Initial Implementation Working Group

For the Canadian Institutes of Health Research
Best Practices for Protecting Privacy in Health Research
(September 2005) document

Final Report with Recommendations

September 13, 2007

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LIST OF ACRONYMS AND ABBREVIATIONS

CAREB	Canadian Association of Research Ethics Boards
CIHR	Canadian Institutes of Health Research
IIWG	Initial Implementation Working Group
NCEHR	National Council on Ethics in Human Research
NSERC	Natural Sciences and Engineering Research Council of Canada
PBPs document	CIHR Privacy Best Practices document. Full title: CIHR *Best Practices for Protecting Privacy in Health Research* (September, 2005)
PRE	Interagency Advisory Panel on Research Ethics
REB	Research ethics board
SRE	Secretariat on Research Ethics
SSHRC	Social Sciences and Humanities Research Council of Canada
SSHSWC	Social Sciences and Humanities Research Ethics Special Working Committee
TCPS	Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002, 2005 amendments). For the most recent version, consult the online version at www.pre.ethics.gc.ca.
Tri-Agency *Tri-Council*	Pertaining to these three federal research agencies: Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and the Natural Sciences and Engineering Research Council of Canada

SUMMARY OF RECOMMENDATIONS

1. Promotion of Educational Value

The Initial Implementation Working Group (IIWG) recommends that the educational value of the CIHR Privacy Best Practices (PBPs) document be promoted widely and complemented by various teaching tools. These should be tailored to a wide range of potential users, including researchers, undergraduate and graduate students, research ethics boards, other funders of research such as health charities, and regulatory colleges.

2. Communications

Communication efforts should be intensified and broadened, and should be ongoing to ensure that the research community is notified of any changes to the document. These outreach efforts should have a broad range of targets, including Vice Presidents--Research, research ethics offices, university research offices, and researchers. The communication mechanisms can be straightforward, such as existing organization email lists (e.g., the member email list of the Canadian Association of Research Ethics Boards), the CIHR *News for Researchers,* and the web sites and forums of the National Council on Ethics in Human Research (NCEHR) and the Canadian Association of Research Administrators. A new email list could be set up by inviting interested users to register to receive notification of changes to the document.

3. (a) No major revision to content or format.
(b) Improvement to the electronic format.

(a) The IIWG recommends no major revision to the document at this point, but there needs to be the capacity to update its contents over time (e.g., update the legal concordance tables and/or add sections). The document should be nimble enough to respond to significant issues and changes that impact on content. Criteria for determining when content changes are appropriate should be developed.

The colourful and tabbed printed format of the document could be a model for this kind of educational document. It is recommended that a base supply of printed copies be maintained. Printed copies are useful for distributing at venues such as conferences and meetings, and can lead satisfied users to refer others to the electronic version.

Recognizing the high costs of printing the document and the need for timely revision, the electronic format of the document should become the official version. The URL of the document should remain the same for successive updates, and previous versions should be archived.

(b) The electronic format of the document should be improved by adding:

- A hyper-linked subject index
- The capability to print only selected sections of the document
- "Thumbnail" tabs in the document.

The electronic and new print versions of the document should have the "How to Navigate the Document" more prominently displayed (e.g., on the cover or first page).

4. Outreach to Social Science Researchers

The IIWG recommends setting an objective of reaching out to social scientists in the development of research guidelines and best practices so that social and health researchers will have "collective ownership" of the outcome. The IIWG recommends that CIHR maintain liaison with the Interagency Advisory Panel on Research Ethics and its Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), in the context of ensuring changes to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans* are more reflective of the social sciences. To that end, CIHR should maintain its representation on SSHWC.

CIHR is encouraged to remind the health sciences community in its communications that CIHR funds social scientists, and social scientists are on CIHR-funded interdisciplinary teams.

There are useful good practices in the PBPs document that are transferable beyond personal health information. Social scientists are encouraged to think of the PBPs document as a valuable resource.

5. Promotion as Voluntary Companion Document to the TCPS

The IIWG recommends that the PBPs document be a companion document to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans (*TCPS), but not become incorporated into the TCPS. The PBPs document should be a voluntary resource for practical assistance in implementing the TCPS, and not mandatory Tri-Council policy. It is also recommended that as initiatives come forward that relate to research integrity relevant to privacy and confidentiality (e.g. data integrity), the PBPs document be used (or revised as needed) to help inform efforts to resolve these issues.

Voluntary use of the PBPs document can be promoted through such means as:

- voluntary "Certificates of Completion" when an online tutorial (to be developed) is completed;
- contribution to points for continuing medical, dental, nursing education credits; and
- where applicable, recognition by accrediting bodies for professional training and teacher training for graduate students.

6. International Recognition

The IIWG recommends that a long-term implementation strategy involve assessing the comparability of the PBPs document with international guidance documents (e.g., those of the United States National Institutes of Health) and fostering international acceptance. For example, CIHR should aim to have the PBPs document included in the *The International Compilation of Human Subject Research Protections,* a listing of the laws, regulations, and guidelines that govern research involving human participants in many countries around the world, compiled by the United States Department of Health and Human Services Office for Human Research Protections.

BACKGROUND

In response to the need for Privacy Best Practices voiced by the broad research community, the CIHR Ethics Office established a multi-sectoral Privacy Advisory Committee (PAC) in 2003 to assist in developing a draft set of Best Practices. PAC consulted on this draft document widely in 2004. A revised document— CIHR *Best Practices for Protecting Privacy in Health Research*—was published in September 2005.

The CIHR Privacy Best Practices document was intended to:

- provide guidance for health researchers in the design and conduct of health research involving personal information;
- be a resource for research ethics boards (REBs) and institutions to consult when reviewing and evaluating health research involving personal information; and
- through the uptake and application of these Best Practices in the development of privacy laws or policies across Canada, contribute toward a more coherent and harmonized framework for addressing privacy and confidentiality issues in health research.

The PAC recommended that the impact of the PBPs document be evaluated after an initial two-year implementation period and revised as needed. PAC expected that, after this two-year evaluation period, the document would be endorsed as CIHR funding policy and referred to the Interagency Advisory Panel on Research Ethics (PRE) with a view to encouraging the document's eventual application, in revised form, as Tri-Agency funding policy.[1]

Responding to comments during the consultations and PAC recommendations, the CIHR Ethics Office established and chaired an Initial Implementation Working Group (IIWG) to shepherd the document through the first two years of the document's implementation. IIWG members are drawn from key stakeholder groups. IIWG Terms of Reference and members list are in Appendix A. During the period 2005- 2007, the IIWG had one to two meetings per year in Ottawa and teleconferences on an as needed basis.

During this initial implementation phase, the IIWG undertook:

- to engage key target users of the document to provide feedback with respect to the use, usefulness and impact of the Privacy Best Practices, on the understanding that the *document* would be evaluated, not the users, and adherence to the PBPs document would be on a voluntary basis; and
- at the end of evaluation period, to make recommendations regarding:
    - any improvements to the CIHR Privacy Best Practices document, and
    - a longer term implementation strategy.

[1] CIHR Privacy Advisory Committee Recommendations and membership are included in the PBPs document (September 2005), and can be accessed online at http://www.cihr.ca/e/29072.html.

EVALUATION PROCESS

The IIWG worked with evaluation experts to fulfill its mandate. From 2005- 2006, an evaluation consultant assisted the IIWG in developing a conceptual framework for the implementation of the CIHR PBPs document (see Appendix B). During this planning phase, evaluation tools targeted at specific user groups were developed and pilot-tested (see overview in Table 1).

Conceptual Framework: Key Desired Outcomes

Within the conceptual framework, the IIWG identified the following key desired outcomes over the short and medium term:

- better understanding of key privacy issues among research ethics boards and of the impacts of the PBPs document on decision-making;
- increased awareness of privacy issues among researchers;
- development of a common language and more harmonious dialogue around privacy issues among researchers and REBs; and
- articulation of the optimal relationship between the PBPs document and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

Priority Evaluation Questions

Based on these desired outcomes, priority evaluation questions were articulated. These questions were:

- **Use:** How is the PBPs document being used? By whom, and in what context (REB policy, teaching, general information, etc.)? Should or could the utilization level be accelerated or intensified, and if so, how?
- **Dissemination:** What is the extent and growth of dissemination of the PCBs document? Should or could the dissemination be accelerated or intensified, and if so, how?
- **Improvements: General:** How satisfied are the users with the PBPs document? What areas for improvement are identified? **Social Sciences:** What are areas for improvement from a social science perspective?
- **Future Promotion and Development:** What is the level of support for linking of the PBPs document to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*? What type of integration is supported: mandatory, educational or other?
- **Impact:** To what extent has use of the PBPs document facilitated better understanding of key privacy issues among REBs? To what extent has use of the PBPs document resulted in increased awareness of privacy issues among researchers? How, if at all, are the PBPs affecting decision-making of REBs and researchers? To what extent has use of the PBPs facilitated development of a shared understanding of privacy issues among researchers and REBs?

- **Privacy Costs:** To what extent does or will application of the PBPs document affect researcher costs? In what ways? Are there implications for institutions employing researchers? For data custodians?

Evaluation Tools and Time Lines

An external evaluation team was hired to conduct data collection and report on the results. The consultants' final report is in Appendix F.

The evaluation team obtained feedback on the use, usefulness and impact of the PBPs document from various user groups by means of a web survey, customized telephone surveys, and focus groups. These tools, target groups and timelines are summarized in Table 1. The CIHR Ethics Office also compiled information for the IIWG on online accessing of the PBPs document and web pages, and on its related communication and dissemination activities (see Appendix C).

Prior to the formal data collection phase, a preliminary mini-survey was posted on CIHR's website for a number of months in 2005/06, asking those who had sought out the CIHR PBPs web pages how they had found out about the document and why they were accessing it. The IIWG used this mini-survey to get preliminary data on effective vehicles to reach target user groups (e.g., via NCEHR and CAREB web sites and university research ethics offices).

Table 1: Overview of Evaluation Tools for the Initial Implementation Phase of the CIHR Privacy Best Practices (PBPs) document

Evaluation Tools & Target Groups	Time line
Web survey: outreach to the general public, researchers, research ethics board members, etc.	September 2006 to Spring 2007
Telephone surveys of key user groups (ethics community stakeholders; government privacy offices and legislative staff; REBs; CIHR peer review committee chairs) and of volunteers from those who received printed copies of the PBPs on request or at conferences	Fall 2006 and Winter 2007
Focus groups with REB members (recruited mainly from attendees of the National Council on Ethics in Human Research annual conference and from members of the Canadian Association of Research Ethics Boards)	Coordinated with the NCEHR Annual Conference, March, 2007
Compilation of outreach information from the CIHR Ethics Office's records and web site (distribution of PBPs, dissemination at workshops and conferences, web statistics, initial mini-survey)	October 2005 to Spring 2007

Limitations

It was recognized at the outset that this evaluation process might be biased toward "early adopters" of the PBPs document. However, the evaluation was not intended to be a repeat of the broad consultations conducted in 2004, but rather, a closer look at the effectiveness of dissemination efforts, and at the current and *potential* usefulness and impact of the PBPs document.

FINDINGS AND RECOMMENDATIONS

These recommendations are provided to the CIHR Ethics Office, with the intention of their being brought forward to the CIHR Standing Committee of Ethics for consideration and for eventual endorsement by CIHR. The IIWG expects that CIHR will refer the CIHR Privacy Best Practices document to the Interagency Advisory Panel on Research Ethics (PRE)[2], with a view to PRE recommending that the three federal research agencies (the CIHR, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada) endorse the Privacy Best Practices document as a voluntary companion document to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), with relevance to all Tri-Agency funded research.

Proposed leads and time lines for each recommendation are outlined in Appendix E.

Priority Evaluation Questions: Use

How is the PBPs document being used? By whom, and in what context (REB policy, teaching, general information, etc.)? Should or could the utilization level be accelerated or intensified, and if so, how?

Findings

Overall, the evaluation of the PBPs document indicated that it is a potentially valuable reference and education document. Respondents did not question the content, which was typically described as accurate.

More than half of the respondents have used the PBPs document for study and for reference purposes. There has also been some use made in teaching and training (of research ethics board members, students, and researchers). Some government officials reported using the PBPs document as a reference in developing guidelines and legislation.

One reason given by many researchers, including CIHR Peer Review Chairs, for not being familiar with privacy issues (or the PBPs document) is that they do not see a need. They view the issue as being well handled elsewhere (e.g., by REBs, provincial privacy legislation, and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*). However, many of the REB members surveyed who used the

[2] PRE is tasked with providing multi-disciplinary independent advice to the Tri-Agencies on the evolution, use, interpretation and associated educational activities of the TCPS.

document reported that the PBPs document enhanced their capacity to interpret and comply with other privacy guidelines, policies or laws, and increased their general awareness of privacy issues.

Recommendation #1: Promotion of Educational Value

The IIWG recommends that the educational value of the PBPs document be promoted widely and complemented by various teaching tools. These should be tailored to a wide range of potential users, including researchers, undergraduate and graduate students, REBs, other funders of research such as health charities, and regulatory colleges (see Appendix D for suggested teaching tools and target groups).

Priority Evaluation Question: Dissemination

What is the extent and growth of dissemination of the PCBs document? Should or could the dissemination be accelerated or intensified, and if so, how?

Findings

The CIHR web site registered high levels of activity in accessing the online PBPs document. For the period April 2006 to March 2007, there were about 1500 downloads a month for the English PDF version of the document, and 100 downloads per month for the French version. During the same period, the html version of the document received 3,397 hits from 1,833 "unique" users in a variety of contexts, including universities, hospitals, health regions and government.

CIHR's targeted dissemination efforts, outlined in the Appendices, were most effective at reaching research ethics stakeholder organizations and government privacy policy and legislative officers, most of whom surveyed were quite familiar with the PBPs document. Although some REBs were very familiar with the PBPs document, about half of those surveyed were either unaware of the document or not sufficiently familiar with it to respond to a detailed survey. Given the small sample of researchers that responded to the online survey and feedback from the CIHR Peer Review Committee Chairs indicating that they had only recently become aware of the document, it is clear that dissemination efforts have not yet effectively reached researchers.

Satisfied users were from various groups, including researchers, research coordinators, research ethics board members, and policy-makers. Therefore, the document does not need to be targeted to a narrow "niche" of users. Outreach efforts should be intensified and aimed at a wide range of potential users.

Recommendation #2: Communications

Communication efforts should be intensified and broadened, and should be ongoing to ensure that the research community is notified of any changes to the document. These outreach efforts should have a broad range of targets, including academic Vice Presidents--Research, research ethics offices, university research offices, and researchers. The communication mechanisms can be straightforward, such as existing organization email lists (e.g., member email list of the Canadian Association of Research Ethics Boards), the CIHR *News for Researcher*, and the web sites and forums of the National Council on Ethics in Human Research (NCEHR) and the Canadian Association of Research Administrators. A new email list could be set up by inviting interested users to register for notification of changes to the document.

Priority Evaluation Question: Improvements- General

How satisfied are the users with the PBPs document? What areas for improvement are identified? What areas for improvement in the social science perspective?

Findings

Overall, those familiar with the PBPs document reported that it was highly readable, well-formatted, comprehensive and very useful. Many respondents did not see the need for major changes to the document.

The document is generally viewed as useful in the area of health sciences research, although it was recognized that privacy issues related to the banking, storage and use of biological materials are beyond the scope of the document. Several respondents reported that they would like guidance on privacy issues of research involving human biological materials.

Many respondents preferred the colourful and tabbed printed copies of the document. Some who use the document less, or not at all, commented that it was too long. There was little criticism of the style and format, except for searching difficulties in the PDF version.

Among the suggestions for CIHR to improve the development of privacy best practices were a tool box of cases and interpretations modelled on the case law approach; an online set of Frequently Asked Questions (FAQs); an ongoing discussion forum on-line; additional training sessions; and more CIHR presentations.

<u>Recommendation #3</u>: (a) No major revision to content or format (b) Improvement of the electronic format.

(a) The IIWG recommends no major revision to the document at this point, but there needs to be the capacity to update its contents over time (e.g., update the legal concordance tables and/or add sections). The document should be nimble enough to respond to significant issues and changes that impact on content. Criteria for determining when content changes are appropriate should be developed.

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<u>Comment on Suggestions for a Bank of Interpretations and Online Discussion Groups</u>

Some respondents suggested developing a bank of "interpretations" but the IIWG did not think interpretations were appropriate for a Best Practices document, which is intended to guide but not dictate appropriate practice. There was also the suggestion of the usefulness of online discussion groups, such as the NCEHR Web Forum. However, the IIWG did not have a consensus on the usefulness of such discussion groups.

Priority Evaluation Question: Improvements- Social Sciences

What areas are identified for improvement from a social science perspective?

Findings

Some respondents from a social sciences perspective indicated that the PBPs document did not deal adequately with issues such as confidentiality and data retention periods which can differ in the social as compared to the health sciences.

Comments from other perspectives included the need for more emphasis on Aboriginal research (although there was recognition of the current CIHR work on the *Guidelines for Health Research Involving Aboriginal Peoples*). There were also comments that there needed to be more focus on cross-cultural and natural sciences research.

Recommendation #4: Outreach to Social Scientists

The IIWG recommends setting an objective of reaching out to social scientists in the development of research guidelines and best practices so that social and health researchers will have "collective ownership" of the outcome. The IIWG recommends that CIHR maintain liaison with the Interagency Advisory Panel on Research Ethics and its Social Sciences and Humanities Special Working Committee (SSHWC), in the context of ensuring changes to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans* are more reflective of the social sciences. To that end, CIHR should maintain its representation on SSHWC.

CIHR is encouraged to remind the health sciences community in its communications that CIHR funds social scientists, and social scientists are on CIHR-funded interdisciplinary teams.[3]

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[3] This recommendation is in line with an early CIHR-SSHRC publication, *Social Sciences and Humanities in Health Research. A Canadian Snapshot of Fields of Study and Innovative Approaches to Understanding and Addressing Health Issues*, CIHR information page at http://www.cihr-irsc.gc.ca/e/30529.html.

Priority Evaluation Question: Future Promotion and Development

What is the level of support for linking of the PBPs document to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)? What type of integration is supported: mandatory, educational or other?

Findings

The PBPs document is generally recognized as one of many influences, policies and laws relating to privacy in the jurisdictions in which the respondents work. Among REBs and research ethics community stakeholders surveyed, most would like to see the PBPs document linked to the TCPS as a voluntary, not mandatory, resource. Most respondents liked the idea of linkage between the PBPs document and the TCPS because the PBPs document provides more detailed clear examples, useful in trying to implement the TCPS.

Recommendation #5: **Promotion as Voluntary Companion Document to the TCPS**

The IIWG recommends that the PBPs document be a companion document to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans (*TCPS), but not become incorporated into the TCPS. The PBPs document should be a voluntary resource for practical assistance in implementing the TCPS, and not mandatory Tri-Council policy. It is also recommended that as initiatives come forward that relate to research integrity relevant to privacy and confidentiality (e.g. data integrity), the PBPs document be used (or revised as needed) to help inform efforts to resolve these issues.

Voluntary use of the PBPs document can be promoted through such means as:

- voluntary "completion certificates" when an online tutorial (to be developed) is completed;
- contribution to points for continuing medical, dental, nursing education credits; and
- where applicable, recognition by accrediting bodies for professional training and teacher training for graduate students.

Recommendation #6: International Recognition

The IIWG recommends that a long-term implementation strategy involve assessing the comparability of the PBPs document with international guidance documents (e.g., those of the United States National Institutes of Health) and fostering international acceptance. For example, CIHR should aim to have the PBPs document included in the *The International Compilation of Human Subject Research Protections,* a listing of the laws, regulations, and guidelines that govern research involving human participants in many

countries around the world, compiled by the United States Department of Health and Human Services Office for Human Research Protections.[4]

Priority Evaluation Question: Impact

To what extent has use of the PBPs document facilitated better understanding of key privacy issues among REBs? To what extent has use of the PBPs document resulted in increased awareness of privacy issues among researchers? How, if at all, are the PBPs affecting decision-making of REBs and researchers? To what extent has use of the PBPs facilitated development of a shared understanding of privacy issues among researchers and REBs?

Findings

Among REBs familiar with the PBPs document:

- it was more frequently reported that the PBPs document was helping their own understanding of privacy issues than that it was contributing to more harmonious dialogue between REBs and researchers;
- most said that the PBPs document had improved their understanding of privacy issues, and some said that the document had not changed their approach to privacy but was useful in confirming the validity of their existing practices;
- many reported that the PBPs document was having an impact on research ethics board decisions related to a number of privacy issues, particularly those of secondary uses of data and conditions for consent (e.g., determining when consent is required, and the conditions for opting out of consent);
- some commented that the PBPs document could lead to shorter time periods for research ethics board approvals because of fewer requests for changes to researcher's submissions, whereas others stated that the document could lead to longer times for approvals due to additional privacy-related requirements for submissions; and
- there was no consensus that there had been any impact on research submissions but the PBPs document was generally viewed as a good reference source for researchers and lay (community) research ethics board members, and helped with a common approach among REBs.

Researchers surveyed were generally less familiar with the PBPs document than REBs. Among those researchers who had views on the impact of the PBPs document on REB submission and approval processes, negative impacts (e.g., longer time to prepare

[4] The international listing is online at http://www.hhs.gov/ohrp/international/.

research ethics applications) were cited as often as positive impacts (e.g., shorter REB approval times).

Comment on Impact

The results of the evaluation indicated that the PBPs document is a sound resource document for both researchers and REBs. However, recognizing that privacy and confidentiality issues require interpretative judgements by REBs, and local autonomy of REBs inevitably lead to some degree of local variation, the tensions between REBs and researchers over how these issues are handled will not be solved with one document alone. Nevertheless, the PBPs document does have the potential to improve consistency across REBs by providing a common reference point, which could help to resolve some of that tension. Also, increased education efforts aimed at researchers have the potential to assist in improving the researcher-REB dialogue concerning privacy issues, and inter-REB dialogue could also be enhanced.

Priority Evaluation Question: Privacy Costs

To what extent does or will application of the PBPs document affect researcher costs? In what ways? Are there implications for institutions employing researchers? For data custodians?

Findings

The small sample of researchers who participated in the evaluation process did not indicate that the PBPs document was being used to anticipate the costs of privacy protections in research, or that it was viewed as having had an impact on the privacy – related costs.

Comment on Privacy Costs

Recognizing that compliance with privacy legislation can have financial implications, this evaluation process did not elicit specific information on financial costs associated specifically with the PBPs document. The findings did elicit views that the PBPs document could lead to more time and care being taken in preparing submissions—and time is money. However, in the REB review process, improved understanding by researchers could result in less back and forth between REBs and researchers, so that overall time is saved. At this point, the findings showed no consensus among REBs and researcher respondents on costs—financial or other—associated with the PBPs document. It is also important to recognize that particular privacy-related issues (such as the content of informed consent forms) can have an impact on REB review processes.

APPENDIX A

Initial Implementation Working Group

Terms of Reference
(June 2007 update)

Working Group Mandate:

- To bring the perspectives of key target users of the PBPs document.
- To provide advice or strategies for the Ethics Office on user engagement and uptake during this initial implementation phase.
- To provide a sounding board for the research community for its comments on the PBPs document.
- To advise and assist the Ethics office on developing mechanisms or tools for an in depth examination of the use, usefulness and impact of the PBPs document.
- To provide recommendations to the Ethics Office on:
    - improvements to the PBPs document (but not to include involvement in revising the document); and
    - a longer-term implementation strategy.

Chair: Sheila Chapman (CIHR Ethics Office)

Deputy Chair: Margo Farren (CAREB Board member)

Members: Susan Hoddinott (CAREB member; University of Western Ontario); Susan Sykes (CAREB member; University of Waterloo), Richard Carpentier (NCEHR Executive Director), Mike Enzle[5] (NCEHR Education Committee Chair; University of Alberta), Thérèse De Groote (SRE; liaison with PRE, NSERC and SSHRC); Karen Szala-Meneok, (CIHR-funded Researcher; qualitative methods; McMaster University, Ontario)

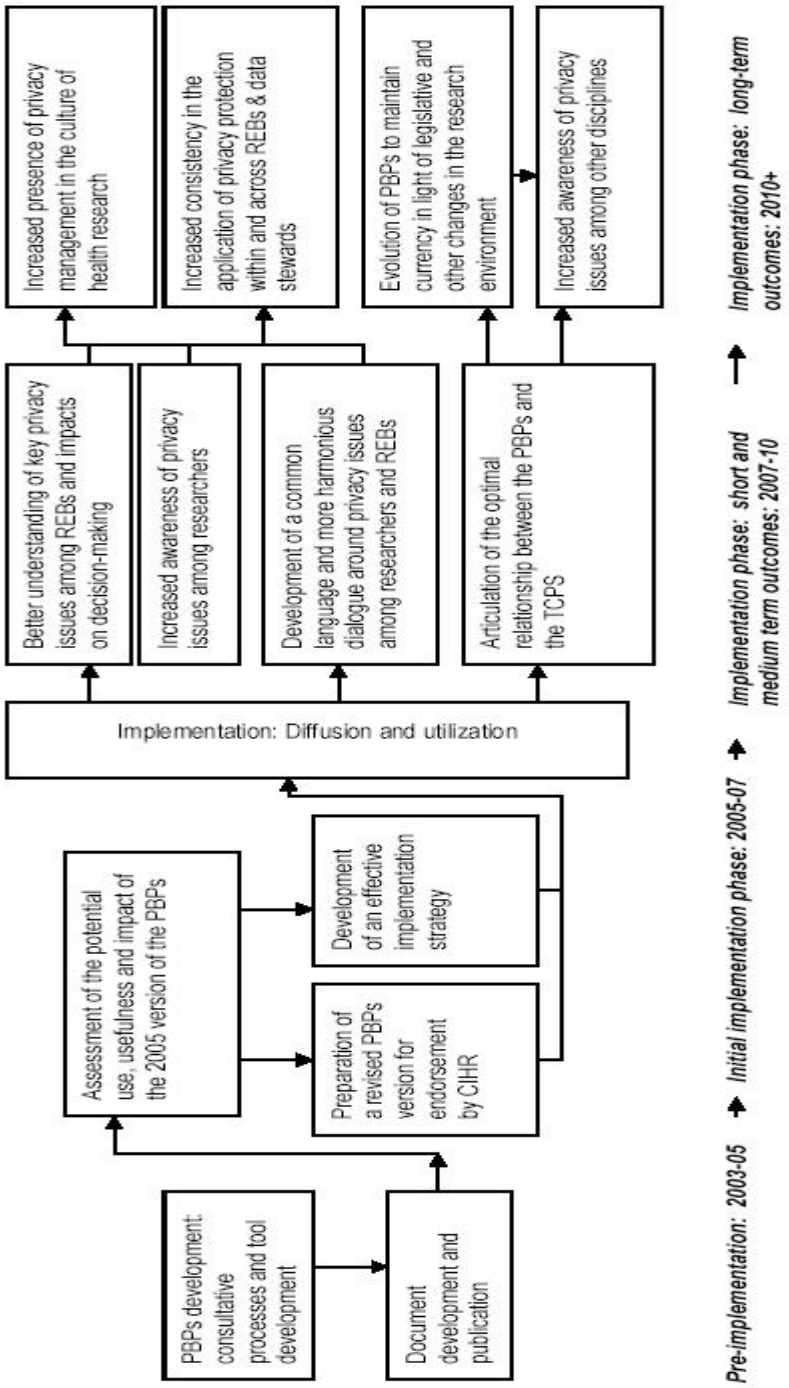
Meetings: As needed. Primarily teleconference and email. One to two face-to-face meeting per year if budget allows.

Period of Mandate: September 2005-2007, ending at release of Initial Implementation Working Group recommendations.

[5] Mike Enzle was an invaluable contributor to the first phase of the IIWG's work.

APPENDIX B

Conceptual framework for the Implementation of the CIHR Privacy Best Practices document



APPENDIX C

Summary of Dissemination Activities and Uptake, 2005- 2007

- **Notification to the research ethics community**: The web sites of the National Council on Ethics in Human Research, the Canadian Association of Research Ethics Boards, and the Canadian Bioethics Society featured news about the release of the 2005 PBPs document.
- **Distribution of printed copies**: About 1600 English and 154 French copies were distributed at conferences (Canadian Bioethics Society Conference, Circumpolar Conference, Symposium on Electronic Health Information and Privacy, National Council on Ethics in Human Research Annual Conference, the Canadian Association of Research Ethics Boards Annual General meeting, and the Canadian Association of University Research Administrators Conference). CIHR received requests from about 60 individuals for one or more copies for research centres, universities, REBs, government departments and health region offices.
- **Presentations at Conferences, Meetings, and Training Sessions**: Between 2005 and 2007, presentations on the PBPs document were given at a variety of venues, including meetings of researchers and data custodians, privacy-related conferences, and four NCEHR training sessions for REBs and researchers in Ontario (Ottawa and Sudbury), Alberta and Prince Edward Island.
- **Information aimed at researchers**: On the CIHR website, the PBPs document was added to the list of resources on the *TIPS for Writing Successful Grants or Request for Renewal* webpage. News about the PBPs document was included in a couple of issues of the CIHR *E-News for Researchers* bulletin. In fall 2006, about 1500 bilingual one-page information sheets about the PBPs document were included in the information packages to successful applicants of CIHR awards or grants and to Peer Review Committee Chairs.

Uptake:

- **Web statistics**: Between April 2006 and March 2007, there were 1,833 unique users of the html version of the PBPs document, which received 3,397 "hits" on the CIHR web site. The PDF version of the document was a popular CIHR document, with roughly 1,500 downloads a month for the English version, and 100 downloads a month for the French version. Users of the online document came from a variety of contexts, including government departments, universities, hospitals, and health region offices.
- **Universities**: Out of the 34 universities for which CIHR has regular communications through University Delegates, only four universities had links to the PBPs document on their websites, on their research ethics web pages.
- **Research Ethics Boards**: Of those REBs randomly surveyed who were familiar with the PBPs document (about half), some reported that their application forms address the ten elements in the PBPs document, and a smaller number said that the PBPs document had been cited in decision letters to researchers, or had been featured in memos or bulletins to researchers.
- **Legislative/Policy makers**. Many legislation and policy makers in the privacy area reported using the PBPs document as a reference document, and for some the document influenced policy and legislation.

APPENDIX D

Suggestions for Education and Communication

Teaching Tools:

- Online PowerPoint presentations:
  - long version with scenarios
  - short version
  - for REBs
  - for researchers
  - for undergraduates and Masters students

- TIPS sheet- 3-hole punched, 8 ½ X 11
  An abridged two-sided TIPS sheet of the PBPs contents should be created, for broad distribution in information packages to researchers, research ethics board members, conference booths, etc. This TIPS sheet could be laminated and three-hole punched, for easy inclusion in binders.

- Online tutorial, with case studies

Target Groups and Communication Mechanisms:

Researchers:
- Continue reference to PBPs in TIPS for Writing Applications, CIHR website
- Include TIPS sheet in CIHR decision letters, and PRC Chairs information packages
- TIPS sheets in CIHR booth at conferences

Research Ethics Stakeholder Organizations:
- Links to websites
- Communications
- Include Rx&D

Universities:
- Senior Grant Officers, Office of Research Services: include TIPS sheet in application writing workshops; mentoring (accessed through CAURA)
- Administrators: CAURA booth (TIPS sheet)

REBs:
- PowerPoint presentations (REBs can customize these presentations for their own training sessions)
- NCEHR training sessions, as part of the basic NCEHR REB 101 session, and as a special theme in REB 201 (in development) sessions
- CAREB training sessions
- Include TIPS sheet in orientation package for new members

Research Participants:
- Access through new NCEHR web page

Privacy Commissioners Offices:
- Web links

Clinical Research Coordinators/Practitioners courses: training, communications
Professionals in the health sciences, epidemiology, nursing, communicable disorders
Health Charities
Government websites
Regulatory Colleges (e.g., the Royal College of Physicians and Surgeons is developing a research ethics tutorial)
Community Colleges

APPENDIX E

IIWG Recommendations, Proposed Leads and Time Lines

IIWG Recommendations	Proposed Lead	Proposed Time Line
1. Promotion of Educational Value The educational value of the PBPs document should be promoted widely and complemented by various teaching tools. These should be tailored to a wide range of potential users, including researchers, undergraduate and graduate students, REBs, other funders of research such as health charities, and regulatory colleges. (See Appendix D for a list of proposed education mechanisms and target groups).	CIHR, with the assistance of relevant stakeholder organizations for tools aimed at particular user groups and with NCEHR with respect to its education mandate. A PBPs education committee could be created.	2007/08 – 2008/09
2. Communications Communication efforts should be intensified and broadened, and should be ongoing to ensure that the research community is notified of any changes to the document. These outreach efforts should have a broad range of targets, including Vice Presidents--Research, research ethics offices, university research offices, and researchers. The communication mechanisms can be straightforward, such as existing organization email lists (e.g., the member email list of the Canadian Association of Research Ethics Boards), the CIHR *News for Researchers,* and the web sites and forums of the National Council on Ethics in Human Research and the Canadian Association of Research Administrators. A new email list could be set up by inviting interested users to register to receive notification of changes to the document.	CIHR	2007/08- ongoing
3. (a) No Major Revision to Content or Format (b) Improve the electronic format (a) No major revision to the document need to be done at this point, but there needs to be the capacity to update its contents over time (e.g., update the legal concordance tables and/or add	CIHR	2007/08

IIWG Recommendations	Proposed Lead	Proposed Time Line
sections). The document should be nimble enough to respond to significant issues and changes that impact on content. Criteria for determining when content changes are appropriate should be developed. The colourful and tabbed printed format of the document could be a model for this kind of educational document. It is recommended that a base supply of printed copies be maintained. Printed copies are useful for distributing at venues such as conferences and meetings, and can lead satisfied users to refer others to the electronic version. Recognizing the high costs of printing the document and the need for timely revision, the electronic format of the document should become the official version. The URL of the document should remain the same for successive updates, and previous versions should be archived. (b) The electronic format of the document should be improved by adding: • A hyper-linked subject index • The capability to print only selected sections of the document • "Thumbnail" tabs in the document. The electronic and new print versions of the document should have the "How to Navigate the Document" more prominently displayed (e.g., on the cover or first page).		
4. <u>Outreach to Social Science Researchers</u> The IIWG recommends setting an objective of reaching out to social scientists in the development of research guidelines and best practices so that social and health researchers will have "collective ownership" of the outcome. The IIWG recommends that CIHR maintain liaison with the Interagency Advisory Panel on Research Ethics (PRE) and its Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), in the context of ensuring changes to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans* are more reflective of the social sciences. To that end, CIHR should maintain its representation on SSHWC. CIHR is encouraged to remind the health sciences community in its communications that CIHR funds social scientists, and social scientists are on CIHR-funded interdisciplinary teams. There are useful good practices in the PBPs document that are transferable beyond personal health information. Social scientists are encouraged to think of the PBPs document as a valuable companion document.	CIHR, in collaboration with SSHRC and PRE's SSHWC	Ongoing

IIWG Recommendations	Proposed Lead	Proposed Time Line
5. <u>Promotion as</u> <u>Voluntary Companion Document to the TCPS</u> The IIWG recommends that the PBPs document be a companion document to the *Tri-Council Policy Statement: Ethical Conduct in Research Involving Humans (*TCPS), but not become incorporated into the TCPS. The PBPs document should be a voluntary resource for practical assistance in implementing the TCPS, and not mandatory Tri-Council policy. It is also recommended that as initiatives come forward that relate to research integrity relevant to privacy and confidentiality (e.g. data integrity), the PBPs document should be used (or revised as needed) to help inform efforts to resolve these issues. Voluntary use of the PBPs document can be promoted through such means as: • voluntary "completion certificates" when an online tutorial (to be developed) is completed; • contribution to points for continuing medical, dental, nursing education credits; and • where applicable, recognition by accrediting bodies for professional training and teacher training for graduate students.	PRE	Pending PRE's recommendation, and Tri-Agency endorsement, of the Privacy Best Practices document as a voluntary companion document to the TCPS.
6. <u>International Recognition</u> The IIWG recommends that a long-term implementation strategy involve assessing the comparability of the PBPs document with international guidance documents (e.g., those of the United States National Institutes of Health) and fostering international acceptance. For example, CIHR should aim to have the PBPs document included in the *International Compilation of Human Subject Research Protections,* a listing of the laws, regulations, and guidelines that govern research involving human participants in many countries around the world, compiled by the United States Department of Health and Human Services--Office for Human Research Protections (OHRP).	PRE (assuming the PBPs document is explicitly included as a companion document to the TCPS) and NCEHR, which provides liaison with the OHRP.	Pending endorsement of the Privacy Best Practices document as a companion document to the TCPS

APPENDIX F

Final Report

Data Collection and Analysis Phase
2006 Evaluation of CIHR Document
Best Practices for Protecting Privacy in Health Research

June 28, 2007

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Data Sources

Table 1 presents the numbers of persons identified to be interviewed for each of the data sets and the numbers of persons actually interviewed in each group. In addition to the five sets of persons individually interviewed, data was also collected by means of focus groups and a web survey. These latter two are not included in Table 1; for neither group was there an estimate of the "Number in Full List".
Following Table 1 is a description of each of these seven groups.

Table 1: Numbers in Each Interview Data Set

Category of Respondent	Number In Full List	Number Interviewed
Recipients of the PBPs document	8	7
CIHR peer review Chairs	32	27
Policy/legislators offices	12	9
Ethics community stakeholders	21	19
Research ethics board members	50	46

Recipients of the PBPs document

CIHR provided a list of eight persons who had requested from CIHR copies of the *Best Practices for Protecting Privacy in Health Research* document and who had accepted to be interviewed. One person, due to personal circumstances, withdrew leaving a total of seven persons who were interviewed.[6]

CIHR Peer Review Committee Chairs

Thirty-four Peer Review Committee Chairs were sent e-mail messages by CIHR in order to provide prior notice of the disclosure of their names to a contractor for purposes of a telephone survey. Two replied that they would not be able to participate. The remaining 32 were contacted by e-mail and by telephone. Of these 32, 27 were interviewed by telephone. The remaining five interviewees either did not respond to the invitations to participate or notified the caller that they were not available for an interview.

Policy/legislators Offices

CIHR defines Privacy Policy and Legislative Staff as "federal and provincial ministries and agencies responsible for privacy-related policy and legislation, particularly in the

[6] CIHR reports that there were addition recipients of the document. About 60 people (of the 60, many were invited to be interviewed and 8 agreed to be interviewed) asked for hard copies from the Ethics Office and other persons picked up copies on display at a range of different venues.

area of heath". The Federal/Provincial/Territorial Privacy Network available to CIHR lists 14 Government Ministries and 2 National Agencies with key roles for health information. Of these, 12 entities were selected with the intention of best representing the full list. Of the set of 12, full interviews were obtained with 8 of the entities. The interviews sought views on the CIHR *Best Practices for Protecting Privacy in Health Research* document (PBPs).

Ethics community stakeholders

A list of 21 ethics community stakeholders was provided by CIHR. Ethics community stakeholders are defined by CIHR as "research funding bodies, research ethics bodies with an education mandate, Aboriginal research and ethics bodies, and federal and provincial data custodians." Two of the persons on the list were also members of the CIHR Privacy Advisory Committee that had developed the Privacy Best Practices document September 2005. Interviews were completed with 19 of the 21 persons.

Research ethics board members

A sample of 50 Research Ethics Boards (REBs) was drawn using random selection from the National Council on Ethics in Human Research (NCEHR) list of Canadian REBs. Two experienced interviewers conducted all of the interviews which were predominantly with the Chair of an REB. They reached representatives of 46 of the REBs. Early in the interview process, the interviewers realized that a large proportion of respondents were either unaware of the document, or had little knowledge of the PBP document. Of the 46, 21 were in this category. In some cases, the respondent had decided, based on a description or a quick scan of the document, that it was not required for the operations of their REB. Therefore, with the agreement of the Project Authority, a variant of the interview schedule was prepared and used for this subset of respondents; it concentrated on REB operations and concerns regarding privacy without reference to the CIHR Document. The other 25 respondents were asked the full set of questions.

Focus Groups

Three focus group sessions sought views on the CIHR Best Practices for Protecting Privacy in Health Research document (PBPs). One focus group was with members of a single REB. The other two brought together members of REBs from different regions and institutions.

Web Survey

Twenty persons volunteered to answer the questions posed by a web carried survey hosted at the CIHR web site over a period of about five months.

Comparability of groups

Of the seven data sources, two represent a defined population. The labels for the other five groups, in spite of being labels for identifiable groups, should not be understood to mean that the individuals within a group represent the population suggested by the group label. The two groups for which samples from known populations were obtained are the Chairs of CIHR Review Committees and the representatives of Canadian REBs.
The implications of this observation are:

A. The views of the Chairs of CIHR Review Committees and the views of the representatives of Canadian REBs may be generalized to the respective populations from which each was drawn.

B. It is also the case that the views of the Chairs of CIHR Review Committees may be compared to the views of the representatives of Canadian REBs.

C. For the other five groups, which cannot be shown to represent defined populations, it would be inappropriate either to generalise from the views of a data sample to an intended population or to make comparisons across these five data samples.

The inability to make comparisons across all of the populations for which such comparisons were wanted is unfortunate. A comparison across groups of respondents is what the IIWG (Privacy Best Practices Initial Implementation Working Group) wished to achieve. When both of two conditions – proper sampling from a known population and an adequate response rate (80% response rate, or higher) - are met, formal comparison across data samples is feasible. If both of the two conditions are not met, then such formal comparison cannot be made and would not be written into a formal evaluation report. Given that the formal conditions[7] for sampling from the intended populations were not achieved for five of the seven groups, formal comparison across the seven data sets is not possible even when the response rate from a designated list of respondents has been achieved.

The reality that some of the data samples do not represent a true sample from a defined population should not be construed as a suggestion that their views are not of value. Their views have been most informative and insightful and are amenable to informal comparison. In the absence of formal comparisons, informal comparisons can still be made. Such informal comparisons (dependent on the adequacy of the judgement that the data sample represents a population) are frequently made and the Appendices to this report allow for such informal comparisons.

Observations

Exposure to the PBPs Document

1. Those who have received a copy of the CIHR *Best Practices for Protecting Privacy in Health Research* document (to be referred to on this report either as PBP or as the Document) typically did so in the period between September 2005 and September 2006; a number received their copy earlier and very few after September 2006.

2. The persons interviewed had most frequently become aware of the document between September 2005 and September 2006 or earlier. The earlier date was especially the case for persons in offices with responsibility for privacy practices.

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[7] The conditions are, essentially: a defined population; the specification of a frame for that population; the selection of a representative sample from the frame; and the obtaining of an adequate response rate from the representative sample. The ideal for a representative sample is a sample whose members are drawn at random from the frame. By adequate response rate is meant a sufficiently high percentage of responses such that the influence of the non-responses is not unacceptable in terms of its impact upon the confidence intervals for the findings.

3. About half of all persons interviewed had participated in some form of training on the document.
4. A commonly voiced problem is to find ways to get the information in the Document to researchers, most of whom are unlikely to review a long online document. Suggestions by which to accomplish this included a short handbook version, an executive summary version and a well indexed Document that allowed for more rapid finding of the item of interest at a given moment.
5. Younger researchers tend to have been exposed already to varying degrees to ethics and privacy requirements. Many respondents find that their greater challenge is to convince the veterans, or just engage their attention, as they are the ones who might view the focus on privacy as an additional requirement, as an obstacle.

Knowledge of the PBPs Document Contents

6. Although many respondents (although not all) were aware that the PBPs document exists, many also claimed little knowledge of its contents, on the grounds that they did not have a need for it. This was particularly the case for CIHR Peer Review Committee (PRC) Chairs and Research Ethics Board (REB) representatives.
7. Since many respondents were not using the document, it is not surprising to find that they also feel that the document is not making a contribution to improving practices. Some respondents made remarks to the effect that since becoming aware (very recent in many cases), they found some of the information in the document to be potentially very useful.
8. The manner in which the Document is used is a function of the role played. REB members did not use the Document directly; their uses are typically in an educational role (other researchers, medical students) and are largely outside the REB context,

Current Utility of the PBPs Document

9. Those who use the Document report it to be highly readable, well-formatted, comprehensive and very useful. Some who use it less (or not at all) criticize its length. There was very little criticism of style and format, except for searching difficulties in the '.pdf' version.
10. The Document is most frequently used as a reference both for own use and as a reference document to which people new to the field (including students) may be referred. At least some of those uses are in the context of policy development for a jurisdiction (political or institutional).
11. Peer Review Committees do not frequently refer to the CIHR PBPs document. There are a number of reasons including: infrequent meetings; high turnover of members; low level of Document knowledge by committee members; and the presumption that others (the REBs in particular) will take responsibility for the proper privacy procedures.
12. More than half of the respondents have used the PBPs document for study and for reference purposes. There has also been some use made in teaching and in

developing guidelines or practices. Those who had not used it explained that it was not pertinent to their day-to-day duties.

13. One reason many researchers, including Peer Review Chairs, are not well versed in the privacy issue is that they do not see a need. They view the issue as being well handled elsewhere (REBs, Provincial Privacy legislation and the Tri-Council Policy Statement).

14. When used as guidance by a REB, it was most frequently used as reference for the conditions for setting up long-term research databases, for data sharing within the research team or institution, for determining if consent is required and for secondary uses of data. The Document served to heighten awareness of key privacy issues; foster changes to research design and process; engender more consistent application of privacy protection and improved understanding of key privacy issues among Research Ethics Boards.

15. The PBP Document is found useful for those tasked with reviewing proposals for privacy issues within Canada. Many felt it could be made even more useful with a more comprehensive, graphical approach to the universe of various requirements. A few signalled a need for more inclusion of the diversity of academic disciplines; for example, researchers in some humanities areas (e.g. English) and other disciplines (e.g. fashion design) do not realize that there are ethical and privacy dimensions to their research involving human subjects.

16. Some REBs, especially smaller ones with lower volumes of cases, think that they may be overly cautious in applying privacy legislation, because they are not aware of a lot of variations and nuances that have become routine in locations with high volumes of health research, and therefore more familiarity on the part of the lawyers and others sitting on the REB. It was also noted that federal and provincial privacy laws, being general in scope, are not self-evident with respect to how they apply to health research specifically. REBs rely on lawyer members for specific guidance.

Additional Utility for the PBPs Document

17. It was recognized that the privacy issues related to the banking, storage and use of biological materials (blood and other human biological materials such as blood type, DNA code and the presence or absence of disease), are beyond the scope of this Document. Several on the persons interviewed indicated they would like to have guidance on the privacy issues associated with the storage and use of such materials.

18. Many researchers are looking for a knowledge base to serve their need to ensure privacy in an appropriate fashion. The full Document may be an excellent starting point for creating such a knowledge base – that is, a dynamic, on line electronic document rather than a static paper document. Resources could include, for example: discussion forums; a facility for contributing; storing and making available cases; and training modules.

19. Privacy issues are becoming increasingly complex for studies which are multi-jurisdictional in nature. The internationalization of research and the broadening of health research into disciplines other than bio-medical increase the complexity.

20. Social science researchers, in particular, pointed to a need for specific guidelines and best practices for Aboriginal health research. It was known that CIHR is now working with this topic and seeks to develop Aboriginal-specific health research guidelines to ensure adequate protections for Aboriginal research participants.

21. For a significant number of Document users, patient consent was a very important issue. Respondents wanted more assistance to determine when consent was required, and when "opting out" was acceptable. [8]

22. It was recognised that the Document does deal with physical and technological security (electronic databases) although inadequately in the views of some. Given that researchers, especially social scientists, also collect audio and video information, and that commercial electronic data security has recently be shown to often be weak, unreliable, it was suggested that CIHR may wish to have a more comprehensive look at the whole area of personal information stored in all media.[9]

23. Two issues emerged for social science researchers in particular with respect to paediatric and education-institution research: (1) the age of consent is seen to be a grey area and (2) educational research, especially school based research. Much research is ongoing in schools without reference to privacy concerns, and without submission for review to REBs. In view of the increasing amounts of school-based research and research in Children's' Hospitals, this 'grey area' is in need of additional guidance.

24. The need to keep the Document up-to-date, current, was stated. This was not a suggestion that the Document was out-of-date but recognition of a rapid pace of change and the increasing depth and scope of the privacy issue area.

25. It was suggested that CIHR should help to harmonize competing demands of federal and various provincial legislation, especially in trials and health research consortia which cross jurisdictional lines, quite often international boundaries.

Improvements Requested of the PBPs Document

26. A number of researchers asked for the information in the Document to be organized to facilitate rapid access; terms such as "chewable chunks", "Coles Notes", "PowerPoint" presentations, training modules in various media and on-going on-line communication among researchers, were used to describe what was wanted here.[10]

27. Suggestions for improvement of the PBPs Document included:

- CIHR funding could be made contingent upon whether privacy concerns have been well handled in a funding proposal.

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[8] Here, as in many other of the respondent comments, it appears that many, if not most, researchers and PRC and REB Chairs, do not realize that many of the issues they raised during the interviews are already well treated by the Document. Notwithstanding this, the issue of approaching individuals to obtain consent is a problem for researchers, and therefore there is value to reviewing this requirement.

[9] The comment was received in this general nature. The suggestion is that CIHR consider how best to improve data security in a rapidly changing data storage environment.

[10] These were the suggestions offered. No one suggestion for how to make the information available was dominant.

- Researchers asked for tools and guidelines to help them deal with privacy requirements efficiently and effectively in their proposals.
- There was a call for better ways and means for treating the privacy issue in the context of multidisciplinary and multi-jurisdictional research proposals such as proposals that involve institutions in several provinces, and, especially in clinical drug trials, the internationalization of research proposals).
- It was suggested that CIHR develop and use marketing, education and awareness programs aimed at the research community; their focus would be to help researchers understand that their interests are well-served if they are familiar with the Privacy Best Practices Document.
- The search for balance between privacy issues and personal health issues was a common theme. Some worry that patients are distracted from understanding risks to their health and security by lengthy explanations of confidentiality safeguards.
- Some see a conflict between the need to respect privacy and the wish to facilitate research. Some voiced concern that privacy issues may act to discourage useful research programs, particularly health related social science research, epidemiological studies on large populations, and secondary research using clinical case records where consent for research use cannot be secured.
- Among the suggestions to CIHR for better fostering the development of privacy best practices in Canada were:
    - A "Tool Box" of cases, interpretations, etc., modelled on the case law approach
    - frequently asked questions (FAQs)
    - an ongoing discussion forum on-line
    - additional training together
    - more CIHR presentations
- It was clearly stated that the privacy issues related to the banking, storage and use of biological materials (blood and other human biological materials such as such as blood type, DNA code and the presence or absence of disease), are not covered sufficiently in this document. Several on the persons interviewed indicated they would like to have guidance on the storage and use of materials.
- Peer Review Committee Chairs pointed to the conflict of values that may occur between patient and privacy rights. Some people see it as in their interest to be research subjects; this includes the wish to have resulting information made available to their physicians or others. At the same time, people seek to limit sharing of their private medical information with employers or insurance companies. Better procedures, guidance, are wanted to accommodate both sets of rights.

Assessments of the PBPs Document

28. Those who use the Document report that they find it to be useful, most frequently as a reference document. Those who use the Document are more than ‘quite satisfied’ with the document. They find it to be well-formatted, readable, user-friendly and helpful.

29. Document users find it “quite easy” or “very easy” to use. They attribute this to their familiarity with the subject matter, and also because it is well written and organized. The main reason that some found it “quite hard” to use is its length. There were also concerns about the challenge of summarizing such a vast and complex issue.

30. Many of the persons interviewed see the Document as large and somewhat intimidating.

Linkages with Other Documents

31. Many were of the view that integrating the PBP Document in a non-mandatory way with the Tri-Council Policy Statement could help produce a knowledge set more useful to social science researchers.

32. There are currently linkages between the CIHR Document and the Tri-Council Policy Statement. Although a small minority of researchers would like to see the PBPs become part of the Tri-Council policy, a substantial number felt that linkage was sufficient. The links from Tri-Council to the Document would usefully provide guidance and clarification for some of ambiguous, less specific, portions of the TCPS.

33. The Document is recognized as one of many influences, policies, and laws in place in the jurisdictions in which the researchers work. Many would like to see the CIHR document linked to the Tri-council but they see it as a voluntary, not mandatory, adjunct. Most respondents liked the idea of linkage between the PBPs Document and the Tri-Council Ethical Conduct for Research Involving Humans policy statement, because the PBPs Document provides more detailed, clear, examples.

Other Comments Relevant to Privacy Concern

34. The majority of respondents are associated with health research. The typical place of employment is a public institution employing researchers, such as a university, college, hospital or public service office. The roles played are, in large part, that of health researcher, research screener, research manager/coordinator or research advisor.

35. The cultural and practical differences between social and biomedical researchers appear to call for different kinds of privacy policies and methods.

36. There is a preference for paper copies of the document. Researchers and reviewers like to have their own hard-copy handy – a copy on which they have entered their personal notations.

37. Several persons complained that they had difficulty obtaining paper copies of the document. Since many current users refer to the paper document, especially at meetings, the paper version is seen as much more useful than an on line version.

38. The continuing use and development of electronic databases raised a host of security issues common to the public focus found in other (non-health) sectors such as banking and commercial enterprises. The continuing interconnection of databases to permit rapid access by health professionals was also seen as a requirement for adequate electronic data security.

39. Some respondents are concerned that ethics and privacy are reviewed only in the context of research proposals, i.e. health research that is seeking funding. They worry that a lot of confidential information is on the unregistered "rogue databases" of individual researchers' laptops and therefore at risk in various ways.

40. There are concerns about monitoring and auditing: do researchers put their professed safeguards of privacy into practice? This is both a policy issue (should it be done? if so, by whom?) and a practical one (where are the resources to do it?).

Appendices

The findings for each of the seven groups are issued as stand-alone appendices. Where a pair of documents has been issued for a particular data set, the two documents are the report of the findings from the answers given and the other is the verbatim record of the answers given to certain of the free response questions.
The appendices are:

Document-Recipients: Interview Findings

Peer Review Chairs: Interview Findings

Peer Review Chairs: Text Responses

Privacy Policy / Legislative Staff: Interview Findings

Ethics Community Stakeholders: Interview Findings

Ethics Community Stakeholders: Text Responses

REB Representatives: Interview Findings

REB Representatives: Text Responses

Focus Groups Report

Web Survey Report: Findings

Web Survey Report: Text Responses

CIHR Note: These Appendices are available on request to the CIHR Ethics Office. These documents are currently in English only.