

Privacy and Confidentiality of Data in Health Research: A summary of CIHR initiatives



Canadians are passionate about both the privacy of their personal information and the potential for health research to improve their health care. These are compelling rights and interests that Canadians relate to and feel - if not legally, then intrinsically - entitled to. To describe the issue simply as a trade-off between the individual right to privacy and society's interest in good health care is an oversimplification.

There are many more dimensions to this issue. On the one hand, privacy is not just an individual right. Communities have an important interest in safeguarding generalizable information about themselves and protecting individual members of their group from possible discrimination. Society too has an interest in protecting the right to privacy within clearly defined boundaries, beyond which, as a free and democratic society, we simply do not want to venture.

On the other hand, efficient health care is not just a collective interest. Individual Canadians have an important interest in sharing their personal information to improve their health and that of their loved ones, to gain access to effective and dependable health care services, and to participate actively in ensuring an open, transparent and accountable health system.

The real challenge lies in promoting constructive and informed dialogue to achieve the delicate balance needed to secure all of these rights and interests. Clearly, however, this is not a challenge unique to Canadians - it is part of a much broader international quest for solutions. CIHR is leading various initiatives as part of this quest.



Understanding the Legal Framework

CIHR's **Compendium of Canadian Legislation respecting the Protection of Personal Information in Health Research (April 2000)** reveals many existing and proposed laws respecting personal information and personal health information at the federal and provincial levels, affecting the public and private sectors. The sheer complexity of all of this legislation highlights the need for a harmonized legislative/policy framework in Canada to ensure minimum protection of privacy for all Canadians, while also enabling important health research to continue nationally and internationally.

CIHR's **Selected International Legal Norms on the Protection of Personal Information in Health Research (December 2001)** frames the current Canadian situation in the global context. It provides the necessary perspective to understand the international source of fundamental principles and how, through binding force or moral suasion, they have evolved over time into national legislation. This comparative international review demonstrates that many of the issues we are struggling with are not specific to Canada, but rather, constitute significant challenges for many nations.

Bridging the Gap

At CIHR's Workshop on **Personal Health Information: Balancing Access and Privacy in Health Research (June 3-4, 2000)**, a wide cross-section of interests were represented, including data holders, data users, data regulators and data subjects, as well as experts in law, ethics, public policy and privacy-enhancing technology. Several substantive issues were articulated, but more importantly, the Workshop revealed an urgent need to bridge the existing knowledge and language gaps between the research and non-research communities. CIHR has since led two parallel initiatives to address this need.

First, CIHR, in collaboration with the Canadian Institute for Health Information and in consultation with Health Canada, Industry Canada and the Office of the Privacy Commissioner of Canada, released **Personal Information Protection and Electronic Documents Act: Questions and Answers for Health Researchers (April 2001)** to inform health researchers of the possible implications of the new federal *Personal Information Protection and Electronic Documents Act* (PIPEDA). These Qs and As are designed to explain how PIPEDA will apply in the health research context, and in cases of uncertainty, outline different possible interpretations and their underlying rationales. This is to assist health researchers in understanding the issues in the current debate and in preparing themselves for the application of PIPEDA.

Second, a CIHR Working Group is currently completing a series of **Case Studies Involving Secondary Use of Personal Information in Health Research (Draft December 2001, completion projected for Fall 2002)**. The aim is to demonstrate in concrete terms: the purpose and rationale for the research; the potential health benefits; what data is required at what level of identifiability and for what purpose; how the data is actually collected, used and disclosed; how consent is obtained and in what form; where consent is not obtained, an explanation of why it is impracticable; what security measures are implemented; how long data is retained, for what purposes and under what conditions; what reviews and approvals were obtained to conduct the research.

Publication of these Case Studies will lead to a major workshop planned for November 2002. The aim of the workshop will be to promote dialogue and understanding among stakeholder groups. These case studies can serve as a tool for policy-makers/legislators as they develop a harmonized policy framework; for consumers and the general public as they reflect upon what they consider acceptable uses of personal information for health research purposes; and for health researchers as they plan a future research and education agenda.

Taking on the Challenge

All of the above initiatives have informed CIHR's **Recommendations for the Interpretation and Application of the Personal Information Protection and Electronic Documents Act in the Health Research Context (December 2001)**. PIPEDA will serve as the minimum template for provinces to develop substantially similar legislation before January 2004, and therefore, is critical for the development of a harmonized, coherent and comprehensive policy framework across the country. The challenge lies in finding workable and feasible ways of respecting the right of Canadians to have their personal information protected, while also enabling access to that information by health researchers seeking to better the health of Canadians, improve health services and strengthen our health care system.

In developing these recommendations, CIHR held consultations in June and November 2001. A **Background Legal Research and Analysis (November 2001)** was also undertaken to examine the legal validity and policy rationale for CIHR's recommendations and to help guide their precise wording and scope.

Looking Forward: Future Research Agenda

Arising from these initiatives is the need for evidence-based research on substantive issues that continue to emerge. As specific research questions arise, they will need to be addressed through either investigator-initiated research or strategic initiatives as part of Canada's national health research agenda. CIHR, through its Institutes, could play an instrumental role in building the necessary capacity to deal with these issues and support research programs in this area. The objective will be to create new knowledge that can bring forth creative and innovative solutions. New knowledge will help inform policy-making processes in a manner that secures the confidence of Canadians that their privacy will be protected and that their health and health services will continue to improve.

For additional information:

www.cihr-irsc.gc.ca/about_cihr/organization/ethics/initiatives_e.shtml

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