particular set of legal and ethical challenges. We chose to focus on population biobank projects as opposed to other endeavours, as the former represent the most recent trends in biobanking projects currently taking place in the field of genomics in Canada. Furthermore, because of their very nature, they are also the type of biobanks that are the most susceptible of collecting data for a broad range of purposes and of archiving it for extensive periods of time. By undertaking internet searches and consulting experts in the area, we identified biobanks representing both Canada's various regions and the nation as a whole. We obtained the model informed-consent documents used by these projects when recruiting subjects, and performed a qualitative analysis to determine the nature of the consent being requested. The conclusions that we drew from comparing the consent forms to the various normative guidelines are discussed below.

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[39] *Halsbury's Laws of Canada* (Markham, Ont: LexisNexis, 2006).

[40] Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds, *Canadian Health Law and Policy*, 3d ed (Markham, Ont: LexisNexis, 2007).

IV. Results

A. Legislation and Jurisprudence

Canadian law generally requires health care professionals and researchers to obtain informed consent from individuals before performing any health interventions or human subject research. This is the case both in the context of research involving human data and in that of research using human samples, although the legal regime applicable in both cases is slightly different. Both situations will be discussed below.

In clinical research, a consent based on anything but "precise information" has been found by the courts to be insufficient to provide the necessary elements of true and valid informed consent.[41] A "full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent",[42] as well as "information about … the specific risks"[43] including those that are "rare or remote"[44] must be communicated for consent to be considered informed.

This high threshold of disclosure is explained by a number of factors. Firstly, researchers and physicians have an obligation to respect the patient/participant's autonomy, dignity, and privacy in relation to his or her

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[41] For examples of cases where broad consent was found not to meet the informed threshold in clinical care, see e.g. *Pridham v Nash Estate* (1986), 57 OR (2d) 347, (*sub nom Pridham v Nash*) 33 DLR (4th) 304 (Ont H Ct J); *Brushett v Cowan* (1990), 83 Nfld & PEIR 66, 69 DLR (4th) 743 (Nfld CA). As Caulfield and Ries describe, " 'In *Pridham*, a patient signed a consent form agreeing to an abdominal procedure and "additional or alternative procedures as may be necessary or medically advisable during the course of such procedures.' The Court ruled that this language only permits a physician to carry out additional, *minor* procedures and specific patient consent must be obtained before engaging in additional serious or major interventions." (Timothy Caulfield & Nola M Ries, "Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context" (2004) 11 Health LJ Supplement 1 at 31, n 141).

[42] *Halushka v University of Saskatchewan* (1965), 53 DLR (2d) 436 at 444, 52 WWR 608 (Sask CA) [*Halushka*].

[43] Caulfield & Ries, *supra* note 41 at 31.

[44] *Weiss c Solomon*, [1989] RJQ 731 at 743, CCLT 280 ("risques… rares ou éloignés" [translated by authors]) [*Weiss*].

body and his or her personal health information.[45] Secondly, a non-standard medical treatment that occurs during clinical research is not considered to be for the (exclusive) benefit of the individual participant, but rather for the benefit of science,[46] which creates a risk of conflict of interest. This potential for a conflict of interest militates in favour of the patient/participant knowing the specific details of the project in order to protect his or her own interests.

In biobank research, other than a possible feeling of altruism arising from a contribution to the advancement of science, there are few, if any, direct benefits for the individual.[47] As in the case of clinical research, there is an obligation for biobank researchers to respect the participant's autonomy, dignity, and privacy with respect to his or her body and his or her personal and health information.[48] Because research platforms or longitudinal studies such as biobanks are even farther from the medical care end of the spectrum than clinical research, the disclosure obligation is arguably higher in this context than in the clinical research context.[49]

Two provinces have enacted specific legislation that regulates consent to research. In Québec, the *Civil Code of Québec* states that biological specimens may be taken for research purposes only with free and enlightened consent from participants,[50] which must be given in writing unless an ethics committee stipulates otherwise.[51] In Newfoundland, the *Health Research Ethics Authority Act* requires research to be authorized by research ethics boards ("REBs") applying either the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("*TCPS 2"*),[52] which provides

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[45] Patricia Kosseim & Megan Brady, "Policy by Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes" (2008) 2 McGill JL & Health 6 at 14.

[46] Caulfield & Ries, *supra* note 41 at 3, 7, 34.

[47] *Ibid* at 34.

[48] Kosseim & Brady, *supra* note 45 at 15.

[49] Caulfield & Ries, *supra* note 41 at 33; Edith Deleury & Dominique Goubau, *Le droit des personnes physiques*, (Cowansville (Qc): Yvon Blais, 2008) at 147.

[50] Arts 10, 11, 20, 22 CCQ. This reference to the CCQ and the subsequent ones refer to the latest version of the *Code* including the changes introduced by Bill 30, *An Act to amend the Civil Code and other legislative provisions with respect to research*, 1st Sess, 40th Leg, Québec, 2013 (assented to 14 June 2013), 2013, c 17.

[51] Art 24 CCQ.

[52] Interagency Advisory Panel on Research Ethics (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and

guidelines for obtaining informed consent to health research, or a similar guideline that has been approved by the Health Research Ethics Authority.[53] Elsewhere in Canada, consent to research is regulated predominantly by case law.[54] The Supreme Court of Canada has repeatedly indicated, on the grounds of autonomy and human dignity, that individuals should be able to make their own decisions about undergoing medical interventions.[55] There is, however, less case law addressing biomedical research.[56] In one of the two cases relevant to our discussion, *Halushka*, Justice Hall stated that "[t]he subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."[57] In *Weiss,* the second relevant case, Justice De Blois reiterated Justice Hall's position and stated that, "in the case of purely experimental research, the doctor must disclose [to the patient/research subject] all the known risks, even those that are rare or remote, and all the more so when they entail serious consequences."[58]

Although these decisions do not provide an explicit definition of what constitutes "full," "frank," "fair," and/or "reasonable" disclosure, they underscore that participants must be provided with the information necessary to allow them to freely and truly determine if they want to participate in the research prior to actually giving consent. The elements of disclosure may therefore include (a) facts related to the study/test, (b) probabilities, (c) opin-

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Social Sciences and Humanities Research Council of Canada), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 2d ed (2010), online: IAPRE <www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf> [*TCPS 2*]. See next section for further discussion of the *TCPS 2*.

[53] Health Research Ethics Authority Act, SNL 2006, c H-1.2, s 9(5).

[54] For an extensive discussion of the regulatory landscape and case law around consent in biomedical research, see Michael Hadskis, "The Regulation of Human Biomedical Research in Canada" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood, eds, *Canadian Health Law and Policy*, 4th ed (Markham, Ont: LexisNexis, 2011) 437 at 441-50, 468ff.

[55] See *Ciarlariello v Schacter*, [1993] 2 SCR 119, 100 DLR (4th) 609; *Starson v Swayze*, 2003 SCC 2002, [2003] 1 SCR 722, 225 DLR (4th) 385.

[56] Hadskis, *supra* note 54 at 469.

[57] *Supra* note 42 at 444.

[58] *Supra* note 44 ("en matière de recherche purement expérimentale, le médecin doit révéler tous les risques connus même rares ou éloignés et, à plus forte raison, si ceux-ci sont d'une conséquence grave" at 743 [translated by the authors]).

ions, (d) potential risks and effects associated with any stage of the research, and (e) inconveniences or discomforts related to the research.[59]

As alluded to above, the assessment in these cases of the type of information that is necessary to enable participants to freely determine whether they want to participate in research is based on the standard of what a "reasonable man might be expected to consider before giving his consent."[60] This idea of a "reasonable man" needs to take into account that the research participant is not an expert in the medical field or the study, and that he or she relies on the researcher's "special skill, knowledge and experience," which puts the researcher in a fiduciary position.[61] This fiduciary position, which requires the researcher to fairly and reasonably inform the research participant, stems from two sources. Firstly, it arises from the transposition of the duty owed by a physician to his patient in ordinary medical practice. This duty is made more exacting in the biomedical research context, where "there can be no exception to the ordinary requirements of disclosure" needed in order to enable research subjects to adequately judge the implications of participation.[62] Secondly, the fiduciary duty arises from a duty to ensure, at all times, the right of the research subject to safeguard his or her integrity, which is an ethical obligation arising from the *Declaration of Helsinki*.[63]

The obligation to obtain informed consent for research should be viewed in conjunction with more general privacy norms that cover the use of health information. This would apply to the collection and use of health data in the context of a biobank, in addition to the specific norms applicable to the use

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[59] *C.f. Halushka*, *supra* note 42 at 442-44; *Weiss*, *supra* note 44 at 740-43. In the context of population biobanks, it has been argued by some researchers that the information provided is consequent with the longitudinal nature of the research. According to this theory, the information provided is material and reasonable and thus the consent informed. Bartha Maria Knoppers, Ma'n H Abdul-Rahman & Karine Bédard, "Genomic Databases and International Collaboration", (2007) 18 King's Law Journal 291 at 305.

[60] *Halushka, supra* note 42 at 444; *Weiss*, *supra* note 44 at 742.

[61] *Halushka*, *supra* note 42 at 444; *Weiss*, *supra* note 44 at 741-42. A slight distinction can be made regarding the "reasonable" patient test in civil law and in common law. For more on this see *Pelletier v Roberge*, [1991] RRA 726, EYB 1991-63575 (REJB) (Qc CA), *Marcoux c Bouchard*, 2001 SCC 50, [2001] 2 SCR 726; Deleury & Goubau, *supra* note 49 at 119-20.

[62] *Halushka*, *supra* note 42 at 444; see also *Weiss*, *supra* note 44 at 742-43.

[63] See *Weiss*, *supra* note 44 at 741, 743; *Declaration of Helsinki*, *supra* note 36, arts 25-29.

of health data and human tissues in research described above. In Canada, apart from narrowly defined exceptions, personal health information can generally only be used for research purposes with the consent of the individual to whom it pertains.[64]

In Ontario, for example, individual personal health information generally may not be collected, used, or disclosed without the individual's consent.[65] Such consent must be knowledgeable, meaning that it must be reasonable in the circumstances to believe that the individual knows the purpose of the collection, use, or disclosure, and that they are able to give or withhold consent.[66] Nova Scotia's legislation uses similar wording, requiring express consent for the use of personal health information for the purpose of research, unless an REB determines that it is not required.[67] In the latter case, the information must be de-identified, confidentiality must be ensured, and it must be impracticable to obtain consent.[68] In Alberta, the collection and disclosure of individually identifying health information requires the informed consent of the individual who is the subject of the information.[69] Custodians of individually identifying health information may then use that information to conduct research or perform services to facilitate the research of others, as long as there is REB approval, which may require that researchers obtain individual consent.[70] Judicial decisions such as *McInerney v MacDonald*,[71] a civil case regarding a patient's access to her own medical files, support the position adopted by the federal and provincial legislatures. In the Supreme Court's judgment, Justice La Forest quoted a policy report stating that indi-

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[64] *Personal Information Protection and Electronic Documents Act,* SC 2000, c 5, ss 7(2)(c), (3)(f) (exceptions provided for "purposes that cannot be achieved without using the information, [when] the information is used in a manner that will ensure its confidentiality, it is impracticable to obtain consent and the organization informs the Commissioner of the use before the information is used") [*PIPEDA*].

[65] Personal Health Information Protection Act, SO 2004, c 3, s 29 [PHIPA].

[66] *Ibid*, s 18.

[67] *Personal Health Information Act*, SNS 2010, c 41, as amended by SNS 2012, c 31.

[68] *Ibid*, s 57.

[69] *Health Information Act*, RSA 2000, c H-5, ss 34 (with respect to disclosure), 20(b), 27(1)(d)(iv) (with respect to collection).

[70] *Ibid*, s 27(1)(d).

[71] [1992] 2 SCR 138, 93 DLR (4th) 415 [*McInerney*].

viduals have a "basic and continuing interest in what happens to [their personal health] information, and in controlling access to it."[72]

In conclusion, it is clear from Canadian legislation and jurisprudence that, to be valid, consent to health research must be voluntarily given by a capable person who has been thoroughly informed of the goals, risks, and benefits associated with the research.[73] However, jurisprudence and legislation relating to this topic is fairly sparse, which means that the precise quantity and quality of information that is necessary to ensure that consent is "informed" in a variety of contexts remains subject to debate. That said, it would appear that broad consent, as described above, may not meet the legal requirements in several Canadian provinces, in light of legislation such as the *Civil Code of Québec*, Newfoundland and Labrador's *Health Research Ethics Authority Act*,[74] and jurisprudence such as *Weiss*[75] indicating that extensive information is required for a participant's consent to experimental research to be considered informed.

B. Ethical Guidelines

Canada's national and provincial guidelines on consent to biomedical research generally require that subjects be substantively informed of the nature of the research to which they are consenting. The *TCPS 2*[76] is a prominent research ethics document, national in scope, which provides guidance on the process of informed consent. This document is a joint project of the primary three federal research funding agencies in Canada (CIHR, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council), that asserts that "the commitment to participation in research, including participation through the use of one's data or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed".[77] Accordingly, Article 3.2 of the *TCPS 2* states that "[r]esearchers shall provide to prospective participants, or authorized

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[72] Canada, *Privacy and Computers*, report of a Task Force established jointly by the Department of Communications and the Department of Justice (Ottawa: Information Canada, 1972) at 14. See also *R v Dyment* [1988] 2 SCR 417 at 429, 55 DLR (4th) 503 (on the importance of informational privacy).

[73] See Caulfield & Ries, *supra* note 41.

[74] *Supra* note 53.

[75] *Supra* note 44.

[76] *Supra* note 52.

[77] *Ibid* at 9.

third parties, full disclosure of all information necessary for making an informed decision to participate in a research project".[78] Such information includes "the purpose of the research, what it entails, and its foreseeable risks and potential benefits".[79] Furthermore, Article 3.3 asserts that the provision of this information must be ongoing during the research, so as to ensure that consent is maintained throughout the project.[80] An exception to this rule, articulated in Article 5.5, is provided for when an REB gives approval for the *secondary* use of personal data without consent, as may occur in the context of biobanks. In order for this to occur, several conditions must be met:[81] the material must be essential to the research, the research must be unlikely to have a negative effect on the welfare of the participant, the privacy of the subject must be safeguarded, the researchers must comply with any known preferences of the subject, it must be impossible or impracticable to seek consent from individuals,[82] and any necessary permissions, for example from local ethics boards, must be obtained. The *TCPS 2* also contains, in Article 12.3, a similarly framed exception that applies to biological samples.[83]

The Canadian College of Medical Geneticists and the Canadian Association of Genetic Counsellors have also developed guidelines requiring that consent in the context of biomedical research be substantively informed. In their *Joint Statement on the Process of Informed Consent for Research* ("*Joint Statement*"), they assert that consent should be a dialogue between the researcher and the participant, including discussion of the scope of the project, potential health-related and/or social risks and benefits, the participant's ability to withdraw from research, privacy and confidentiality protec-

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[78] *Ibid* at 30.

[79] *Ibid* at 9.

[80] *Ibid* at 33-34.

[81] *Ibid* at 62-63.

[82] According to the *TCPS 2*,

> "Impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Consent may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to track and contact members of the group may raise additional privacy concerns. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship on the researcher" (*ibid* at 63).

[83] *Ibid* at 172-74.

tions, and whether/how results will be disclosed.[84] Additionally, the *Joint Statement* recommends that "[p]rior to participation in a genetic research project, when applicable, participants should be asked to provide consent for future use [of samples] that includes as much detail as possible."[85] Also, if biological material is collected for banking purposes, the use of the specimens must be discussed with the donors. Banked material may be used for additional research without consent as long as the specimens are "anonymously and irretrievably unlinked from the source," and the process is otherwise in keeping with any "local REB approval requirements."[86] The *Joint Statement* concludes by reiterating the importance in genetic research of ensuring that "participants have all access to all of the information they need to make a truly informed decision to participate in a particular research project."[87]

A number of provincial organizations in Québec provide a broader spectrum of guidelines for informed consent in the biobank context. The *Final Report: Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research*, prepared for the FRQS, draws on the first edition of the *TCPS*, the *Civil Code of Québec*, and international guidelines such as the *Declaration of Helsinki* to articulate consent requirements.[88] The FRQS Advisory Group argues, however, that these normative tools do not provide the flexibility needed to maximize the scientific value that biobanks promise.[89] According to the FRQSAdvisory Group, if participants are informed of the main themes and general objectives of the biobank and the research for which their samples might be used, as well as the properties of the biobank's governance system, then broad consent is an acceptable way of

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[84] Diane J Allingham-Hawkins et al, *Joint Statement on the Process of Informed Consent for Genetic Research* (Canadian College of Medical Geneticists and Canadian Association of Genetic Counsellors, July 2008), online: CCMG-CAGC <www.ccmg-ccgm.org/documents/Policies_etc/Pos_Statements/PosStmt_EPP_CAGCInformedConsent_16Jul2008.pdf> at 3-5 [Joint Statement].

[85] *Ibid* at 6.

[86] *Ibid* at 7.

[87] *Ibid*.

[88] Fonds de la recherche en santé du Québec, *Final Report: Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research* (Québec: FRSQ, 2006) online: Fonds de recherche du Québec – Santé <www.frsq.gouv.qc.ca/en/ethique/pdfs_ethique/Rapport_groupe_conseil_anglais.pdf> at 12 [FRQS].

[89] *Ibid* at 60.

respecting participant autonomy.[90] In contrast, the Réseau de médecine génétique appliquée, which published several early statements on genetic research, has recommended that participants be informed of "the research team, the goals of the research, its nature, its length, the method followed as well as the tests used, where and how the research data/information and samples will be kept, … the risks and the benefits to the participant or society…, the actual limitations and future of the project as well as the right to withdraw from research."[91] In relation to the scope of consent obtained, Québec's Commission de l'éthique de la science et de la technologie has published *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation*, which recommends that participants' samples not be used for secondary research at all. Instead, researchers should ask participants whether they consent to being recontacted for the purpose of being asked to participate in new research projects.[92]

In summary, with the exception of the report of Québec's FRQS Advisory Group, pertinent ethical guidelines in Canada require the disclosure of specific information concerning research in the consent process. The guidelines provide some specificity regarding what is meant by the term "informed"; participants require a significant amount of information regarding the nature and scope of the research for which their data and genetic material will be used in order for their consent to be considered informed. In the population biobanking context, it is possible for participants to be informed regarding the nature and scope of the biobank project itself but at the time of consent, researchers are unable to provide participants with significantly de-

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[90] *Ibid* at 59-60.

[91] Réseau de médecine génétique appliquée/Network of Applied Genetic Medicine, *Statement of Principles: Human Genome Research* (2000), online: RMGA <www.rmga.qc.ca/en/documents/Enoncedeprincipesrechercheengenomiquehumaine_en_000.pdf> at 5. In a more recent statement, the RMGA encouraged the adoption of an ongoing research consent process where patients would be informed of significant changes to the research protocol. They also encouraged the development of a biobank governance committee to oversee the management and creation of the bank; Réseau de médecine génétique appliquée/Network of Applied Genetic Medicine, *Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations* (2003), online: RMGA <www.rmga.qc.ca/en/documents/encartANG_2609_2e_000.pdf>.

[92] Commission de l'éthique de la science et de la technologie, *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation* (2003), online: CEST <www.ethique.gouv.qc.ca/index.php?option=com_docman&task=doc_download&gid=121&Itemid=16&lang=fr> at 11.

tailed information regarding the future uses to which their samples may be put, and the associated prospective risks. Accordingly, consent at this stage is inevitably broad, and essentially involves asking participants to agree to having their samples used in research for which information such as anticipated risks and benefits, outcomes, and the identity of the future researchers is not presently available. This does not seem to meet ethical requirements put forward in a substantial subset of the ethics texts reviewed. Additionally, it is unlikely that biobanking research, which in the case of coded samples benefits from linking data to personally identifying information, would meet the conditions needed in order to obtain an REB exception to informed consent as presented in the *TCPS 2*.

C. Funding Policies

Organizations that provide the majority of public funding for genetic research in Canada predominantly require researchers to share their data and biological materials broadly. Genome Canada, for example, which since 2000 has received $915 million from the Canadian government to support large-scale genomics and proteomics research projects,[93] requires funded projects to share data and resources, including biological specimens, "as rapidly as possible" and "with minimal or no restrictions."[94] This data-sharing norm is reinforced by the requirement that publications supported by Genome Canada be made freely accessible online as quickly as possible.[95] Similarly, CIHR, which in 2012 financially supported over 13,639 health researchers and trainees across the country,[96] requires grant recipients to make both publications and related biomedical research data freely accessible in public databases, and has committed to improving open access to "research materials and other research data in the future."[97] Grand Challenges Canada,

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[93] Genome Canada, "Research Portfolio", online: GC <www.genomecanada.ca/en/portfolio/>.

[94] Genome Canada, "Data Release and Resource Sharing Policy" (2008), online: GC <www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf> at 1.

[95] Genome Canada, "Policy on Access to Research Publications" (2008), online: GC <www.genomecanada.ca/medias/PDF/EN/DataReleaseandResourceSharingPolicy.pdf> at 1.

[96] Canadian Institutes of Health Research, *CIHR Three-Year Implementation Plan and Progress Report 2012–15*, online: CIHR <www.cihr-irsc.gc.ca/e/documents/cihr_impl_plan_2012-15-en.pdf> at 3.

[97] Canadian Institutes of Health Research, "CIHR Open Access Policy" (2013), online: CIHR <www.cihr-irsc.gc.ca/e/46068.html> at s 5.1.

an initiative launched by the federal government in 2010 that has awarded $93 million in peer reviewed grants as of March 2013,[98] reserves itself the discretionary right to impose data access agreements to its grantees and directs that "grantees should ensure that relevant aspects of their grant proposal are conducive to data access, i.e. permissions to share data are included in informed consent documents, and in collaboration and consortia agreements."[99]

Together, the policies of all of these research agencies indicate that genetic researchers in Canada supported by public funding have a strong incentive, linked to the receipt of their grants, to rapidly and openly share research data, results and materials. That being said, the precise scope of these policies and any possible exceptions are not always clear, and vary from one organization to another.

D. Consent Forms

We reviewed consent forms for large-scale biobanking projects that are members of the Canadian Partnership for Tomorrow Project ("CPTP"), an initiative funded by Health Canada as well as the formerly privately owned Genizon Biobank.[100] See Table 2 for a description of each of the projects examined in this study. The CPTP projects include the Ontario Health Study, the British Columbia Generations Project, Alberta's The Tomorrow Project, Québec's CARTaGENE, and the Atlantic Partnership for Tomorrow Project, which is taking place across the four Atlantic provinces. We also obtained a model consent form for use in biobanking research from the Public Population Project in Genomics (P^3G), a non-profit consortium with administrative headquarters in Montréal that was created to facilitate collaboration between researchers and projects in the area of population genomics. These consent forms differ from one another in a number of ways, for example in terms of whether and how individual results will be returned to participants and the period of time during which samples and data will be stored. They are re-

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[98] Grand Challenges Canada, "Bold Ideas with Big Impact" (May 2013), online: GCC <www.grandchallenges.ca/wordpress/wp-content/uploads/ 2013-CEO-Letter-EN.pdf > at 1.

[99] Grand Challenges Canada, "Data Access Policy" (September 2012) online: GCC <www. grandchallenges.ca/wordpress/wp-content/uploads/data-access-policy-2012Sep06-EN.pdf> at 2.

[100] Although the Genizon Biosciences Inc. research model was principally disease-based, the company also developed a biobank for more prospective research initiatives.

markably similar, however, in that they uniformly require that participants provide broad consent, albeit with ongoing ethical monitoring of new projects.

Each of the forms we reviewed was seeking consent for collection of, at minimum, urine and blood or saliva samples. They all asked for access to past, current, and future health information, either contained in medical records or collected by organizations such as provincial cancer registries. The forms explained that the samples and data collected would be used in unspecified studies, using general language such as "health research projects" (the British Columbia Generations Project) and "future health-related research" (the Atlantic Partnership). Some forms explicitly stated that the samples and data would be used in ways currently unknown, for example explaining: "It is impossible to predict all the studies that could use the blood and urine samples over the course of the next 50 years. They will be used, among other biomedical projects, for research on the structure and the functioning of the genome" (CARTaGENE).[101] Each project stated that the samples and data would be used by researchers both within and outside of Canada. Participants were uniformly assured, however, that researchers would not receive identifying information and that the proposed projects would need to be approved by an REB before data and samples would be provided. It is clear from this substantial sample of current consent forms, therefore, that seeking broad consent is a common practice in large-scale Canadian population biobanking research.

IV. Discussion

Analysis of Canadian legislation, jurisprudence, ethical guidelines, and funding policies indicates that researchers are facing a complex array of conflicting requirements when it comes to informed consent in the context of biobanking. In congruence with traditional consent norms, both legal instruments and ethical guidelines require researchers to provide subjects with substantive information regarding the uses to which samples and data will be put. Funding policies, on the other hand, expect researchers to make the materials and data they collect widely available with minimal restrictions on their use by other scientists, thereby indirectly pressuring the researchers they support to adopt broad consent policies. Unsurprisingly, Canadian researchers are fulfilling the requirements imposed upon them by funding bodies at the expense of those currently imposed by legal and ethical instruments. This is problematic.

A. Legal Implications

While no known suits have yet been brought against Canadian biobanks in relation to the nature of their consenting practices, it is possible that such a suit may arise in the future. Parallels may be drawn to a recent case in British Columbia, *LD (Guardian ad litem of) v Provincial Health Services Authority*, in which governmental health agencies were sued for banking newborn bloodspots without obtaining explicit parental consent.[102]

In *LD*, a mother of two infants sought to commence class proceedings against the Provincial Health Services Authority in relation to their policy of taking and storing newborn bloodspots for 19 years for, among other purposes, medical research. The chambers judge dismissed the appellant's claims on the basis that she had no genuine issue for trial, ruling that the Authority's failure to disclose its intentions to maintain and store the samples would not have vitiated the original consent given for the collection of the samples, as any reasonable person in the position of the parent would have consented to having their children's samples collected and tested, even knowing of their storage intentions.[103] The British Columbia Court of Appeal overturned this decision. Ryan JA, delivering judgment for the Court, agreed with the chambers judge that "consent to the taking of the samples [was] central to the appellants' case."[104] But he ruled that, "[i]t is very much an open question as to what the test for consent should be when the plaintiff or claimant seeks damages alleging that his privacy rights have been breached under s. 8 of the *Charter*. The same can be said about the *Privacy Act*."[105] The appellant's statement of claim was reinstated, so that the "proper factual foundation on which to explore, develop and apply the tests" for articulating the scope of the parents' consent could be debated in court.[106]

Although, the primary purpose of the banking was a different one (for population newborn screening), this case is relevant to the biobank context as it also deals with the issue of consent to the storage of human biological sam-

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[102] 2012 BCCA 491, 331 BCAC 43, 225 ACWS (3d) 401 [*LD* 2012]. For two US cases where the issue of consent to newborn bloodspot banking was discussed, see *Higgins v Texas Department of Health Services*, 801 F Supp (2d) 541 (WD Tex 2011); *Bearder v Minnesota*, 806 NW (2d) 766 (2011).

[103] *LD (Guardian ad litem of) v Provincial Health Services Authority*, 2011 BCSC 628 at paras 38, 42, 234 CRR (2d) 84, 201 ACWS (3d) 1071.

[104] *LD* 2012*, supra* note 102 at para 13.

[105] *Ibid* at para 18.

[106] *Ibid* at para 19.

ples on a population scale for long-term research purposes. The decision concerned only whether the appellant had a genuine issue for trial, and so left extended discussion of the type and amount of information that would need to be provided to obtain adequately informed consent for the lower court to decide. That said, *LD* confirms that the meaning of informed consent in the context of the storage of human biological tissues for research purposes is still very much up for debate. Though the eventual outcome of *LD* has yet to be decided, the existence of this consent-related case indicates that there are members of the public who are willing to take legal action to ensure that consent norms in biomedical research are respected. If this were to occur in the context of large-scale population biobanking, it could lead to the loss of thousands of research samples and other data in the event that the consent that had been provided by subjects to collect, store, and use the human biological samples were found to be invalid.

B. Policy Implications

There are a number of approaches that may be pursued in an effort to dispel the tension that exists between legal and ethical informed consent requirements and the practice of obtaining broad consent for the purposes of data sharing. Firstly, clarification of what the "informed" criterion for consent in Canadian law and policy substantively requires is needed. The Québec Ministry of Health and Social Services has recently reviewed the section of the Québec Civil Code on medical research, including article 22 CCQ which deals with consent to the removal of tissues and bodily substances for research purposes. It was reported that a priority objective of this revision was to improve the legislative framework of biobanks and databases.[107] Sadly, the new revision will have little impact on consent to research involving biobanks. Although the new provisions bring some welcome changes to the Québec research framework, they address more traditional issues (e.g. research with minors, formal requirement of research consent, substitute consent for deceased individuals) and do not propose innovative solutions to the current dilemma in biobank research that would provide some flexibility to consent requirements. Given the low prevalence of psychosocial risk associated with biobank research, relative to the much more concrete prevalence of physical risk in clinical research, and in view of the eminently social dimension of biobank projects, such legal reform seems desirable. The challenge

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[107] Denis Lalumière, "Pour que l'éthique de la recherche continue de prendre des forces" in Peut-on se faire confiance? Actes de la 5e édition des Journées d'étude des comités d'éthique de la recherche et de leurs partenaires (Québec: Ministère de la santé et des services sociaux du Québec, Direction des communications, 2011) 4 at 8.

for the legislature will be to adopt more progressive consent requirements for the research context that will not vitiate the informed-consent process. One option worthy of consideration may be an exception to the strict consent requirement in the form of a proportionate approach that would allow broad consent for biobanks. This exception would require the researcher to justify the use of broad consent and to meet well-delineated privacy and governance requirements. Such an exception could also promote a more active role for research participants, for example via the inclusion of various preferences in consent documents, greater communication with the biobank and ongoing ethics review.

In the meantime, however, little doctrine exists in regard to the meaning of "informed" for legal purposes in the context of human subject research, and what does exist does not address recent technological developments that challenge traditional conceptions of consent. The principle that the farther from the medical care end of the research spectrum, the more complete the subject's knowledge and understanding of the research must be[108] and the importance of promoting individual autonomy and respecting the subject's right to self-determination[109] have been invoked to justify strict informed consent requirements. Yet, the low level of risk generally associated with participation in biobank projects and the impracticability of carrying out such research with narrowly framed informed consent requirements seem to suggest that a more nuanced position could be more appropriate.

In this paper, we have suggested that a preliminary analysis indicates that broad consent does not seem to fulfill legal and ethical informational requirements. However, current research regulation is largely based on a narrow view of the research enterprise, contemplating individual consent for well-delineated research projects.[110] This regulation, we argue, needs to be reconceptualized in the context of the increasing prevalence of biobanking. Future work providing more sustained consideration of what information is legally and ethically required for consent to be valid, especially in the novel context of large-scale population biobanking, would help researchers and policy makers navigate these diverging considerations.

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[108] See *Weiss*, *supra* note 44 at 741.

[109] JG Castel, "Nature and Effects of Consent with Respect to the Right to Life and the Right to Physical and Mental Integrity in the Medical Field: Criminal and Private Law Aspects" (1978) 16 Alta L Rev 293 at 301.

[110] See Mark A Rothstein, "Expanding the Ethical Analysis of Biobanks" (2007) 33:1 JL Med & Ethics 89 at 91.

One response to this claim might be to argue that research done using anonymized samples[111] from biobanks may be interpreted as not involving human subjects, which would obviate the need for human subject protections such as informed consent. In the US, for example, where human subject research is defined by the "Common Rule," some have argued that when biobankers collect anonymized samples from third-party researchers, and thus have no contact with subjects, this "secondary" research might not be subject to Common Rule regulations.[112] However, in Canada, human subject research is defined as any research involving living human participants or human biological materials, derived from living or deceased individuals.[113] Additionally, the use of individual personal health information for research purposes generally requires informed consent, even if such information is not directly derived from medical intervention by the researcher.[114] Privacy norms will therefore generally apply to biobank research with anonymized biological samples, and/or with anonymized health data in Canada. However, there are a number of narrow exceptions provided for where it is possible to use health information without obtaining informed consent.[115]

More importantly, anonymization does not represent a realistic solution to the problem of informed consent. Firstly, as the genomic literature demonstrates, it is misleading to claim that information contained in biobanks can be fully anonymized, thereby completely negating the risks of discrimination or psychosocial harm to individuals.[116] Moreover, this approach takes too

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[111] Anonymized human biological materials are materials that have been "irrevocably stripped of direct identifiers, a code is not kept to follow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low." *TCPS 2*, *supra* note 52 at 170. The word anonymized is often used with a similar meaning in the context of health data.

[112] See Henry T Greely, "The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks" (2007) 8 Annu Rev Genomics Hum Genet 343 at 353-55.

[113] See *TCPS 2*, *supra* note 52 at 15, article 2.1; see also art 22 CCQ.

[114] PIPEDA, *supra* note 64 at Schedule 1, Principle 4.3.

[115] See e.g. *ibid,* s 7(2)(c).

[116] See e.g. 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 Genetics 1 at 9; Zhen Lin, Art B Owen & Russ B Altman, "Genomic Research and Human Subject Privacy" (2004) 305 Science 183; Eric E Schadt, Sangsoon Woo & Ke Hao, "Bayesian Method to Predict Individual SNP Genotypes from Gene Expression Data" (2012) 44:5 Nat Genet

narrow a view of the interests of research subjects. Individuals have an inherent interest in the decision to consent to research, even when their participation is limited to previously collected, anonymized data, as a result of their fundamental right to self-determination. They may object to having their samples used for particular types of research, irrespective of what risks this research poses to them personally. Additionally, biobanks with anonymized information have a very limited value for researchers, as a result of the limitations that anonymization puts on the health and environmental data available. This indicates that it is both ethically and scientifically undesirable that biobanks be anonymized in an attempt to circumvent informed consent requirements.[117]

An alternative way in which the tension between informed consent requirements and broad consent practices might be alleviated is to increase the inclusion of subjects as partners in biobank research. This can happen both at a community level, through public engagement, and at the level of the individual subject. In Canada, public engagement exercises seeking to obtain diverse input on policy issues in biobanking have been undertaken in British Columbia and Québec with significant success.[118] Such initiatives increase public knowledge and understanding while providing policy-makers with information regarding public concerns, and so improve the background conditions out of which specific informed-consent processes arise. On the individual level, while it may be impractical and unduly burdensome for researchers to contact subjects for every new research project, it is not unreasonable for large-scale population biobanks to keep subjects apprised of ongoing activities, for example through regular newsletters and/or interactive websites that provide information on how samples are being used. Given appropriate privacy safeguards, subjects could be provided individual online accounts to which they could log on in order to update their health information and research preferences, and review the details of the research projects in which their personal samples are being used, with the option of opting out if de-

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603 at 607; Melissa Gymrek et al, "Identifying Personal Genomes by Surname Inference" (2013) 339:6117 Science 321.

[117] See Greely, *supra* note 112 at 356.

[118] See KC O'Doherty & MM Burgess, "Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation" (2009) 12:4 Public Health Genomics 203; Béatrice Godard, Jennifer Marshall & Claude Laberge, "Community Engagement in Genetic Research: Results of the First Public Consultation for the Quebec CARTaGENE Project" (2007) 10:3 Community Genetics 147.

sired.[119] Options for participants to take an even more active role in the development of a public biobank project have been proposed.[120] Such initiatives would honour the spirit of informed consent as an ongoing, dynamic process and ensure that subjects have access to relevant information regarding their participation in research as it arises. Increasing the level of subject participation in the biobank endeavour via these methods will contribute to reducing the existing tension between legal and ethical informed consent requirements and data sharing initiatives.

In response to problems of consent and concerns around public involvement in the context of biobanking, David and Richard Winickoff have proposed the legal solution of a "charitable trust" model for biobank governance.[121] Under such a model, research subjects would transfer their property interest in donated tissue to a trust. The trustee of this property would have legal fiduciary duties to manage the property to the advantage of the beneficiary, which in the case of a charitable trust, is the general public. According to the Winickoffs, such a model is superior to the usual governance framework of private biobanks for a number of reasons. It can be structured so as to provide the donor groups with an advisory role in the governance of the trust, which would promote a sense of community amongst donors. It also recognizes tissue donation as an altruistic gift intended to benefit mankind, which fits the normative conception of the human genome as a universally shared resource. The charitable trust model aims to promote donor participation in research governance and stimulate research that will benefit the public at large, and so could contribute to alleviating many of the tensions currently associated with broad consent in the biobank context.[122]

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[119] For a description of a "[w]eb-based, interoperable personally controlled health record" system supporting a research regime, see Isaac S Kohane et al, "Reestablishing the Researcher-Patient Compact" (2007) 316 Science 836 at 836-37.

[120] Edward S Dove, Yann Joly & Bartha M Knoppers, "Power to the People: A Wiki-governance Model for Biobanks" (2012) 13 Genome Biology 158.

[121] David E Winickoff & Richard N Winickoff, "The Charitable Trust as a Model for Genomics Biobanks" (2003) 349:12 New England Journal of Medicine 1180 at 1182-83.

[122] *Ibid* at 1182-83. For a broader discussion of governance, see Robert O Keohane, "Governance in a Partially Globalized World (Presidential Address, American Political Science Association, 2000)" (2001) 95:1 American Political Science Review 1.

However, even if inclusionary measures are adopted, whether in the form of public engagement or through formal legal structures such as the charitable trust, it will remain the case that more communication is needed between the various funding bodies and professional associations that finance, regulate and oversee biomedical research in order to develop harmonized policies that are more connected to the contemporary research challenges. Funding bodies in particular are currently promoting open data-sharing practices while ignoring the fact that this encourages the adoption of consent practices that may conflict with traditional legal and ethical norms. While the promotion of data sharing and open access to biomedical research resources is an admirable goal that could very well procure valuable benefits to health research, it is important that it be pursued in a way that is congruent with legal and ethical requirements. The legal and ethical obligations requiring that consent to biobank research be substantively informed may eventually be modified, but in the meantime, the bodies providing funding and oversight for this research must present researchers with clearer and less contradictory policies, as well as guidance and options on how to undertake these responsibilities in the Canadian legal context.

Table 1: Types of Consent

There is little consistency or consensus in the literature regarding the definition for different types of consent, when they are even defined at all. The following table provides some examples of types of consent that have been described.

Type of Consent	Example of Descriptions from the Literature	Defined in
Narrow or Traditional	This model presents an incredibly exacting standard, requiring at minimum that researchers "provide information about all potential risks, no matter how remote, and material information about the nature of the research protocol."[123]	Caulfield, Upshur & Daar (2003)[124]
Dynamic	Participants are continuously recontacted and, each time, they are asked to provide "real-time" consent for the use of their data in every new research project as it arises. The model allows research participants to have an interactive relationship with the custodians of biobanks and the research community, and to easily provide or revoke their consent at any time.[125]	Pawlikowski, Sak & Marczewski (2009)[126] Steinsbekk, Myskja & Solberg (2013)[127]
Tiered	This model allows research participants to choose from a checklist of items on the consent form, such as the types of research in which they are willing to participate.[128] Participants may permit only some use, thereby requiring new consent for other studies.[129]	Ram (2004)[130] Bunnik, Janssens, and Schermer (2012)[131] Master et al (2012)[132]
Broad	"[P]articipants must be clearly informed that that they are consenting to future, unspecified research with their biospecimen and genomic data."[133] Within this framework for future research, participants may be reassured that each research project involved will undergo independent ethical review. They will be contacted to provide new consent if this framework is significantly modified.[134]	Salvaterra et al (2008)[135] Wallace, Lazor & Knoppers (2009)[136] Steinsbekk, Myskja & Solberg (2013)[137]
Blanket	Potential research participants may be asked, for example, simply if they consent to having their samples used for research purposes, without being given any additional information about what that research may involve. [138]	Shickle (2006)[139] Caulfield (2007)[140]
Presumed (opt out)	Opt out systems assume the subject understands the information, freely chooses, and takes action if he or she does not want to participate.[141] When consenting to medical treatment, individuals can opt out of having their DNA included in the biobank by checking a box on the consent to treatment form.[142]	Wendler & Emanuel (2002)[143] Árnason (2004)[144] Petrini (2010)[145] Pulley et al (2010)[146]

Table 2: Examples of Population Biobanks in Canada

Population Biobank	Atlantic Partnership for Tomorrow's Health*	BC Generations Project*	CARTaGENE*	Ontario Health Study*	The Tomorrow Project*	Biobanque de Genizon (currently Genome Quebec, acting as trustee)
Territory Covered	Atlantic Canada (Nova Scotia, New Brunswick, Newfoundland & Labrador, Price Edward Island)	British Columbia	Québec	Ontario	Alberta	Québec
Year Created	2009[147]	2009[148]	2009[149]	2010[150]	2000[151]	1999
Number of Projected Participants	30 000[152]	40 000[153]	37 000[154]	225 000 (current number of participants) [155]	50 000[156]	50 000 (final number of samples) [157]
Privacy Measures	Coded[158]	Coded[159]	Coded[160]	Coded[161]	Coded[162]	Coded
Consent Language	"We will be keeping the blood and toenail samples, along with the physical measures and information from the questionnaires to allow them to be used for future health related research. The samples and all of the information gathered for the study will be stored for 30 years, during which time they will be made available to researchers." [163]	"If you volunteer to take part, you will be asked to agree to the following: …Allow storage of your samples and health-related information obtained for this study in a coded form which does not identify individuals. This information may be used for health research projects until the year 2058."[164]	"Participants in CARTaGENE accept that data and samples collected from them will be used for health and genomic studies in the future… It is impossible to predict all the studies that could use the blood and urine samples over the course of the next 50 years. They will be used, among other biomedical projects, for research on the structure and the functioning of the genome." [165]	"I understand that most of my blood sample will be coded and stored for future research. I recognize that it will be possible for components of my blood to be examined for research purposes. I understand that my DNA may be used for genetic research. I recognize that in the future, my blood and/or DNA could be analyzed in ways that are currently unknown." [166]	"I accept that my data and samples will be stored for at least 50 years to support research related to cancer, and potentially other health conditions… I accept that my data and samples may be used, in coded form, by approved researchers from Canada and other countries for research related to cancer, and potentially other health conditions." [167]	"By accepting to participate in the Biobank, you are authorizing Genizon to use part of your DNA already collected as part of the research project to which you initially consented, for purposes of achieving Biobanks' goal (finding the genes associated to common genetic diseases) … Your information and genetic material may be accessed by researchers located inside and outside Canada." [168]
Possibility to Re-Contact	Yes[169]	Yes[170]	Yes[171]	Yes[172]	Yes[173]	Yes

This table was developed by the authors of this article using a number of sources including the biobanks' websites and consent forms and CTP Project Catalogue at Public Population Project in Genomics and Society online. *Member of the Canadian Partnership for Tomorrow Project

Table References

[123] Caulfield, Upshur & Daar, *supra* note 32 at 2.

[124] *Ibid*.

[125] Kristin Solum Steinsbekk, Bjørn Kåre Myskja & Berge Solberg, "Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?" (2013) European Journal of Human Genetics, advance online publication, doi: 1018-4813/13 at 2.

[126] Jakub Pawlikowski, Jaroslaw Sak & Krzysztof Marczewski. "The Analysis of the Ethical, Organizational, and Legal Aspects of Polish Biobanks Activities" (2009) 20:6 European Journal of Public Health 707 at 709.

[127] *Supra* note 125.

[128] Master et al*, supra* note 6 at 885.

[129] Natalie Ram, "Tiered Consent and the Tyranny of Choice" (2008) 48 Jurimetrics J 253 at 254-55.

[130] *Ibid*.

[131] Eline M Bunnik, A Cecile JW Janssens & Maartje HN Schermer, "A Tiered Layered-Staged Model for Informed Consent in Personal Genome Testing" (2013) 21 European Journal of Human Genetics 596 at 597-98.

[132] *Supra* note 6 at 885.

[133] Susan Wallace, Stephanie Lazor & Bartha Maria Knoppers, "Consent and Population Genomics: The Creation of Generic Tools" (2009) 31:2 IRB: Ethics and Human Research 15 at 16.

[134] Steinsbekk, Myskja & Solberg, *supra* note 125 at 1.

[135] Elena Salvaterra et al, "Banking Together. A Unified Model of Informed Consent for Biobanking" (2008) 9:4 European Molecular Biology Organization Report 307 at 309-10.

[136] Wallace, Lazor & Knoppers, *supra* note 133 at 16.

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[138] Darren Shickle, "The Consent Problem Within DNA Biobanks" (2006) 37 Studies in History and Philosophy of Biological and Biomedical Sciences 503 at 510.

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[140] Caulfield, *supra* note 20, at 213-14.

[141] Petrini, *supra* note 25 at 219

[142] Jill Pulley et al, "Principles of Human Subject Protections Applied in An Opt-Out, De-identified Biobank" (2010) 3:1 Clinical and Translational Science 42 at 43.

[143] David Wendler & Ezekiel Emanuel, "The Debate Over Research On Stored Biological Samples: What Do Sources Think?" (2002) 162:13 Archives of Internal Medicine 1457 at 1461-62.

[144] Vilhjálmur Árnason, "Coding and Consent: Moral Challenges of the Database Project in Iceland" (2004) 18:1 Bioethics 27 at 33.

[145] *Supra* note 25.

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[149] CARTaGENE, *Brochure for Participants*, online: CARTaGENE <cartagene. qc.ca/sites/default/files/brochure_25_oct_finale_en_sans_salive.pdf> at 3.

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[159] BC Generations, "BC Generations Project Protocol", *supra* note 153 at 9.

[160] CARTaGENE, *supra* note 149 at 6.

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