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.

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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[i]. 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[ii]. 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[iii]. 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[iv] 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[v]. 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[vi]. 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[vii].

- An in-depth legal research and analysis was carried out to examine the legal validity of the proposed recommendations. This legal research and analysis[viii] 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. Clarification of the definition of "personal information"

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. Clarification of the term "in the course of commercial activities"

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

[ii] 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).

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

[iv] 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).

[v] 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).

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

[vii] 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.*

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