Research in the biotech age: Can informational privacy compete?

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This article examines the privacy of personal medical information in the health research context. Arguing that biomedical research in Canada has been caught up in the government's broader neoliberal policy agenda that has positioned biotechnology as a strategic driver of economic growth, the author discusses the tension between informational privacy and the need for medical information for research purposes. Consideration is given to the debate about whether privacy for medical information serves or hinders the "public good" in respect of medical research and to discussions of informed consent as an element of "fair information practices" designed to safeguard the privacy of personal information, including attempts to subvert requirements for informed consent in the medical research context.

Keywords: privacy; informational privacy; informed consent; fair information practices; biotechnology; medical research

The advent of the new economic order is calling for a new and challenging public policy paradigm where social policies that are social, educational and skills development become the drivers of information-era growth and competitiveness, especially in terms of research and innovation.

Leaders' Forum Steering Committee, 2004, p. 6

This statement from the Leader's Forum on Health Research' in Canada, which acknowledges the "new economic order" commonly referred to as neoliberalism, is indicative of the environment in which health research is conducted, an environment in which pressure is exerted on medical researchers to secure corporate funding sources and to develop research agendas that yield discoveries that can be exploited for economic value through intellectual property rights. Moreover, policy makers in Ottawa increasingly emphasize the value of research as a mechanism by which Canada can ensure its future economic sustainability. This article argues that the prominence the neoliberal policy agenda has attached to scientific innovation, particularly biotechnology and medical research, as drivers of Canadian growth and prosperity comes at the expense of privacy protections for personal medical information. I build my argument by first outlining how biotechnology has come to be promoted by the Canadian government as one of the new pillars for progress and economic advancement. The considerable emphasis placed on the economic implications of this science and its technological applications tends to derogate other social issues that attach to biotechnology research, including privacy interests. Within this discussion, I outline how neoliberal policy agendas are congruent with conceptual models and strategies designed to "balance" privacy protection with other public policy goals. The next section briefly illustrates the major legislative mechanisms that have been promulgated in this country to protect personal medical information; legislation that responds more to data flow requirements, albeit with limitations, rather than to strict privacy protection. Despite the flaws inherent in the "balance model," it remains the dominant approach in contemporary policy debates, in large part because it satisfies a broader neoliberal agenda that attributes substantial economic promise to biotechnology research. Given the prominence of balancing, the next section of the article goes on to offer a possible counterweight to the traditional individual versus society dichotomy inherent in much of the debate about the privacy of personal medical information. The goal here is to offer an alternative conception of the "public good" that, by according substantial import to individual privacy, is capable of marshalling enough heft to tip the balance in policy discussions toward stricter privacy protection. The final section of the article considers informed consent, as one element of "fair information practices" that allies with both the balancing approach inherent in policy debates as well as the notion that individual privacy can contribute to the public good of medical research.

Biotechnology, Neoliberalism, and Balancing

Biotechnology presents an exceptional economic opportunity for Canada in the 21st century. This enabling technology can strengthen Canada's competitiveness and open up export markets by creating value-added industries in the health, pharmaceuticals, agriculture and natural resources sectors. It holds the key to a productive, prosperous economy that creates knowledgeable, skilled and creative labor that is both highly productive and highly skilled. It opens up new opportunities for Canadian health care and drug development. It provides new opportunities for Canadian health care and drug development. It provides new opportunities for Canadian health care and drug development. It provides new opportunities for Canadian health care and drug development. It provides new opportunities for Canadian health care and drug development.

The above passage articulates clearly the increasing government-promoted commodification of biotechnology in this country, in which impetus for growth in biotechnology derives from the predicted economic benefits to be reaped as this branch of industry expands. As a result, policy makers are increasingly compelled to actively promote new science and technological sectors to underwrite national competitiveness in a globalized trade environment characterized by capital mobility and free trade (Jessop, 1994; McCallum, 2005). In addition to the promise of Keynesian advantage, a number of potential social benefits are attributed to biotechnology, including the development of new diagnostic tools and therapeutic procedures to combat disease, new rules to help address world hunger, and new technologies that might help reverse environmental degradation (Gissell, Bower, & Durant, 1998). Genomics, a branch of biotechnology that examines the complete set of genes and their interactions for an organism, forecasts an array of positive contributions, including the identification of disease genes and the development of corresponding treatments or preventive measures. The assumption is that as researchers discover more links between particular diseases and genetic mutations, genetic tests can be developed to examine individuals who indicate symptoms or have a family medical history of a certain disease. The expanded molecular understanding of diseases facilitated by genomics research might also aid in developing more effective therapeutic measures, such as improved vaccines. These very brief examples are offered to illustrate the range of products and applications that researchers believe can be developed through genetic engineering. But, as an introductory quotation to this section, such development increasingly is driven by corporate profit imperatives fueled by neoliberal government agendas that focus predominantly on economic growth and prosperity. There are certainly institutions that are engaging in discussion about the broader ethical, social, and political issues that surround biotechnology, including privacy concerns. However, such work does not tend to yield tangible results beyond position statements or declarations capable of challenging, at least in any substantial way, the progress and economic growth imperatives that dominate debate about the developmental trajectory of biotechnology in Canada.

Situated within the widespread assumption that social progress is realized through unmitigated technological development and its attendant economic accumulation, the development of biotechnology appears both natural and predestined. In the context of the now-clichéd information society, biotechnology, which itself was greatly facilitated by modern advances in computer technology, has become one of the celebrated means of realizing society's informational destiny. Yet, because the information society and biotechnology are complicated by the potential negative economic implications of stringent regulation on the commodification of science and technology, including genetic research and development (R&D). Against a backdrop of neoliberalism that
"extends the class power of large capital and erodes the collective capacity of labour and the popular sector" (Burke, Moore, & Shields, 2000, p. 12), governments respond to this contemporary constellation of forces with agendas of deregulation and the abandonment of once public goods and services to the logic of the marketplace in an effort to stimulate national competition and economic growth (Lyon, 1988).

This situation is particularly pronounced in respect of biotechnology research which is pursued in publicly funded institutions, such as universities, that themselves are progressively subjected to the imperatives and corresponding constraints imposed by capital. Reduced funding to institutions of higher learning as a direct result of the neoliberal restructuring of government agendas over the previous two and a half decades has caused universities to seek out alternative financial sources. Coupled with this is the now well-established gospel among many governments that economic growth and development depend on the ability of private enterprise to commercially apply and exploit the knowledge and innovation developed in educational institutions (Etkowitz & Webster, 1998). Indeed, the university landscape today is characterized more and more by pressure on faculty to commercialize research and develop partnerships with commercial companies—a development Etzioni terms an epistemic drift through which the utility of science is measured according to market criteria (Etkowitz & Webster, 1998; Healey, 1998).

Of course, it might be objected that scientific ideas have long been translated into industrial applications as evidenced by the historical importance of the chemical and electrical industries to the Industrial Revolution. The difference today is that whereas such processes have intensified in terms of the reduced temporal span between discovery and application, the strategic importance to industry of the knowledge developed in academic institutions has been prolonged by public funding to encourage (coerce) universities into becoming incubators for economic growth and development through partnerships with business (Etkowitz et al., 1998).

In short, the labor market for life scientists has been greatly expanded, and the cross-traffic between universities and industry is now so extensive that it is fair to consider biotech firms and universities as part of a common research community. (Powell & Owen-Smith, 1998, p. 263)

In Canada, aside from admonitions from the Canadian Biotechnology Advisory Committee (CBAC) to commercialize university research, the Association of Universities and Colleges of Canada in 2002 signed a framework of agreed principles with the Government of Canada that commits Canadian universities to double the amount of research they conduct and to triple the amount of commercialization they undertake of such research (Association of Universities and Colleges of Canada, 2002). The contemporary university might thus be viewed as providing part of an enabling infrastructure that contributes to capitalist growth and development, which increasingly relies on knowledge creation (Florida & Cohen, 1999). According to Industry Canada (2000), as of 2005, most Canadian biotechnological companies (defined as companies for which biotechnology is the principal activity and that conduct biotechnology R&D activities) were spinoffs based on discoveries made in Canadian universities, research hospitals, and government laboratories. Between 1997 and 2000, the National Research Council Canada (NRC), a tax-funded federal research agency, alone had spun off more than 20 biotechnology companies from its 5 biotechnology laboratories.1 Between 1998 and 2003, the NRC applied for 340 patents, of which 123 had been issued by 2004. During this same period, the NRC signed 41 license agreements with various companies to transfer its research and subsequent technologies to the marketplace. (Government of Canada, 2004). The Canadian Institutes of Health Research (CIHR) is also active in moving research from universities and research hospitals to the marketplace through such programs as the NCE Framework of Principle. Similarly, the Intellectual Property Management Program, which is jointly administered by CIHR, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council, aids universities and hospitals in developing their intellectual property (Government of Canada, 2004).

Such strategies are bearing fruit for governments and universities; according to a report by the Association of University Technology Managers, commercialization at Canadian universities and hospitals was at an all-time high level ever seen in fiscal year 2005 (latest available data) (Boston, Bruce, & Flanagan, 2007). In sum, the context within which biomedical research in Canada is being conducted is influenced heavily by both government and industry, both of whom presume biotechnology to be a strategic enabling technology that will help drive this country's economic growth and development.

This broader environment has direct implications for privacy policy in this country, in that debates of the privacy of personal information must often yield to, or at least be balanced with, the imperatives of economic growth and development. Policy discussions about privacy protection have thus developed into instrumental or functional discussions about how privacy must be balanced against competing interests, an approach that is reflected in the majority of data protection laws and policies promulgated in the past 30 years (Bennett & Raab, 2006). Regan (1983) notes that the problems related to the task of defining privacy are quite problematic in the policy process. Though there is a range of ideas that attempt to outline the boundaries of the privacy concept, many are too abstract or too general to be of any practical value to policy discourse. The result is that most policy actors default to legal concepts, such as "expectation of privacy," which are able to garner wide consensus, although with different meanings. Aside from being ambiguous, such notions of privacy presume it to be a right—a right that runs up against and must be balanced with other social and individual rights and interests (Regan, 1995). The problem is that in such debates, the amoral weighting attributed to privacy erodes its prominence via-à-vis opposing policy interests to such an extent that the former is dispensed of its legitimacy as a crucial policy issue.

A major conceptual weakness of the balancing model, as applied to privacy, is that it is quite difficult to quantitatively determine the costs and benefits associated with privacy protection. As Raab (1999) says, "privacy often seems inexplicable in the currency of serious policy debate, in which some numbers are thought to be better than no numbers." (p. 78). Balancing requires some degree of parity between the two interests in question, which is almost impossible to determine in the context of tradeoffs involving privacy. This problem is compounded by the fact that, presumably, in many instances, in and out of policy debates, data protection legislation is not based on user and data subjects will attach divergent weightings to the competing claims, and in many instances, the interests opposed to privacy are better equipped for battle, either due to their political clout and political clout and political power (Raab, 1999). Moreover, the balancing model functions at an aggregated level that neglects much of the granularity that would better involve the complete range of actors and interests involved in efforts to effect a balance in the privacy debates.

In matters of "public interest," privacy tends to be what is left over after more pressing elements have been resolved. Whether the type of privacy is census, information users employ a common set of terms that are hostile to privacy. In the parlance of banks, police, and government agencies, privacy is a value rather than a right. It is a right that impairs efficiency and shields criminals. It is the natural enemy of freedom of information. It is a concept without definition or form. Its enforcement is cumbersome and expensive. Thus, privacy is cast in the bithe noir of law enforcement, openness, progress, efficiency, and good government. (Davies, 1997, pp. 152-153).

The neoliberal policies that dominate the political and economic agendas in Canada are reflected in the balancing model that informs policy debates and legislation in recent years. By establishing this broader context, the following section will offer a schematic outline of the extant legislative framework that regulates the flow of personal medical information in Canada, including an assessment of the degree to which such legislation reflects the promises of the "balancing model."

Canadian Data Protection Legislation"
information to provide health services and manage the health system; to prescribe rules for the collection, use, and disclosure of personal health information; to provide individuals with rights of access to and correction of their medical records; to establish remedies for contravention of the Acts; and to provide for independent reviews of decisions made under the Act. All four provincial Acts apply to identifiable personal health information, which includes genetic health information.\(^7\)

All of these acts, whether at the federal or provincial level, set out exemptions for the use of personal health information for research purposes. In the case of the federal statute, an exemption from the consent requirement is permitted if the information is used for research or statistical, scholarly study and it is impracticable to obtain consent. All four of the provincial Acts contain provisions that require ethics approval for research using personally identifiable health information. Section 50 of Alberta's HEA empowers the ethics review board to determine whether consent is required from the individual to whom the information pertains. Similarly, Saskatchewan's HIPA allows for use of personal health information without consent if "in the opinion of the research ethics committee, the potential benefits of the research project clearly outweigh the potential risk to the privacy of the subject individual.\(^{48}\) Manitoba's PIIPA and Ontario's PIIPA contain very similar provisions.\(^7\) Also of interest is the fact that the Ontario and Alberta acts, which define research, draw no distinction between public sector and commercial research.\(^{46}\) Legislation in Saskatchewan and Manitoba does not specifically define research.

Even this summary sketch of the data protection legislation in Canada at both the federal and provincial levels should impress on the reader that such laws have been enacted to facilitate rather than completely restrict the flow of personal information. That is, all of these statutory instruments are based on "fair information practices" that seek to balance informational privacy with other interests rather than guarantee strict informational privacy protection. A major problem with "fair information practices" is that they are less protective of privacy than personal information. They form the basic of information laws that regulate how personal data may be collected, used, and disclosed rather than addressing the complete range of privacy and associated surveillance issues. Moreover, the protection regimes developed from "fair information practices" tend to provide a number of exemptions for governmental and research purposes. But most problematic is the fact that data protection laws fail to prevent or circumscribe the collection of personal information. In fact, by establishing regulatory regimes in respect of the collection, use, and disclosure of personal information, data protection laws actually legitimate an unchecked expansion in the number of information systems that may be developed to service individuals (Davies, 1997). Current statutes designed to protect informational privacy reflect broader neoliberal policies that seek to ensure economic imperatives figure in policy development and legislation. In the Canadian context, it is clear that there is a wealth of research that would greatly facilitate genetic analysis by permitting the assessment of transgenerational effects. Although the Canadian Longitudinal Study on Aging will not be fully launched until 2008, funds are in place for the developmental and piloting work has been provided in the amount of $797,000 in 2004/2005 and $770,000 in 2005/2006 (CIHR, 2003). Both studies would collect biological samples for genetic and biochemical analysis, health records, and socioeconomic data such as household income, occupation, and place of residence (Caulfield & Ries, 2004).

The importance attributed to such long-term health research studies has been outlined by the Leaders' Forum for Health Research (2004, p. 10), which, in a report prepared for the government, articulated the assessment of its "health research enterprise" as "being vital not only to health and health care but also to Canadian economic growth and international competitiveness:"

In a knowledge-based economy where businesses and jobs cluster around talent, human capital will increasingly be at the cutting edge of economic competitiveness. A significant portion of our investment in research that will enhance the health, education and skills of Canadians will be a principle avenue for fostering growth and innovation. (Leaders' Forum Steering Committee, 2004, p. 11)

This evolution of health research into an "enterprise" reflects the changing nature of the research landscape in Canada and belies the notion of a public research domain. A short approach to investing. Nowhere in this document is consideration given to discussions about how the raw data, which in many cases will be personal health information, should be collected, used, and disclosed. In the context of a research environment increasingly driven by private interests and where much of the remaining public sector interests seem to mimic many of the goals espoused by the private sector, perhaps it should not come as a surprise that privacy discussions fail to translate into stringent privacy protections that would likely erect barriers to the use of personal information. "Neither government nor the private sector really likes the privacy business, whatever it is, because it gets in the way of their continuing to do business as usual with personal information" (Flaherty, 1997, p. 171). In our contemporary context, characterized by an expanded emphasis on the commercial viability of biotechnology research, more voices are being raised in a chorus that seeks to further erode some of the already limited privacy protections recorded to date. It is important, therefore, not to come as a surprise that many researchers and their funding sources would prefer to avoid the additional encumbrance of having to obtain consent or any other requirements that would arise from strong privacy protection for personal health information. It is precisely to these issues that the remainder of this article is devoted.

Privacy, Medical Research, and the Public Good

Arguments in favor of disclosing personal health information, despite the wishes of the individuals to whom the information pertains, are often couched in terms of "the need to know" to serve some higher public interest. Framing the issue as a "need," particularly one in service of broader societal requirements, lends it a normative imperative in favor of its fulfillment. However, what is often underdeveloped in such calls for a "legitimate need to know" is the justification of what makes a particular call legitimate (Macklin, 1992). The general claim advanced to avoid obtaining informed consent maintains that significant benefits accrue to all of society from large-scale medical research projects while the potential privacy risks for patients are apparently minimal (Ettzioni, 1999; Kuyrkyn & Korn, 2002). In the case of Canada, and many other countries where basic health care is subsidized by the state, some commentators assert that patients have a social obligation to allow their health information to be used for medical research without consent (Tu et al., 2004; Uppuluri, Morin, & Gouin, 2001). Arguments are also advanced for what they are: attempts by interest groups with a dominant stake in the "health research enterprise" to construct a particular "public good" or "public interest" argument in respect of privacy and medical research that conceptualizes privacy as an interest pursued by selfish individuals in opposition to broader societal obligations. This type of thinking often leads theorists who advance arguments about the importance of medical research to equate researchers' interests with the broader public good, which, as one commentator convincingly argues,
is a false equation (Willison, 2003). Perhaps a better approach is the one espoused by Priscilla Regan (1995), which frames privacy as a common value that promotes the public good.

In a similar vein, Tunick (2001) considers the oft-touted charge alleged by privacy opponents that privacy encourages an isolated life and sense of individualism that works against the community need for public-mindedness and frequent interaction with others. Tunick references the sociological and anthropological literature that posits a necessary link between a certain degree of privacy and the maintenance of community. Privacy engenders respect for people, which in turn promotes the mutual respect and recognition necessary for community. Respecting the privacy of someone else demonstrates recognition of that person as a bearer of rights and worthy of some degree of self-determination. It signals the trust that this person has in another to act responsibly. Thus, a compelling justification for respecting privacy is the potential for harm to broader society that would result if an individual’s privacy were violated. That is, if we accept that privacy contributes to the social good, then society collectively is harmed by privacy violations even if, as individuals, people are not directly affected by the intrusion (Mackin, 1992).

A further implication of framing privacy as a public good is that questions of medical research, which proponents of reduced privacy protection assert is a public good, come up against a similar public good rather than the private interest of a few individuals. As Valerie Steeves (2004) notes, to argue that privacy must give way to these secondary interests misses the fact that health care is delivered in the context of social relationships among medical actors. Surveillance that violates the sociological experience of privacy as it is lived in the [sic] our daily lives will break down the trust that is an essential part of health care delivery. (p. 7)

She thereby turns a typical argument advanced by medical researchers against them and points out that privacy is, in fact, necessary to ensure unbiased data as people might alter their behavior in response to privacy intrusion. Opponents of strict privacy protection are thus compelled to demonstrate the societal value of any proposed research that would impinge on individual privacy (Steeves, 2004). If one accepts that a privacy invasion of one individual negatively impinges on society, then benefits to the need for individual privacy rights, then a compelling case can be developed in support of strict privacy protection for medical and genetic information. This position, of course, is the other side of the “public interest” debate that is so often invoked by medical researchers to justify unimpeded use of personal medical information. But informed consent, as a component of “fair information principles” and information privacy, might be more appropriately conceptualized as a safeguard not only for individual information privacy but also as a means of ensuring participation in medical research studies. A way of avoiding these potentials for harm is to guarantee the right of informed consent before personal information may be used in health research projects.

**Informed Consent in the Research Context**

The debate over the privacy of medical information focuses in large part on the purported negative effects that the requirement of obtaining informed and explicit consent for the use of patient information would exercise on medical research. Opponents of informed and explicit consent perceive it to be an unnecessary hurdle that could result in partial enrollment in health studies, which, in turn, would vitiate the value of any data such studies produce (Al-Shahi & Wardlaw, 2000; Ingelfinger & Drazen, 2004; Tu et al., 2004). The central articulation is that low enrollment rates might result in participation bias and thus jeopardize the generalizability of research, as those who decline to authorize access to their medical information may be different in a clinically significant way from those individuals who do participate (Gostin & Hodge, 2002; McCarthy, Shatin, Drinkard, Kleiman, & Gardner, 1999; Upshur et al., 2001). A number of medical researches in both Canada and the United States, citing apparent costs for research projects that a requirement for informed consent would generate, advocate informed consent exceptions for minimal-risk observational research.

Yet as opposed to what Tu et al. (2004) assert to be the case in Canada, studies in the United States have found that the Health Insurance Portability and Accountability Act (HIPAA) regulations are not adversely affecting the work of medical researchers. Dr. Maurie Markman, chair of medical research at the University of Texas M.D. Anderson Cancer Center in Houston, contends that the regulations have had only a minimal impact on recruitment of patients into clinical trials.

That doesn’t mean there haven’t been any problems, concerns, or frustrations involving individual protocols or patients. However, we have the impression that, other than the additional work required to make sure we’re HIPAA compliant and the initial conversion effort, that the regulations have not had a major impact on our ability to conduct trials. (Tankhead, 2004, p. 1758)

In another case, the Christiania Care Health System in Newark, Delaware, found that patient acquisition for clinical trials has actually increased from 17% to 24% since the HIPAA regulations entered into force (Tankhead, 2004). In terms of added cost incurred as a result of HIPAA complaint, researchers at Northwestern University Medical Center in Chicago found that despite an initial spike, costs returned to near-pre-HIPAA levels once investigators adapted to the changes mandated by the regulations (Tankhead, 2004). Similarly, Spira Simmons (1995) recounts experiences in Germany where such protection for the data subject increased both participation rates and data reliability.

Critics of the doctrine of informed consent also claim that such detailed processes impose an unreasonable burden on both patient and researcher in the context of studies that involve genetic materials. The reason advanced is that it is virtually impossible to describe all potential future research protocols that might be performed on a person’s tissue or information and therefore that informed consent is ill suited for research that does not email their specific practices. Such concerns add significant cause for concern in the large cohort studies that follow thousands of individuals over a large span of time, as is the case with the two major Canadian health research studies outlined earlier (Caulfield & Riess, 2004). Nonetheless, a question arises as to whether consent can be truly informed if a patient does not have all the necessary information about a specific project. The intuitive response is that this has continued to eluding negative result to Worries surrounding the privacy of medical information assume added force when one considers the growing technological capabilities that allow ostensibly anonymous samples to be identified. In an attempt to reconcile privacy protection with the need to advance medical research, some researchers advocate the removal of personal identifiers from medical data before research begins (Lowrance, 2003). However, at least one Canadian study has confirmed a concern raised by privacy proponents: “We removed all direct identifiers before transferring information from the electronic medical records. It was, however, still possible to indirectly identify an individual through the variables that remained” (Walter, Fyfe, Goldsmith, & Holbrook, 2003, p. 376). That is, simply removing personal identifiers from information fails to completely respond to privacy concerns, as residual information in such “deidentified” databases, including date of birth, postal code, gender, and so forth, when matched with other publicly available data sets, offers a mechanism to link medical records to individuals (Bukhvalov, 2000; Kebony & Korn, 2002).

Alternatively, blanket consent for any and all future research uses is sometimes proposed. However, as opponents of informed consent themselves point out and as discussed earlier, it is nearly impossible to predict all the secondary uses of personal health information that might be made after initial collection, thus rendering consent meaningless and offering no privacy protection while providing false assurances that informed consent originally had been secured (CIHR, 2002). Perhaps more important, certainly with regard to respect for the autonomy of human subjects, is the contention that individuals whose information has been informed, in residual for which their samples will be used. Such a truly informed consent would allow people the opportunity to decline to participate in research of which they disagree (Clayton, 1995). Moreover, stringent privacy polices might actually have the effect of alienated by privacy opponents. If human subjects are convincingly assured that their health information will not be disclosed to third parties for purposes other than the research, patients might also see the research could be increased such that more citizens might be motivated to participate in research studies (Powers, 1997).

Although a number of authors assert that the use of health data without informed consent poses only a minimal privacy risk, there is very little empirical evidence to support this claim or at least to explore what “minimal risk” concretely entails for individuals and their health information. Moreover, personal information for research purposes very often involves a use that does not correspond to the original data collected. Indeed, the data were collected. There are strong commercial incentives for accessing health information, which in turn raises further possibilities for function creep. As more and more individuals and organizations gain lawful access to health data, there also arise the substantial opportunities to lawfully collect, use, and sell personal information for purposes that patients never considered, let alone consented to, when the data were originally collected. The intimate nature of health information and thus this data stigmatize, particularly in the case of genetic information, tends to compound the negative effects of potential privacy violations. It is quite difficult to predict with any degree of reliability what harms might occur as a result of disclosure of personal information (Mackin, 1992). A failure to protect personal medical information might therefore simultaneously exacerbate and reinforce
broad social inequalities. For these same reasons, Similit (1995) argues that legislation must ensure that development projects respect and preserve their rights, meaning that personal information collected for one purpose and subsequently used for research purposes would require informed consent. As a proponent of informational self-determination and critique of approaches to data protection that assume that individuals should have the right to determine whether their information may be used for research (Similit, 1995).

The discussion in this section is offered to illustrate that there are real reasons in support of demands for informed consent as a privacy protection mechanism in the context of medical research. Situating this idea within the broader context of this article, we notice that admonitions against the necessity of obtaining informed consent violate an important element in the fair information practice that help constitute the balancing model. Although we may fault the balancing model for insuffi- ciently protecting privacy, the fact remains that it provides a conceptual mechanism employed predominantly by Canadian governments when developing privacy policies. Researchers and institutions need to be reminded that engaging in research projects without obtaining informed consent violates a tenet of the fair information practices that undergird current privacy frameworks, thus threatening tothrow off any balance.

Conclusion

In this article, I have tried to advance the argument that the privacy of personal medical information in the context of biomedical research is necessary to compete against neoliberal policies that have institutionalized biomedicine as one of the key drivers of Canadian economic growth. The proponents of minimally restricted access to personal medical information for research purposes have thus been provided with an additional weapon in their discursive arsenal that attempts to position research as part of the "public interest" and as a "public good" worthy of trumping privacy concerns. As the brief overview of Canadian legislation indicated, all statutory mechanisms promulgated in this country contain exceptions that permit the release of personal medical information for research purposes. Although most of the acts examined do require the approval of research ethics boards before personal information may be released without explicit consent, the legislation of universities and other research institutes beg the obvious question of just how effectively these boards can function as defenders of personal privacy. As former Canadian Federal Privacy Commissioner Roman Phillips argues, although one might easily rationalize the benefits of collecting personal medical information for health research, the "collection of medical data can slide imperceptibly from health care to medical supervision to lifestyle surveillance and, ultimately, to a more generalized and invasive surveillance by the state." (Roman Phillips, 1997, p. 5). I have also tried to demonstrate how the balancing model implicit in current legislation, and that informs much of the policy debate in Canada, could possibly be recastified in terms of re-conceptualizing "public good" arguments that take as their starting point the importance of individual privacy. Participation in medical research studies must be voluntary, despite calls by some that the potential social benefits be to be weighed outweigh any incursion on personal informational privacy. Advancing knowledge is not a part of the social contract, particularly in our current system, in which knowledge, including that generated in public institutions, is increasingly appropriated by capital in service of its economic growth and efficiency imperatives. Perhaps most ironic of all is that in our current conjuncture of neoliberalism rampant, an ideol- ogy premised on the autonomy of the individual free to make independent decisions in a marketplace resort to circumscribe individual freedom and privacy interests. One is left wondering whether the "public good" argument employed to facilitate the prominence of biotechnology research over individual privacy rights will be applied with the same fervor to pricing decisions for the biotechnological applications that flow from the research based on personal medical information.

Notes

1. The Leader’s Forum on Health Research in Canada was formed in 2003 by the Council for Health Research in Canada as a multistakeholder partnership, comprising federal and provincial research agencies, pharmaceuticals, researchers, health care research institutes, universities, health charities, scientific societies, industry, and health professionals and research advocacy organizations.

2. Hansen notes that there is a wide debate in the literature about the difficulties that attend any attempt to define a "privacy." For purposes of this article, I conceptualize informational privacy as being essentially articulated by Alan Westin (1967). Privacy is a "claim of individuals, groups or institutions to determine for them- selves what is private and to have this right continue to be honored and acknowledged by others." (Westin, 1967, p. 7). I do so for a number of reasons. First, the privacy legislation enacted in Canada under its "basic informational right" to safeguard the personal information of individuals against government and corporate intrusion. Second, the protection of personal medical information is often what is meant when people consider and debate privacy in the medical context. Third, part of the discussion developed in this arti- cle considers informed consent, which is an element of the "fair information practices" that comprise the critical standards employed in legislative and policy debates about increasing privacy, particularly in the medical context.

3. The Genome Canada (n.d.) Web site also provides a wealth of fur- ther information about the benefits that genetics and genomics initiatives hold for human health and the environment, including a list of current and projects currently being funded through this federal organization (http://www.genomecanada.com/).

4. For example, in Canada, one of the main organizations doing work on these aspects of biotechnology in Genome Canada, is the principal investigator of "Mammalian Biodiversity through Conservation," and Ulgyow (1980) assert that the prominence accorded to the "efficiency" criteria in contemporary organizational behavior pro- vides justification and rationale for the extended use of surveillance in increasing areas of social life. They maintain that the efficiency criterion itself debates about privacy, such that data protection principles require to focus on the management of personal data rather than the more cautious issues of whether surveillance is a legiti- mate form of bureaucratic action. The result has been an emphasis on "fair information practices," which argue for the need to ensure that their surveillance activities all the while appearing to protect the pri- vacy of the individuals with whom they deal (Rule et al., 1983).

5. Elsewhere, I have explored an extended analysis of Canadian privacy legislation in respect of medical information (see Peckhaus, 2000).

6. Concerned about the effect that disparate national treatment of personal data could have on commerce, the Organisation for Economic Co-operation and Development (OECD) adopted and published in 1981 the "Guidelines for the Protection of Specific Aspects of Transborder Flows of Personal Data (OECD Guidelines) in an attempt to spur harmonization of national legislation. The OECD Guidelines set out eight basic principles that establish what are often referred to as "fair information practices": collection limitation principle, data quality principle, purpose specification principle, access and correction principle, security principle, accountability principle, and responsibility principle. These guidelines, which are also guidelines adopted in Canada, represent a balance between respect for privacy and the right of the citizens to participate in the management of information data flows. The IPPEDA sets out the bulk of its requirements related to the laws of this province. One of the critical to the protection of personal information, developed by the Canadian Standards Association in 1996, which itself is based heavily on the OECD Guidelines. This is the IPPEDA is formulated using what was originally a voluntary guide to conduct. At the federal level, the Personal Information and Electronic Documents Act, SC 2000, c. 5 (IPEDA), s. 2 (1).


