



OFFICE OF THE
INFORMATION & PRIVACY
COMMISSIONER
— for —
British Columbia

**Personal Information & Health Research
What Price Consent? What Value?**

Insight Health Privacy Conference
September 29 & 30, 2003
Toronto

Let me first thank the organizers of this conference for having invited me to join you today to share a few observations with you. By way of a word of caution, you can be sure that nothing I am about to say is original or particularly earth-shattering. Having said that, I do hope that my remarks today will give you some assurance that privacy commissioners do understand the delicacy and importance of the debate over privacy and health research.

From where I sit out on the West Coast, where for 10 years as of this coming Saturday we've had a privacy law governing the public health sector, the timing of this conference couldn't be better. Obviously, the impending implementation in broad swathes of the Canadian private sector of the federal *Personal Information and Electronic Documents Act* (PIPEDA) makes this conference particularly timely.

I'd like to first say a few things about PIPEDA. A number of medical associations and professional governing bodies have been very public in voicing their concerns about PIPEDA. They are trying to either permanently carve health information out of PIPEDA or have its application to health information deferred. Many of the concerns about PIPEDA's impact on health care and health research have been overstated. But in light of the increasing commercialization of health care, and indeed the conduct and products of health research, the uncertainty PIPEDA will introduce must be addressed sensibly.

I oppose a permanent carve-out of personal health information from PIPEDA. It strikes me as somewhat perverse that, in many parts of the country, a carve-out would leave sensitive personal health information unprotected. To me there's something wrong with that. I do, however, share some of the concern about the impact of PIPEDA on health care within the continuum of patient health care and on health research in this country. This is why I would support amendments to PIPEDA necessary, at the earliest practicable opportunity, to ensure that it supports and enhances the direct provision of health care services to Canadians and to ensure that it does not impede health research in this country. This could take the form of a deferral of PIPEDA's application, with adoption by provinces and territories of harmonized health privacy laws in a timely fashion.

Quite how we are going to achieve this, or when, is another issue. This is a perennial Canadian challenge. How would we, given the need to co-ordinate legislative developments among 14 jurisdictions, move effectively to fill any gaps left by a PIPEDA deferral? We haven't managed to really co-ordinate the regulation of Canadian capital markets despite half a century of trying, and that's something that most certainly affects our economic health.

My goal today is not to parse the ins and outs of federal/provincial/territorial relations or machinations. I will, however, touch on the issue of harmonization, if not standardization, of rules in the area of health research. Before doing so, I'll first address the question of consent and health research.

“What price consent? What value?” Good questions, you might say, but tough to answer. Well let me try, though please be clear that what follows is not informed by any particular understanding of the ethics or philosophical dimensions of the question.

Whenever I hear privacy advocates arguing that consent is key to research uses of personal health information, I inevitably ask myself “What does consent represent in this context? Or more generally?” More generally, surely consent is an act of will that involves an individual's knowing and free choice between alternatives? Consent is said to be an element of personal autonomy and liberty. Consent is, for example, a necessary condition for another to be able to touch me without that act being, in the eyes of society and the state, an assault. In this example, consent underpins our individual physical autonomy and well-being. This example has, as you know, direct application in the health care context. Any non-consensual medical treatment involving physical intervention may be an assault, with civil or even criminal consequences.

I don't for a minute question the importance to our communities and our legal system of the principle of consent. The law of assault is an important example of how consent protects personal autonomy. But personal physical autonomy grounded on consent is not inviolable, is it? Of course not. Society has, through many of our laws, determined that physical autonomy, and liberty more generally conceived, are not absolute. How could they be? If I viciously punch someone so hard that he dies, without my meaning to kill him, I am guilty of manslaughter at the very least and can be jailed for it. I don't consent to being imprisoned any more than my victim consented to my hitting him. My consent is overridden.

Take a less bloody-minded example. A citizen may not like the kinds and levels of taxes that she has to pay, but she is not liable to pay taxes only if she consents. In fact, failure to pay taxes can, in theory at least, land you in the cell next to the person guilty of manslaughter. So much for the primacy of consent.

These examples make the obvious point: in many ways and for many reasons, society encroaches on individual liberty, including the right to be free from interference with our physical beings. In each of these cases, we have decided that the interests of others (individually or as a community) outweigh individual interests or rights.

We make these decisions all the time. These observations lead me naturally to the issue of why is there so much concern on the part of some privacy advocates about collection, use and disclosure of personal health information for health research purposes without consent. This focus on, and demand for, consent leaves me as concerned today as I was four years ago that, in the health privacy debate, consent threatens to become a *shibboleth*, something that defeats understanding.

At this stage, I should define some terms. First, I'm not going to wade into the morass of exhaustively defining what health research is. This isn't a cop-out. I know there can be serious and passionate debate about what health research really is—I've sat in on a few sessions where academics have gone at each other hammer and tongs about it. Let me identify, though, a few examples of what I have in mind when I refer to health research:

- The investigation of the causes of various diseases or conditions, including with a view to finding treatments for them,
- The investigation of the history or development of diseases or conditions,
- Population health analysis,
- Analysis of quality of care, and
- Study of resource allocations within the health system and their impact outcomes.

You will note two things about this list. First, it includes population health analysis, which I believe should almost certainly include surveillance for the purposes of combating infectious disease outbreaks. It may be debated whether this kind of public health analysis is “research”, of course, and perhaps this use of health information should be considered separately when it comes to deciding whether it should continue not to require consent. Second, I do *not* consider analysis or investigation that is aimed at making decisions about individuals, including regarding their entitlement to health care, to be health research properly understood.

The second definitional point I'd like to make is about what kinds of data health research requires. It often strikes me that some commentators forget that much, if not all, health research doesn't require individually-identifiable data. As I understand it, almost all health research of the kinds I've just mentioned can be pursued using de-identified data. Even longitudinal research can go forward using encrypted unique identifiers, with the encryption key being held securely in escrow. The point to bear in mind here is that privacy advocates must focus on the fact that research can be and is done very often using de-identified data. As we'll see later, this reduces privacy risks while diminishing the consent argument. (It is often forgotten, I might add at this point, that researchers don't generally care about the personal particulars of their data subjects. It's not that they're callous or unfeeling people. They care about data, about its quality and quantity, as tools for understanding, but they don't have a specific interest in the personal particulars of a given individual.)

The starting point for assessing consent to collection, use and disclosure of personal health information for health research is, obviously, whether health research is a sufficiently compelling public benefit that individual interests, and therefore consent, should be overcome. Many of you will, rightly in my view, consider the public benefits of health research to be self-evident. I don't propose to prove the correctness of that view. The literature abounds with proof of the public and individual benefits of health research. One passing example suffices. It's safe to say that the mortality from lung cancer has dropped in recent decades. Why is that? Because Sir Richard Doll and others were able to establish a link between smoking and lung cancer. How many lives—including perhaps my father's, since he quit smoking soon after publication of Sir Richard's work—have been spared through this groundbreaking analysis of data from disparate sources? How many of our scarce health care dollars have been freed up to attack other forms of illness? Could this research have been done, or done so quickly, if the researchers had been forced to get consent from dying patients or perhaps even the survivors of lung cancer victims?

If polls done in the past few years are any indication, Canadians understand the importance of health research. It's not as clear, though, that they understand some of the data protection issues I've touched on: that researchers generally don't care about their personal circumstances or particulars; that most if not all research can be done using de-identified data; that various processes, rules and laws are in place to regulate the collection, use and disclosure of personal health information for research purposes.

To say there are processes, rules and laws in place to protect personal information of course begs the question of their efficacy. I'll return to this theme later. For now, let me say in passing that, as we move forward in Canada toward as harmonized and effective a regime of privacy protection as is practicable without impeding health research, I challenge researchers, governments, public and private research funding agencies, universities, health care providers and others to be much more transparent about their work and about their privacy practices.

Transparency is indispensable to accountability, so if researchers are going to be accountable, the public has to know what the accountability framework is and must have information relevant to the actual practices and experience of the research organization. Transparency is also critical, though, to ensuring Canadians continue to understand the benefits of health research and remain satisfied that their privacy is being protected in health research. This support is indispensable to their support for health research, particularly if their consent is not sought.

One organization that understands the importance of transparency is the Canadian Institute of Health Information, which continues to roll out its ambitious transparency initiative. By online posting of privacy impact assessments for its data-holdings and by providing other information to the public about its privacy practices, CIHI is enhancing its accountability for compliance with its internal privacy code while also informing Canadians about what is being done to protect their personal privacy in health research. It is also fostering greater public awareness of the importance of health research and support for research.

Let's review the main discussion so far. First, while personal autonomy and liberty remain important in our liberal democratic tradition, which emphasizes individual interests, individual interests are often overridden to protect the interests of others, including the community as a whole. This point must sometimes be driven home to privacy advocates who focus on consent. Second, health research is undoubtedly important for our community, but it is also critical for our health individually. The literature is full of proof that health research is in the public interest, an observation Canadians appear to understand at present to varying degrees.

In this light, how do we go about weighing individual autonomy, as represented by consent, against the public interest in health research?

I've been persuaded that, in many, many cases, we cannot afford the bias that can be introduced through a consent requirement, at least in relation to secondary uses of existing data (for example, clinical and other data found in hospital charts). Nor does the practicality of a consent requirement respecting research using existing data leap off the page if one assumes that there exists a strong and meaningful regime for data protection. If meaningful rules exist to restrict further uses and disclosures, to protect the confidentiality and security of information, and to prohibit the use of research data or outcomes to make decisions that directly relate to data subjects—if, in other words, realistic risks of harm to individuals have been removed or sufficiently mitigated—then I suggest the price of consent is too high.

One could argue the die has in any case already been cast. Canadian legislation, including PIPEDA, is full of exceptions to the contention that there must be consent to the collection, use and disclosure of personal health information before it can be used for health research. At my end of the country, British Columbia's *Freedom of Information and Protection of Privacy Act* has, since 1993, governed the disclosure and use of personal information for research purposes by what is now our Ministry of Health Services—and also by health care bodies such as hospitals and educational bodies such as universities. Section 35 of that Act allows a public body to disclose, for research purposes, personal information—which means “recorded information about an identifiable individual”—without the knowledge or consent of the individual. Disclosure is permitted if the research purpose cannot reasonably be accomplished without identifiable data and s. 35 requires the public body to, by contract, impose on the researcher obligations to ensure confidentiality and to strip identifiers as soon as practicable. Other conditions are that data linkage must only be undertaken if its benefits outweigh any harm to the individuals involved. New research uses are permitted only with the consent of the public body.

While this provision may not, in its details, be particularly sophisticated, I believe it showed considerable foresight, over ten years ago, on the part of the drafters of the law. Section 35 contains, in my view, most of the essentials of a workable approach to privacy and health research, certainly as regards secondary use of data for research purposes. I mention s. 35 because the guts of that provision are echoed and elaborated upon in many other laws across the country, including those in Alberta, Saskatchewan, Manitoba and federally. A common element in these approaches is that individual consent to collection, use and disclosure of personal health information for research purposes is not a necessary condition before research can be pursued.

The details vary from place to place, of course, and this is a convenient point to ask: “What might the elements of a sound privacy protection regime look like in the context of health research?” Policy-makers have no trouble finding guidance or support in identifying the elements of a good regulatory approach. The essentials of a sound approach can be gleaned from existing Canadian legislation and policy, including the health privacy laws of British Columbia, Alberta and Manitoba. We could also look to laws and practices abroad for guidance. Some aspects of the United Kingdom's 1998 *Data Protection Act*—which was enacted in response to the well-known 1995 European Union Directive on data protection—could be, for example, informative. Section 33 of that Act, which addresses research uses of existing data, might, for example, offer some useful insights.

My thinking at this date is that a harmonized research code or law should do at least the following (and this list is not necessarily exhaustive):

- As a general matter, the law should require health care providers and health care facilities to make reasonable efforts to notify patients or clients of the possible use of their health information for research purposes. Health ministries and departments should also, through websites or other means, publicize the possible research uses of health information. This public information need not specify every type of research that might be undertaken.
- The actual administration of health research privacy rules could perhaps be given to research ethics boards (REBs), although some role for a fall-back agency might be necessary for cases where a REB is not relevant to research approvals. I recognize that this role for REBs, which already exists in many important respects under the Tri-Council Policy Statement, would require resources for education, technical support, audit and enforcement. Such a role for REBS also should not lead to unnecessary delays in the conduct of research.

- REBs could approve secondary use of identifiable health information for research where the research purpose could, to use the British Columbia criterion, not “reasonably be accomplished” without identifiable data. While general criteria might be given for the determination of what is or is not identifiable information, it should be left to REBs to determine if information is identifiable in the circumstances of each case, and as technology and research tools evolve.
- In almost all cases, researchers should be required to de-identify data as far and as soon as is practicable. As indicated earlier, this can effectively be done, for practical purposes, in a way that permits longitudinal analysis, with unique identifiers being substituted for other identifiers and the key being held securely by the researcher or perhaps by a trusted third party (perhaps under an escrow agreement).
- Either the REB should publish, or the law itself should prescribe, minimum criteria for information security measures and practices. I’m not thinking here of prescribed technical standards—those tend to be a waste of effort. But standard practices for information handling, storage and security can and should be laid down.
- The researcher should be required, by contract, to adhere to the law or policy, including as regards prohibition on further uses or disclosures of health information and respecting information security. The same goes for employees or associates of the researcher.
- The REB, blessed with the resources to do so, should seriously pursue powers to audit compliance, which should be part of the research agreement just mentioned. Spot or surprise audits are a very useful tool, especially if their results (good or bad) are known within the research community.

As I said a moment ago, these are only some of the elements of an appropriate approach to research and privacy. I should say that, in cases of clinical research where participants are being recruited prospectively, the best practice, at least, should be to seek consent. If a researcher is seeking consent for a drug trial, it seems to me not unreasonable to expect the researcher to include an explicit privacy element to the consent to participate in the trial.

The challenge now, it seems to me, is to devise a harmonized approach to privacy in health research, in terms of the rules and their oversight. Earlier I mentioned the difficulty we Canadians face in actually managing to take a consistent approach—whether you call it a national or, these days, pan-Canadian approach—to regulating anything. But that attempt is, when it comes to privacy and health research—not to mention and privacy and health care broadly—well worth making, for a number of obvious reasons. These include the fact that multi-centre, multi-jurisdictional health research is increasingly common in this country. The minute data cross a provincial or territorial boundary—never mind a national border and all that that implies for privacy protection—the question is begged as to what rules apply and who enforces them.

A number of initiatives are under way to formulate a common approach to privacy in health research, and I am working on one of them. The Canadian Institutes of Health Research, the umbrella organization for a number of separate national research institutes, has over the past few years taken the lead in studying issues involved in privacy and health research. Last November, it hosted a two-day national workshop in Ottawa to examine a series of case studies it had chosen to illustrate the complex issues involved in this area. Two further initiatives have grown out of this. First, CIHR has called for applications for research, which it will fund, into issues involving privacy in health research.

Second, CIHR has struck a Privacy Advisory Committee to draft privacy guidelines, policies or best

practices—the precise nature of the product has yet to be determined—to address privacy interests in the research context. I am a member of the PAC and we are working on completing a draft that can then be opened up for comment. One of the key aspects of CIHR’s work in this area, and therefore the PAC's work, it seems to me, will be to ensure up-take of our work by research ethics boards and others in the coming years. This is something CIHR is keenly aware of and working on.

Of course, CIHR's work might, I suppose, be superseded by the miraculous appearance of harmonized health research privacy provisions that are seamlessly and effortlessly adopted across Canada. That would be a welcome development, but while I'm certainly willing to do whatever I can to help it happen, I'm not persuaded that it's going to come easily or soon. For several years the Advisory Committee on Health-Infostructure, an advisory body working under the auspices of the federal/provincial/territorial ministries of health, attempted to formulate a consensus approach to health privacy. They ultimately succeeded in producing an agreement, but that foundered when it came to ultimate federal agreement.

I understand a new FPT harmonization effort is underway. While the ACHI's earlier work could form part of this effort, it should be a much more open effort than the ACHI’s was. The input of stakeholders and opinion-leaders such as CIHR, CIHI, privacy commissioners and others—including the National Council on Ethics in Human Research—is key. I would also include in this group the Canada Health Infoway, whose work on electronic health records is critical to the successful development of pan-Canadian solutions for e-health systems and for whose leaders and experts I have considerable respect.

My goal today has been to give you my perspective, as one of many privacy commissioners in this country, about the role of consent in health research. Returning to the title for my remarks, let me conclude with a few observations. I have suggested the price of consent to secondary data use for health research is too high. I have suggested that consent for prospective research is a good practice. Consent may have value there, but its value in the context of secondary research is in the main far from apparent to me. Thank you for your patience in listening for so long after lunch.

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