Appendix 1

CIHR IRSC

Institute of Aboriginal Peoples' Health
Institute of Cancer Research
Institute of Circulatory and Respiratory Health
Institute of Gender and Health
Institute of Genetics
Institute of Health Services and Policy Research
Institute of Healthy Aging
Institute of Human Development and Child and Youth Health
Institute of Infection and Immunity
Institute of Musculoskeletal Health and Arthritis
Institute of Neurosciences, Mental Health and Addiction
Institute of Nutrition, Metabolism and Diabetes
Institute of Population and Public Health

Institut de la santé des Autochtones
Institut du cancer
Institut des appareils circulatoire et respiratoire
Institut de la santé des femmes et des hommes
Institut de génétique
Institut des services et des politiques de la santé
Institut du vieillissement
Institut du développement et de la santé des enfants et des adolescents
Institut des maladies infectieuses et immunitaires
Institut de l'appareil locomoteur et de l'arthrite
Institut des neurosciences, de la santé mentale et des toxicomanies
Institut de la nutrition, du métabolisme et du diabète
Institut de la santé publique et des populations

December 3, 2001

Honourable Michael Kirby, PC
Senate of Canada
471-S Centre Block
Ottawa, Ontario
K1A 0A4

Dear ~~Sir~~ Michael:

Pursuant to our meeting of April 30, 2001, we are pleased to provide you with CIHR's recommendations regarding the interpretation and application of PIPEDA to health research activities. We believe regulations are vital to clarify critical terms and provide greater certainty of law.

CIHR is mandated by Parliament to encourage integrative health research across *disciplines*, including bio-medical research, clinical research, research involving health services and health policy, as well as research on population and public health. Much of this research, particularly in the latter areas, critically depends on the secondary use of both health data and non-health data.

CIHR must work in collaboration with provinces to advance health research and to help disseminate and apply new research knowledge across *regions*. CIHR must also forge an integrated health research agenda across *sectors* by engaging voluntary organizations, the private sector and others, both nationally and internationally.

Most importantly, CIHR research must meet the highest international standards of scientific excellence and ethics; it must foster the discussion of ethical issues and the application of ethical principles to health research.

Given the ambit of its role and its express undertaking to Canadians, CIHR is clearly interested in how this federal Act governing the protection of personal information – *including personal health information* - in the private sector might eventually impact health research in this country. The attached regulations will, we believe, help achieve a more stable balance between the respect for individual privacy and the societal need to advance health research. We trust these regulations will be useful to you and your Committee, as you prepare your report to Senate on the developments of PIPEDA since it received Royal Assent in April 2000.

President

Canadian Institutes of Health Research
410 Laurier Avenue W., 9th Floor, Address Locator 4209A
Ottawa, Ontario K1A 0W9 Tel.: (613) 954-1809
Fax: (613) 954-1802 **www.cihr.ca**

Président

Instituts de recherche en santé du Canada
410, avenue Laurier O., 9e étage, Indice de l'adresse 4209A
Ottawa, Ontario K1A 0W9 Tél. : (613) 954-1809
Fax : (613) 954-1802 **www.irsc.ca**

Canada

We will be pleased to send you a signed version of these regulations in approximately one week's time, along with all of the background documents in support thereof. On behalf of CIHR and its health research community, we thank you for your continuing interest in this very important issue.

Sincerely,

Dr. Alan Bernstein, FRSC
President

cc: Hon. Yves Morin, Senator
Encl.

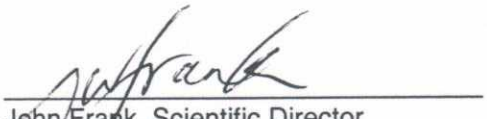
Recommendations for the Interpretation and Application of the *Personal Information Protection and Electronic Documents Act* (S.C.2000, c.5) in the Health Research Context

Canadian Institutes of Health Research

November 30, 2001

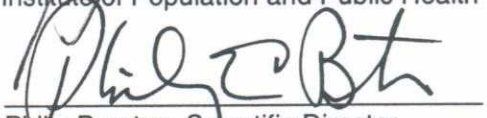
Signed on this 4th day of December, 2001.

Alan Bernstein, President

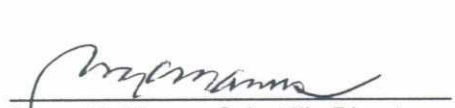


John Frank, Scientific Director
Institute of Population and Public Health

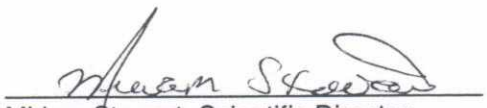
Jeff Reading, Scientific Director
Institute of Aboriginal People's Health



Philip Branton, Scientific Director
Institute of Cancer Research

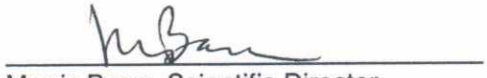


Bruce McManus, Scientific Director
Institute of Circulatory and Respiratory Health

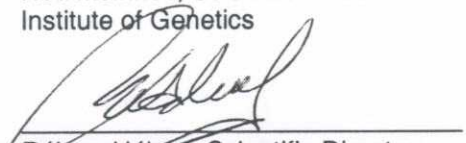


Miriam Stewart, Scientific Director
Institute of Gender and Health

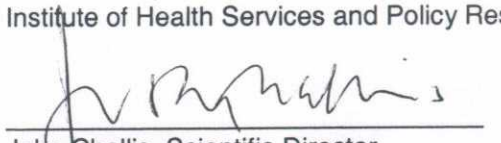
Rod McInnes, Scientific Director
Institute of Genetics



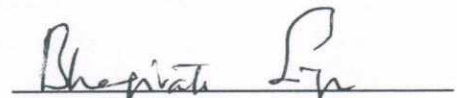
Morris Barer, Scientific Director
Institute of Health Services and Policy Research



Réjean Hébert, Scientific Director
Institute of Aging



John Challis, Scientific Director
Institute of Human Development, Child & Youth Health



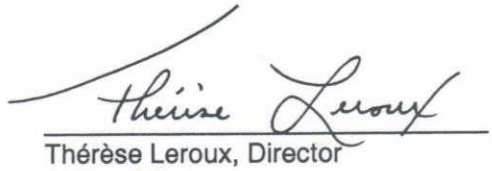
Bhagirath Singh, Scientific Director
Institute of Infection and Immunity

Cyril Frank, Scientific Director
Institute of Musculoskeletal Health and Arthritis

Rémi Quirion, Scientific Director
Institute of Neurosciences, Mental Health and Addiction

Diane Finegood, Scientific Director
Institute of Nutrition, Metabolism and Diabetes

Patricia Kosseim, Senior Policy Advisor
Ethics Office



Thérèse Leroux, Director
Ethics Office

CIHR's Recommendations
for the Interpretation and Application of the
***Personal Information Protection and Electronic Documents Act* (PIPEDA)**
(S.C.2000, c.5)
in the Health Research Context

November 30, 2001

The following document summarizes CIHR's recommendations with respect to the interpretation and application of PIPEDA in health research. These recommendations are the result of background research, analyses and consultations with various stakeholders over a two-year period[1]. More specifically, these recommendations are informed and inspired by the following process.

- CIHR conducted a comparative survey of all proposed and existing Canadian legislation respecting the protection of personal information in the context of health research[2]. Significant disparities in the rules and approaches adopted by various provinces and different sectors demonstrated the critical need for a more harmonized, comprehensive and coherent policy framework in Canada.

- An analysis of select international norms respecting the protection of personal information in health research helped situate the current Canadian position in a more global context[3]. This provided the necessary perspective to understand the source of existing principles and compare some interesting models used in various countries.

- A CIHR Workshop held in June 2000[4] brought together various data holders, data users, data subjects, regulators and others to encourage dialogue about how to balance the right to have personal data protected and the need to access that data for health research purposes. Participants discussed, identified and articulated important issues, including the critical need for a more informed debate.

- Pursuant to the recommendations of the June 2000 Workshop, CIHR, in collaboration with CIHI, and in consultation with Health Canada, Industry Canada and the Federal Privacy Commissioner's Office, prepared a series of questions and answers about PIPEDA in the health research context[5]. The purpose of the document was to inform health researchers of the implications of the Act, prepare them for its entry into force and further articulate issues arising from its possible interpretation and application in practice.

- In a further attempt to inform the debate, CIHR struck a Working Group composed of population health and health services researchers to prepare a series of actual case studies involving secondary use of data[6]. These case studies illustrate, in concrete terms: why researchers need data; what are the real social benefits resulting from health research; how data is collected, used and linked; what safeguards are put into place to protect the data; what review and approval processes have been deployed; what legal and ethical issues arise; and, what are some possible best practices emerging from each case.

- In June 2001, a consultation session was held with key stakeholders in the health research field to discuss an earlier draft of CIHR's proposed recommendations. All comments and concerns were recorded in a discussion document and many of the suggestions were integrated in the revised version[7].

- An in-depth legal research and analysis was carried out to examine the legal validity of the proposed recommendations. This legal research and analysis[8] helped guide the precise wording and scope of each recommendation in accordance with fundamental principles of statutory construction and delegated legislation.

- Under the strategic advice of some members of CIHR's Governing Council and Scientific Directors, alternative options were also explored. A final round of consultations was held in November 2001 before selecting and finalizing this preferred option.

The following recommendations are in the form of regulations to the present Act. These regulations have been developed as the most realistic, short-term solution, recognizing that the legislation will not likely be amended before January 1, 2002. This solution is less than ideal in that these regulations are significantly limited by the current wording and structure of the Act. However, CIHR believes that they will, at the very least, provide the necessary guidance to clarify certain ambiguous terms of PIPEDA. This will help ensure that the Act is interpreted and applied in a manner which achieves the objectives of the Act, without obstructing vitally important research needed to better the health of Canadians, improve health care services and strengthen the health system.

At this stage, CIHR believes that regulations *are* necessary. As legally binding instruments, regulations will attain greater certainty of law. Researchers, and Canadian citizens generally, have a right to know with certainty what the law expects of them and how to govern their conduct accordingly. Waiting for clarity to be achieved through legal decisions by the Privacy Commissioner, the Federal Court and further appellate bodies, risks paralyzing important research activities in the meantime. The potential chilling effect may be worsened by the time it will take to establish a consistent body of precedents and to distinguish situations from one another. Moreover, regulations to PIPEDA have the added advantage of serving as an important template during this critical time as provinces develop substantially similar legislation before January 1, 2004.

Finally, CIHR fully recognizes that further effort is needed beyond these regulations to work with various stakeholders and the provinces towards the establishment of a more harmonized, comprehensive and coherent legal or policy framework governing the protection of personal information in the health sector generally. A National Forum may eventually assist in achieving this aim. Quite apart from formal legal or policy instruments, there is a critical need for researchers to establish, over time, more detailed guidelines for promoting best information practices in their day-to-day work. Further development and public discussion of CIHR's case studies will be instrumental in this regard.

1. <u>Clarification of the definition of "personal information"</u>

1) a) For greater certainty, "information about an identifiable individual", within the meaning of personal information as defined by the Act, shall include only that information that can:

i) identify, either directly or indirectly, a specific individual; or,
ii) be manipulated by a reasonably foreseeable method to identify a specific individual; or
iii) be linked with other accessible information by a reasonably foreseeable method to identify a specific individual.

b) Notwithstanding subsection 1(a), "information about an identifiable individual" shall not include:

i) anonymized information which has been permanently stripped of all identifiers or aggregate information which has been grouped and averaged, such that the information has no reasonable potential for any organization to identify a specific individual; or
ii) unlinked information that, to the actual knowledge of the disclosing organization, the receiving organization cannot link with other accessible information by any reasonably foreseeable method, to identify a specific individual.

c) Whether or not a method is reasonably foreseeable under subsections 1(a) and 1(b) shall be assessed with regard to the circumstances prevailing at the time of the proposed collection, use or disclosure.

Rationale: It is recognized that information may fall along a whole spectrum in terms of its potential to identify individuals, depending on its nature, its relation to other information and the context in which it was generated. In order to properly carry out the purposes and provisions of Part I, it is recommended that a test of reasonableness be adopted as the determining criterion.

2. <u>Clarification of the term "in the course of commercial activities"</u>

2) For greater certainty, personal information is collected, used or disclosed "in the course of commercial activities" within the meaning of paragraph 4(1)(a) of the Act, when the organization's activities are aimed primarily at making a pecuniary gain for the personal benefit of its members, as opposed to recovering its costs or promoting its philanthropic, charitable, scientific, health or other like objects.

Rationale: In this modern era of health research, as in other areas, the nature of an organization's activities may involve a mixture of commercial and non-commercial attributes. This reality is likely to cause some uncertainty with respect to the applicability of Part I to health research. Accordingly, the present recommendation is intended to introduce a "primary aim" test to facilitate the interpretation and application of paragraph 4(1)(a) of the Act (hereinafter the *"application clause"*), whereby Part I "applies to every organization in respect of personal information that [it] collects, uses or discloses in the course of commercial activities".

3. Clarification of the terms "scholarly research" and "scholarly research purposes"

3(1) For greater certainty, the term "scholarly research" referred to in paragraphs 7(2)(c) and 7(3)(f) of the Act shall mean research which:

a) aims primarily at establishing facts, principles or generalizable knowledge, which are of social value and intended to be publicly disseminated; and,

b) has been approved by a research ethics board that is specially designated by law or that is duly established by a university, affiliated institution, professional body, funding agency, or other similar body, where required by, and in accordance with, current applicable national and international ethical standards.

Scholarly research may include research jointly funded by the private and public sectors.

Rationale: Use and disclosure of personal information without consent are permitted under the conditions found in the exceptions at 7(2)(c) and 7(3)(f), respectively. One of these requirements consists of using or disclosing the personal information for scholarly research purposes. This proposed provision seeks to expressly define scholarly research thereby importing greater certainty in the interpretation and application of these critical exceptions.

This proposed provision also seeks to expressly recognize review and approval by research ethics boards as a central condition for allowing scholarly research to proceed in any Canadian university or affiliated institution receiving federal funding from granting agencies such as CIHR. It is also a requirement under federal regulations in respect of clinical trials. For greater certainty and clarity then, this reality should be reflected in the very meaning ascribed to the term.

3(2) For greater certainty, the term "scholarly research purposes" referred to in paragraphs 7(2)(c) and 7(3)(f) of the Act shall include consistent purposes, such as, validating and auditing research results, conducting related research which is reasonably and directly connected to the original research purpose, and notifying individuals of any unanticipated, long-term risk of potentially adverse effects.

Rationale: This provision identifies the scope of scholarly research purposes by referring to directly related purposes which would not constitute new purposes requiring new consent and which would justify the ongoing retention of data until such time as those directly related purposes were also fulfilled. This is especially important in order to attribute a practical, workable and feasible meaning to the principles governing the retention and destruction of data set out in the CSA Code, incorporated as Schedule 1 of the Act.

4. Receipt of personal information under conditions contemplated in paragraph 7(3)(F)

4) In order to give effect to the exception provided for in paragraph 7(3)(f) of the Act, an organization may receive personal information without the knowledge or consent of the individual under the conditions provided for in that paragraph.

Rationale: In order to give effect to the exception at paragraph 7(3)(f) and its conditions, this proposed provision would provide the necessary clarity to ensure that the scholarly researcher may still receive the personal information under the same conditions even though the transaction may involve consideration or the research may have some commercial attributes.

5. Clarification of the term "impracticable to obtain consent"

5) For greater certainty, in assessing whether "it is impracticable to obtain consent" for scholarly research purposes within the meaning of paragraphs 7(2)(c) and 7(3)(f) of the Act, consideration shall be given to all of the relevant factors which may apply in the circumstances, including:

a) the size of the population being researched;

b) the proportion of individuals likely to have relocated or died since the time the personal information was originally collected;

c) ***the risk of introducing potential bias into the research thereby affecting the generalizability and validity of results;***

d) ***the risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek their consent;***

e) ***the risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or in certain circumstances;***

f) ***the difficulty of contacting individuals directly when there is no existing or continuing relationship between the organization and the individuals;***

g) ***the difficulty of contacting individuals indirectly through public means, such as advertisements and notices; and,***

h) ***whether, in any of the above circumstances, the requirement for additional financial, material, human, organizational and other resources needed to obtain such consent will impose an undue hardship on the organization.***

Rationale: In order to assist in the interpretation and application of the term "impracticable to obtain consent", this recommendation attempts to capture actual situations where, in practice, consent either cannot be feasibly or realistically obtained or, if obtained, would defeat the very purpose of the scholarly research. This list of factors has been directly inspired from CIHR's draft case studies involving secondary use of personal information, specifically in the context of health services and population health research.

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[1] All background documents are available on CIHR's website at www.cihr.ca/about_cihr/ethics/initiatives_e.shtml

[2] Canadian Institutes of Health Research, *Compendium of Canadian Legislation respecting the Protection of Personal Information in Health Research* (Ottawa: Public Works and Government Services Canada, 2000).

[3] Canadian Institutes of Health Research, *Selected International Legal Norms on the Protection of Personal Information in Health Research* (forthcoming).

[4] Canadian Institutes of Health Research, June 2000 Workshop Report entitled, *Personal Health Information: Balancing Access and Privacy in Health Research: Summary, Recommendations and Follow Up* (June, 2000).

[5] Canadian Institutes of Health Research, *Personal Information Protection and Electronic Documents Act: Questions and Answers for Health Researchers*, (Ottawa: Public Works and Government Services Canada, 2001).

[6] Canadian Institutes of Health Research, *Draft Case Studies Involving Secondary Use of Personal Information in Health Research* (December, 2001).

[7] Canadian Institutes of Health Research, *Draft Recommendations for the Interpretation and Application of the Protection of Personal Information and Electronic Documents Act in Health Research: Discussion Document resulting from a Consultation Session Held June 1, 2001.*

[8] Canadian Institutes of Health Research, *Background Legal Research and Analysis in Support of CIHR's Recommendations* (November, 2001).

Appendix 2

December 7, 2001

The Honourable Michael J.L. Kirby
Chairman
Standing Senate Committee on Social Affairs, Science and Technology
Senate of Canada
Ottawa, Ontario K1A 0A4

Dear Senator Kirby,

I am writing to you in follow-up to our meeting of November 29th, 2001. At that time you requested the Privacy Working Group to forward principles for the privacy protection of personal health information to your Committee for consideration during your upcoming December 12, 2001 review of the Personal Information Protection and Electronic Documents Act (PIPEDA).

As you are aware, the Privacy Working Group was formed in response to the 1999 report of the Standing Senate Committee on Social Affairs, Science and Technology on Bill C-6 (PIPEDA), which expressed the Committee's concern "that the requirements under Bill C-6 in respect of the collection, use and disclosure of personal information may not be sufficient to adequately protect health information." The Privacy Working Group could not agree more. Unfortunately, we regret to report that nothing substantive has occurred at the federal government level since the Committee report to change this reality.

Another key observation made in your report was that, "It is clear that the health care community is not part of the broad consensus supporting the bill and that there is no consensus within the health community itself as to an appropriate solution." In response to this concern, the Privacy Working Group came together in an attempt to find consensus and to work collaboratively on achieving appropriate solutions. The Privacy Working Group worked together on a project focusing on the principles underlying the privacy of health information. This group project culminated in the document entitled: *Privacy Protection and Health Information: Understanding the Implementation Issues* (December 2000). While we were unable to produce a unified position on all issues, the group has reached agreement on many issues and most importantly, on a process to address the unresolved issues; a process that would require the leadership of the federal government.

The Privacy Working group has attempted over the past months to engage the federal government to work with us on finding solutions and clarifying issues in regard to the application of PIPEDA to health information. We believe it is imperative that federal departments such as Health Canada and Industry Canada are actively involved in resolving these issues so as to ensure the appropriate application of the Act. Collectively, we suggested several options

Canadian Pharmacists Association – Association des pharmaciens du Canada
1785, prom. Alta Vista Drive, Ottawa, ON K1G 3Y6
Tel: 1-800-917-9489 or/ou (613) 523-7877; Fax: (613) 523-0445
Email: cpha@pharmacists.ca; www.pharmacists.ca

to resolve the outstanding issues. Our first preference was the establishment of a separate regulatory agency for personal health information. Alternatively, we suggested a process that would lead to the establishment of interpretative guidelines. Collectively and individually, members of the Privacy Working Group approached Industry Canada and Health Canada to discuss these options and find solutions to some very real concerns in need of clarification. Again, we regret to report that representatives of these departments have been less than enthusiastic in engaging in discussion about our proposed solutions regarding a process to resolve the outstanding issues related to the application of PIPEDA to personal health information.

If you recall, your Committee report requested the equal participation of the stakeholders and the government: "The Committee believes that the certainty of the deadline will operate to motivate stakeholders and governments to formulate a solution that is appropriate for the protection of personal health information." The Privacy Working Group believes that it has fulfilled its responsibility in good faith. However, we believe the federal government's efforts have fallen short.

While we are disappointed with the federal government's response on this issue, we are appreciative of the leadership demonstrated by you and the members of the Standing Senate Committee.

As requested please find attached principles that we propose to guide the development of interpretative guidelines relating to PIPEDA and personal health information. These principles were developed with a view of working with policy-makers to fine-tune them and to adjudicate on areas where, as a diverse group, consensus was difficult to achieve. We see these first principles as a vital piece in moving towards resolution of issues, but not as the final product.

As these principles were being developed, the research community worked in a parallel and supportive process to address the impact of PIPEDA on research. We support the regulatory approach proposed by CIHR. However, we would like to see "scholarly research" in the Act, changed to "research". Also, we would like express re-assurance that "research" includes research related to policy, planning and evaluation of health services.

We would also ask that the Senate Committee recommend that the federal government, particularly Health Canada and Industry Canada, work with the stakeholders on a process to further clarify the application of PIPEDA in respect to health information.

.../3

Canadian Pharmacists Association – Association des pharmaciens du Canada
1785, prom. Alta Vista Drive, Ottawa, ON K1G 3Y6
Tel: 1-800-917-9489 or/ou (613) 523-7877; Fax: (613) 523-0445
Email: cpha@pharmacists.ca; www.pharmacists.ca

To conclude, in your 1999 report you indicated that health information was in need of special protection and treatment: "Witnesses pointed out that health information is private, sensitive and vulnerable to abuse. The Committee agrees." You suggested that PIPEDA was insufficient in this regard and needed clarification: "There is thus a significant degree of uncertainty surrounding the application of the bill to personal health information that requires clarification." We trust that you will once again communicate this message to the federal government.

On behalf of all members of the Privacy Working Group, I thank you and Committee members for their consideration. We look forward to receiving the Committee's report.

Yours sincerely,

Jeff Poston, PhD., MRPharmS
Chair, Privacy Working Group

Attachment

Canadian Pharmacists Association – Association des pharmaciens du Canada
1785, prom. Alta Vista Drive, Ottawa, ON K1G 3Y6
Tel: 1-800-917-9489 or/ou (613) 523-7877; Fax: (613) 523-0445
Email: cpha@pharmacists.ca; www.pharmacists.ca

Principles for the Privacy Protection of Personal Health Information in Canada

The members of the Privacy Working Group* have proposed the following principles to guide the development of interpretative guidelines relating to the application of the Personal Information Protection and Electronic Documents Act (PIPEDA) to personal health information.

Overarching Principle

An individual's right of privacy of personal health information is paramount; however, it is not absolute. This right is subject to reasonable limits prescribed by law, to appropriately balance the individual's right to privacy and societal needs, as can be demonstrably justified in a free and democratic society.

1. **Privacy:** Individuals have a right of privacy with respect to their personal health information.

2. **Consent:** Individuals have the right to provide or withhold consent with respect to the collection, use, disclosure, or access of their personal health information.

3. **Knowledge:** Individuals have a right of knowledge with respect to their personal health information.

4. **Individual Access:** Individuals have the right to access their own personal health information.

5. **Accuracy:** Individuals have the right to have their personal health information recorded as accurately as possible and to review and amend their health records to ensure accuracy.

6. **Recourse:** Individuals have the right to recourse when they suspect a breach in the privacy of their health information.

7. **Confidentiality:** Providers and organizations have an obligation to treat personal health information as confidential.

8. **Trusteeship and Accountability:** Providers and organizations entrusted with personal health information have an obligation to safeguard the privacy of individuals and the confidentiality of this information.

9. **Access and Use - Identifiable Health Information:**
   a) To provide direct care to individuals, providers and health care organizations should have access to identifiable health information.
   b) Identifiable health information shall only be used with the consent of the individual, except in extraordinary circumstances where there is:
      - a demonstrated legal requirement; or
      - compelling evidence for individual or societal good and a privacy impact assessment that are adjudicated by an independent body according to strict protocols.

10. **Access and Use - De-Identified Health Information:**
   a) Access to and use of de-identified information should be available to improve population health status and to improve the effectiveness and efficiency of the health system.
   b) Disclosure, collection and use of personal health information for purposes such as billing, research, evaluation and quality assurance activities should be restricted to de-identified information unless the user can demonstrate why identifiable information is required.

11. **Security:** Security safeguards must be in place to protect the integrity and confidentiality of health information.

12. **Implementation and Enforcement:** Providers and organizations should implement policies, procedures and practices to achieve privacy protection.

* The Privacy Working Group is composed of representatives from the Canadian Dental Association, the Canadian Healthcare Association, the Canadian Medical Association, the Canadian Nurses Association, the Canadian Pharmacists Association and the Consumers' Association of Canada.

Appendix 3

Privacy Commissioner of Canada

112 Kent Street
Ottawa, Ontario
K1A 1H3
Tel.: (613) 995-8210
Fax: (613) 947-6850
1-800-282-1376
www.privcom.gc.ca

Commissaire à la protection de la vie privée du Canada

112, rue Kent
Ottawa (Ontario)
K1A 1H3
Tél.: (613) 995-8210
Télec.: (613) 947-6850
1-800-282-1376
www.privcom.gc.ca

November 20, 2001

Hon. Michael Kirby
Chair
Social Affairs, Science and Technology Committee
Room 473-S, Centre Block
Ottawa, Ontario
K1A 0A6

Dear Senator Kirby:

As you requested in our telephone conversation last Friday, this letter is to confirm the approach I will take under the *Personal Information Protection and Electronic Documents Act* to the use and disclosure of personal health information for health research.

I know that members of the health community are understandably concerned about the possible impact of the Act in this regard and have raised some important questions. I want to assure you and your Committee that bona fide health research, carried out with appropriate sensitivity to the privacy rights of Canadians, has nothing to fear from the Act or my Office.

In my Annual Report to Parliament, which would have been public by now were it not for the aftermath of September 11, I will set out my position on this important issue as follows:

Personal health information is perhaps the most privacy-sensitive of all personal information, and as a general rule individuals must have the right to control who can collect, use or disclose this information, and for what purpose. At the same time, however, our society has a vital interest in the continuation and development of health research, which holds the promise of great benefits for all individuals.

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The Purpose clause of the Act specifies that its rules are intended to balance "the right of privacy of individuals with respect to their personal information and the need of organizations to collect, use or disclose personal information for purposes that a reasonable person would consider appropriate in the circumstances." In the case of health research, it appears clear to me that the appropriate balance is one that safeguards the genuine privacy interests of individuals while permitting the conduct of legitimate health research that uses information in ways that can have no possible impact on the individuals to whom it pertains. I do not believe that the Act was in any way intended to deter or impede such research, and my provincial and territorial counterparts with whom I discussed the issue this summer share this view.

Accordingly, I intend in this regard to interpret broadly the intent of Paragraph 7(2)(c) of the Act, which permits an organization to use personal information without the knowledge or consent of the individual if "it is used for statistical, or scholarly study or research, purposes that cannot be achieved without using the information, 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." Paragraph 7(3)(f) makes a parallel provision for the disclosure of personal information without knowledge or consent.

I will take the view that bona fide health research carried out by duly accredited organizations under appropriate safeguards does in fact constitute statistical or scholarly study or research, whether or not there is an element of pecuniary interest involved. Merely because research into a particular medical condition may receive funding assistance from a pharmaceutical company that hopes to reap financial benefit from the discovery of an effective new medication, for example, does not in my view change its legitimacy as health research from the perspective of privacy rights.

With regard to the impracticability of obtaining consent for such research, I accept the view of the health research community that cost factors and/or the difficulty of obtaining consent from 100 per cent of a target population make it impracticable to obtain individual consent for many health research studies.

The Act requires that the information in question must be used in a manner that will ensure its confidentiality. I consider this requirement to be of paramount importance.

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I will accordingly take the position that personal health information can be disclosed and used without consent for health research as described above, but only provided that it remains strictly within the confines of the research project and that it can in no way harm the individual to whom it pertains.

Without limiting the generality of the foregoing, I will consider it an absolute requirement that personal health information disclosed and used without consent for health research purposes can under no circumstances whatsoever find its way to the individual's employers, insurers, relatives or acquaintances, governmental or law enforcement authorities, marketers or any other third parties, nor can the individual be contacted as a result of this information by anyone other than his own physician or other primary health care provider, as the case may be.

I and my Office will maintain vigilant oversight over this requirement, and any breach of it would be considered, ipso facto, an extremely grave violation of the Act.

I am convinced that this approach will fully meet the intent of the Act, effectively protect the privacy rights of Canadians, and permit all legitimate health research to proceed without impediment.

Should you have any further questions on this matter, please do not hesitate to contact me.

Yours sincerely,

George Radwanski
Privacy Commissioner of Canada

Minister of Health | Ministre de la Santé

Allan Rock

Ottawa, Canada K1A 0K9

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SEP. 24 2001

Mr. George Radwanski
Privacy Commissioner of Canada
112 Kent Street
Ottawa, Ontario
K1A 1H3

Dear Mr. Radwanski:

I am writing to follow-up our meeting earlier this month concerning recent proposals from the health sector to amend the *Personal Information Protection and Electronic Documents Act (PIPEDA)*.

I believe it is essential that there is a comprehensive regime to protect the privacy of personal information, including personal health information. This is particularly important given the sensitive and deeply personal nature of this information to Canadians.

As I indicated to you when we met, I do not support the creation of a separate regulatory agency to deal with personal health information under *PIPEDA*. The *Act*, as passed by Parliament just over one year ago, is clear that oversight, redress and audit responsibilities rest with the Privacy Commissioner. The Deputy Minister of Health has also made it clear to stakeholders in the health sector that we are not contemplating amendments to *PIPEDA* to create a separate Agency for the health sector, nor do we support a delay in the application of *PIPEDA* to the health sector.

I also understand that some health organizations are seeking further clarification regarding the application of *PIPEDA* in the health sector. The Deputy Minister of Health has encouraged health stakeholders to bring their concerns to your attention. I believe that for these discussions to be fruitful we need as clear an articulation as possible of the issues involved. To that end, I have asked that Health Canada work with concerned parties to facilitate this discussion.

I enjoyed our discussions earlier this month, and the Deputy Minister of Health will follow up with you on the next steps.

Yours very truly,

Allan Rock

Allan Rock

Canada

Health Canada / Santé Canada
Deputy Minister / Sous-ministre
Ottawa Canada
K1A 0K9

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Your file / Votre référence

Our file / Notre référence

EXECUTIVE OFFICE ACTION
TO: BT
TO:
REC'D. OCT 10 2001
CC:
CC:
LOG NUMBER: 01-0576

OCT - 5 2001

Mr. William Tholl
Secretary General and CEO
Canadian Medical Association
1867, Alta Vista Drive
Ottawa, Ontario
K1G 3Y6

Dear Mr. Tholl:

Our meeting of September 20, 2001 provided an opportunity to hear first hand the concerns of a number of the health sector organizations about the application of Bill C-6.

I would like to thank you and the other representatives of the group of six national health associations for your continued work with the federal government and the health community in addressing protection of personal health information issues, specifically the *Personal Information Protection and Electronic Documents Act (PIPEDA)*.

You should be aware of Minister Rock's position as set out in the attached letter of September 24, 2001 to George Radwanski, the Privacy Commissioner of Canada. In the letter, the Minister states that the Act is clear that oversight, redress and audit responsibilities rest with the Privacy Commissioner. The Minister notes that we have made it clear that we are not contemplating amendments to PIPEDA, nor do we support a delay in the application of *PIPEDA* to the health sector. He understands that some health organizations are seeking further clarification regarding the application of PIPEDA in the health sector.

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The Minister has asked Health Canada to work with you and other concerned parties to develop as clear an articulation as possible of the issues involved. I believe that stakeholder involvement is key and anticipate that the discussions leading to clarifications will also assist stakeholders in presenting their issues to the federal Privacy Commissioner.

Health Canada will contact you and other stakeholders shortly, to arrange for these discussions to take place. To expedite this process, we would appreciate if you could provide us with your concerns, at a level of specificity beyond that provided thus far (e.g. the specific concepts requiring clarification and the context under which their interpretation could be cause for concern). This information would be of great assistance in structuring a productive agenda around the issues as you see them.

I look forward to continuing our on-going discussions.

Yours sincerely,

Ian C. Green

Attachment