Draft recommendations for the interpretation and application of the *Protection of Personal Information and Electronic Documents Act* in health research

DISCUSSION DOCUMENT
resulting from CIHR Consultation Session held

June 1, 2001
Ottawa, Ontario

Draft recommendations for the interpretation and application of the *Protection of Personal Information and Electronic Documents (PIPED) Act* in health research

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resulting from CIHR Consultation Session held
Friday June 1, 2001
9:00 am - 5:00 pm

Participants

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Regrets

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INTRODUCTORY REMARKS

A. About CIHR

The objective of CIHR is to excel in the creation of knowledge and its translation into improved health of Canadians, more effective health care services and products, and a strengthened health system. In order to fulfil this objective, CIHR is expressly mandated by Parliament to exercise leadership within the Canadian research community; forge an integrated and interdisciplinary health research agenda; foster collaboration with the provinces; engage voluntary organizations, the private sector, individuals and organizations with complementary research interests, both nationally and internationally; encourage innovation, facilitate commercialization and promote economic development through health research in Canada.

CIHR is likewise mandated to promote, assist and undertake research that meets the highest international scientific standards of excellence and ethics; foster the discussion of ethical issues and the application of ethical principles to health research; monitor, analyze and evaluate ethical issues pertaining to health or health research; advise the Minister of Health in respect of any matter related to health or health research.

For these reasons, CIHR is concerned with both the need to access personal information for health research purposes, and the right to have that personal information protected. CIHR's strategy, since its creation, has been to catalyze informed debate, encourage collaboration, and build consensus among various stakeholders regarding how we might eventually achieve an appropriate balance between access *and* privacy of data in health research.

Past and ongoing initiatives include: the publication of a compendium of relevant federal and provincial legislation; an international supplement; a workshop report; questions and answers about the application of new federal privacy legislation (hereinafter, "the PIPED Act" or "the Act") to health research; case studies illustrating, in concrete terms, what personal information researchers actually need and how it is, in fact, used to answer important research questions; and, the identification of potential research priorities which, if supported/promoted, could help inform the development of a more evidence-based, practicable and harmonized policy framework for Canada and beyond. These various initiatives have involved, and continue to involve, the valuable contribution of many participants to whom CIHR is very grateful.

B. Present Session: Purpose and Expectations

The purpose of the June 1st consultation was to invite input into the development of CIHR's draft recommendations on how the PIPED Act should be interpreted and applied in order to work practically and feasibly in the health research context. The PIPED Act adopts an internationally-recognized framework which begins with the individual right to privacy premised on the notion of consent, while allowing for certain exceptions in limited circumstances. **The present CIHR initiative was planned on the assumption that the PIPED Act would not be amended before January 1, 2002 and would hence apply as is.** Based on this assumption, draft recommendations could take one of two forms: either interpretation guidelines or proposed regulations to the Act as currently worded. In both cases, there are limitations to what can be done to clarify the current Act, without changing it. These limitations are well-established in fundamental principles of statutory construction and basic rules of delegated legislation. Moreover, interpretation guidelines or regulations under the current Act will not be able to resolve all of the important issues which may eventually require the development of an overall more coherent framework and/or far more detailed best practices (*e.g.* consent processes; linkage protocols; physical, technological and organizational safeguards; oversight and audit mechanisms). This session, therefore, was planned to better inform the development of CIHR's draft recommendations *within* all of these limitations and operating constraints.

C. Process

In order to facilitate the session and catalyze discussion, the draft recommendations were prepared and sent in advance of the meeting. The draft recommendations were selected on the basis of two considerations:

1) what, based on CIHR's analysis to date, appear to be the most problematic issues for health research under the PIPED Act; *and*
2) what limited solutions would be possible under the current Act, (*i.e*. any regulations would have to be *intra vires* the Act, and any interpretation guidelines would have to be sustainable on its current wording).

The purpose of the meeting was to review those draft recommendations with a view to improving them. The objective was not to wordsmith the draft recommendations, but rather, *to test the criteria underlying each draft recommendation* in order to reflect upon their acceptability in principle, and to assess their feasibility in practice. Time permitting, participants would be asked to prioritize among them and brainstorm about any other criteria and/or new draft recommendations that participants thought should be added.

Participants who attended the session were present as individuals. Thus, they were not asked to approve CIHR's draft recommendations on behalf of their respective groups or organizations. They were asked only to help advance the debate by bringing to bear their different perspectives and begin to explore, together, what may be *some* possible solutions based on the assumption that the PIPED Act would not be amended before January 1, 2002. While CIHR's hope is to eventually build consensus within the health research community, this process would not bind participants, nor preclude them, either as individuals, groups or organizations, from pursuing different strategies vis-a-vis the PIPED Act.

D. Next Steps

Following this session, the draft recommendations would be revised to take into account the comments and suggestions of the participants. Every effort would be made to incorporate proposed changes. Where this is not possible, the views of participants would nonetheless be recorded in the present discussion document. This discussion document would then be sent to participants, posted on CIHR's website and incorporated in a description of the process leading up to the eventual development of CIHR's final draft recommendations.

It was noted that, even following the session, the draft recommendations would continue to evolve and other potential solutions would be explored through parallel consultations with several other stakeholders, CIHR's Scientific Directors, Institute Advisory Boards and Governing Council.

DRAFT RECOMMENDATION # 1: CLARIFICATION OF THE DEFINITION OF PERSONAL INFORMATION

A. General comments

It was suggested that the definition of personal information should remain broadly worded, and any qualifications should be brought at the level of the exceptions.

The test for reasonable foreseeability should capture the prevailing context at the time of the purported contravention. Simply put, the test should cause organizations to pause and ask themselves, "*what are – or might be – the consequences of my action or inaction*?". "Reasonableness" is recognized by courts as a living and evolving test that allows the law to respond to technological advances.

It was thought important to include within the definition of personal information, information that can either directly *or indirectly* identify an individual.

It was also suggested that the meaning of personal information should be further clarified in relation to anonymized, aggregate or de-identified information.

Finally, the possibility of linkage must be assessed from the perspective of the organization seeking to collect or use the data, as opposed to the organization disclosing it.

B. Revised Draft Recommendation # 1

In light of these general comments, draft recommendation # 1 was revised as follows:

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 readily:*

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 by a reasonably foreseeable method with other accessible information 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 which, from the perspective of an organization seeking to collect or use it, cannot be manipulated or linked by any reasonably foreseeable method, to readily 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 or actual collection, use or disclosure.

C. Comments/Questions requiring further exploration:

The current wording of this draft recommendation does not address from whose perspective the test of reasonable foreseeability is to be applied: an information technology expert, the researcher collecting, using or disclosing the data, the general community of researchers similarly situated, the research ethics board called upon to review the specific research project, or the data subject(s) concerned? Clearly, this is a crucial question that will affect how the proposed standard will apply.

The group also discussed the meaning of information *per se*. Does it include actual tissue, blood or DNA? Or does it only include information concerning its donation or information derived from its testing or examination? A more plausible interpretation of the definition of personal health information at subsection 2(1)(c) of the Act would seem to suggest the latter.

Is personal information, information that can readily identify, either directly or indirectly, a specific individual or could it also include information that can identify small groups or communities? Although an important question, the Act seems to answer it quite clearly in its definition of personal information as "information about an identifiable *individual*".

DRAFT RECOMMENDATION # 2: "IN THE COURSE OF COMMERCIAL ACTIVITIES"

A. General comments

The reality is such that health research increasingly involves a mixture of commercial and non-commercial elements through joint ventures between academe and industry, the creation of spin-off companies and contractual stipulations securing intellectual property rights.

The test for determining whether collection, use or disclosure of personal information occurs "in the course of commercial activities" needs to be sufficiently sensitive to capture the gradient of research activities from those that are purely commercial in nature to those that are purely non-commercial in nature.

It should be noted that "commercial activity" is defined in the singular (and includes the selling, bartering or leasing of donor, membership or other fundraising lists). Yet, the application clause in subsection 4(1)(a) refers to commercial activities in the plural. On the one hand, the wording of the Act itself seems to suggest the need to consider not just one distinct activity in isolation, but rather, the whole of the organization's activities when determining whether the primary aim or preponderant purpose of those activities is to make a profit (traditional test of commercial activity borrowed from the civil and common law). On the other hand, a complete shift of focus from the "impugned" activity to the organization's overall activities may allow certain commercial transactions to fall between the cracks.

It should also be noted that the application of the Act focuses on an organization's activities, rather than the organization per se. However, the assessment of whether the primary aim or preponderant purpose of those activities is to make a profit, still needs to be informed by the organization's overall mission. For instance, even when non-profit health organizations "make a profit" in the course of a distinct transaction (strictly defined as revenue minus costs), the fact that the profit does not benefit individual members, but rather, is reinvested to further the charitable mission of the organization, ought to be taken into account. In this regard, the commercial law definitions of profit and non-profit organizations could be insightful.

The notion of profit-making should be distinguished from that of pure cost-recovery. The latter should not be considered as profit-making activity (*e.g.* where aggregate data is sold by CIHI to researchers on a cost-recovery basis

B. Revised Draft Recommendation # 2

In light of these general comments, draft recommendation #2 was revised as follows:

2. *For greater certainty, personal information is collected, used or disclosed "in the course of commercial activities" within the meaning of subsection 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.*

C. Comments/Questions requiring further exploration:

This draft recommendation was the subject of much debate among participants. Their views and perspectives varied significantly.

In addition to proposing regulations or interpretation guidelines, further discussion should perhaps be promoted in the health research community to better work out and articulate the different interests at stake in various complex situations at the interface of commercial and non-commercial activity. A case study approach could be useful in navigating through some of the types of examples raised in *Question 7* of the *Questions and Answers for Health Researchers: Personal Information Protection and Electronic Documents Act.*

DRAFT RECOMMENDATION # 3: "SCHOLARLY RESEARCH PURPOSES"

A. General Comments

The definition of research in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) should be taken into account to include the establishment of *facts, principles* or generalizable knowledge.

The public dissemination of research results would be a useful criterion for further distinguishing between scholarly research and non-academic research.

The requirement that research be applied for the greater social benefit should be reworded to better capture the imperative for social value, which is more consistent with the principles of the TCPS.

REB review was seen as a useful criterion. However, it needs to be recognized that REB approval will not always be required (*e.g.* quality assurance studies), and that expedited review will be permitted in some exceptional cases (*e.g*. research protocols involving no more than minimal risk or review of patient records by hospital personnel).

Also, the reference to the TCPS should be replaced by a more general reference to applicable legal standards or national and international guidelines.

Peer review was offered as a possible criterion. However, peer review, as such, was not considered to be necessarily determinative of scholarly research.

The related purposes should be tied in more closely to the original research purpose to avoid opening the door too broadly.

B. Revised Draft Recommendation # 3

In light of these general comments, draft recommendation # 3 was revised as follows:

3. *For greater certainty, the term @scholarly research purposes@ referred to in subsections 7(2)(c) and 7(3)(f) of the Act shall:*

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

   b) refer to purposes which have 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 in accordance with current applicable national and international ethical standards; and

   c) 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.

C. Comments/Questions requiring further exploration

The line between quality assurance and research remains a blurry one in practice.

Although REBs play an important and defining role in scholarly research, the public accountability of REBs, their workload and available resources are crucial issues which form part of the larger context around research governance in Canada.

Moreover, REBs face the practical difficulty of recruiting highly specialized, permanent members with recognized expertise in privacy matters.

Although reference to applicable “national and international ethical standards” is more appropriate than reference to the TCPS alone, fundamental principles of delegated legislation and statutory interpretation might require more certainty, precision and clarity in final drafting.

Some participants expressed concern about the related purposes being worded too broadly, such that these might be invoked as justification for using personal information in perpetuity without consent.

DRAFT RECOMMENDATION # 4: RECEPTION OF PERSONAL INFORMATION FOR SCHOLARLY RESEARCH PURPOSES

A. General Comments

There was general support for the need to clarify the disclosure exception at section 7(3)(f) by expressly stipulating that the receipt of personal information should be lawfully allowed under the same conditions provided for in that section.

B. Revised Draft Recommendation # 4

In light of these general comments, draft recommendation # 4 was revised as follows:

4. *In order to give effect to the exception provided for in subsection 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 subsection.*

DRAFT RECOMMENDATION # 5: "IMPRACTICABLE TO OBTAIN CONSENT"

A. General Comments

None of these factors should, in and of itself, be determinative of impracticability (especially, the factor regarding unreasonable burden, which should not be invoked as a convenient excuse for collecting, using or disclosing personal information without consent). Rather, consideration should be given to all factors relevant in the circumstances when determining whether the consent requirement is so impracticable as to render the undertaking of the research virtually impossible.

The range of variables being examined was considered to be irrelevant. In essence, it is the size of the population that is the more telling factor.

Two additional factors were suggested as indicative of impracticability:

- the risk of actually causing psychological harm to individuals (*e.g.* mental health patients) or social harm to families (*e.g.* relatives of deceased individuals) by the very fact of contacting them in order to obtain consent; and,

- the difficulty of successfully contacting individuals, not only through direct means, but also, indirectly through public means such as advertisements or notices.

There were varying levels of comfort/discomfort expressed about some of the factors for fear that they might be too narrowly, or too broadly interpreted.

B. Revised Draft Recommendation # 5

In light of these general comments, draft recommendation #5 was revised as follows:

5. *For greater certainty, the assessment of whether "it is impracticable to obtain consent" for scholarly research purposes within the meaning of subsections 7(2)(c) and 7(3)(f) of the Act shall take into account all factors which may be relevant, 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 the requirement for additional financial, material, human, organizational and other resources needed to obtain such consent will impose an undue hardship on the organization.

C. Comments/Questions requiring further exploration

Two additional factors were further suggested:

- the potential harm that might be caused to individuals by collecting, using or disclosing their personal information *without* their consent (especially when dealing with data of a sensitive nature); and,
- the overall social value of the research.

However, these factors would need to be further examined to assess whether they actually go to the notion of *impracticability to obtain consent* or whether they introduce a whole new condition (*e.g.* a type of harm/benefit analysis) not at all contemplated in subsections 7(2)(c) and 7(3)(f) of the Act. If seen as a whole new condition, this might not be viewed as appropriate substance either for a regulation or interpretation guideline since, in effect, it might be tantamount to adding to the Act. Nonetheless, the broader harm/benefit analysis of the type carried out by research ethics boards was viewed as critical to the review/oversight process.

Likewise, it was suggested that, *when consent cannot be obtained* from individual data subjects, there be an added requirement for the deployment of alternative strategies *(e.g.* consulting with representative members of their groups in order to better anticipate and understand what their concerns might be). However, this suggestion should also be further examined with a view to ensuring that the imposition of such a requirement would not be tantamount to adding a new condition to those specifically mentioned in subsections 7(2)(c) and 7(3)(f) of the Act.

Finally, it was suggested that the discretion of determining whether or not it is impracticable to obtain consent should be entrusted to a duly constituted research ethics board to ensure greater responsibility and accountability in the assessment process. As well, the burden of demonstrating difficulty should be placed on the researcher. However, here again, delegating discretion to a specific body not mentioned in the Act and establishing who shall have the burden of proof, are conditions that need to be carefully examined to ensure that they are not viewed as altogether new conditions being added to those contemplated in subsections 7(2)(c) and 7(3)(f) of the Act.

Note: The retrospective or prospective nature of the study was recognized as a very important consideration. However, this dimension, rather than constitute an additional factor, should be taken into account implicitly in the application of the other factors, *e.g.* see factors (b) and (f).