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CIHR IRSC

Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research: Best Practices – Consultation Draft April 2004

Report on 2004 Consultation Feedback

Prepared by CIHR Ethics Office
February 2005

Canada

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Executive Summary

The Canadian Institutes of Health Research (CIHR) is Canada's major federal health research funding agency, and has a mandate to promote health research that meets the highest standards of scientific excellence and ethics. One of the key ethical challenges facing CIHR and others in the research community is how best to protect privacy while enabling valuable research and evidence-based decisions that will maintain and improve peoples' health. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) provides an ethical framework for research. This framework includes respect for privacy and confidentiality among other fundamental guiding ethical principles. However, there is general acknowledgement that the TCPS needs further clarification in this area.

In June 2003, CIHR established a multi-sectoral Privacy Advisory Committee (PAC) to advise CIHR on the development of privacy best practices guidelines for health research, and on a communication and knowledge translation strategy. In early discussions, PAC recommended that CIHR conduct broad consultations to enable wider participation and input from all interested parties. This is particularly important if the best practice guidelines might eventually be incorporated, in some form, into the TCPS.

The consultation period for CIHR's draft privacy best practice guidelines extended from March to September, 2004, with some written comments being received through mid-October. There were three streams for obtaining feedback: (1) written comments received in response to invitations sent to key stakeholders, and through an on-line feedback questionnaire; (2) three multi-stakeholder workshops on specific themes aimed at addressing potential gaps in coverage; and (3) two small group dialogue sessions with citizens.

The consultations were an opportunity to hear whether the guidelines were meeting the needs of the broad research community, including research ethics boards and legal oversight bodies, and if stakeholders were supportive of the guidelines. Many comments indicated that the best practice guidelines were a useful and value-added resource. Some of the key criticisms related to:

- the need for more practical advice for researchers and research ethics boards;
- a perceived lack of clarity with regard to how the best practice guidelines interface with the TCPS, applicable legislation, codes of professional ethics, and institutional policies; and
- the resources required from institutions, researchers and research ethics boards to comply with these best practices.

A number of comments related to how well the best practice guidelines dealt with the key goals of simultaneously protecting privacy while enabling health research. Views ranged among, and within, stakeholder groups as to whether the draft guidelines were too privacy-protective or too research-enabling.

The consultation workshops constituted an opportunity to focus on how well the draft guidelines addressed privacy issues associated with genetic research; the spectrum of research involving the use of personal information funded by the three main federal research funding councils[1]; and research involving the health care context such as clinical research and research requiring the analysis of patient records. In brief, we heard the following:

- In the area of genetic research, most comments indicated that the draft privacy guidelines applied reasonably well and there was general agreement among workshop participants that genetic data should be included in the scope of "personal data". Some commented on the need for greater recognition of the rights and concerns of implicated family members and communities, and of unique issues around human biological materials.

[1] The three main federal research funding councils, also referred to in this report as the Tri-councils, are CIHR, the Social Sciences and Humanities Research Council of Canada (SSHRC), and the Natural Sciences and Engineering Research Council of Canada (NSERC).

- Regarding the coverage of research involving personal information funded by the Tri-councils (important if the guidelines ultimately are to provide input into the TCPS), there was general agreement among workshop participants that the guidelines needed further elaboration with respect to emergent (inductive) research and qualitative research methods generally, and to population-based research involving secondary use of data.
- For research involving the health care context, various suggestions were made for further work to better address privacy issues associated with specific research purposes, methods and contexts. For example, some participants wanted more attention to privacy issues arising from public health research, long-term research databases, research conducted within institutions, invasive as compared to non-invasive research, and research funded partially or entirely by private industry.

In the citizens' dialogue sessions, participants were generally supportive of health research, and of the presented recruitment scenarios and options for informed consent for future research. However, many expressed concern about providing researchers with access to personal health records for recruitment purposes, without the data custodian having first obtained the consent of the individuals whom the information was about. Many people were not aware of the use of government databases for research, or of the existence of research databases with linked information on individuals from various sources. Overall, participants wanted assurances that their information would not be used in ways that could harm them or for particular research studies that they did not agree with.

To address perceived gaps and to provide more opportunities for input, there were suggestions that CIHR should hold additional consultations with particular sectors, including:

- the Aboriginal community,
- the social sciences and humanities community,
- research ethics boards,
- physician regulatory authorities, and
- pharmaceutical companies and other private sector interests.

We heard a range of views on an implementation strategy for the guidelines. Some wanted the guidelines to have "teeth" and others recommended that they be voluntary, at least initially, to gain buy-in from the research community. Overall there was general support for releasing the privacy best practices as voluntary guidance initially, accompanied by active pilot-testing and a long-term education and training strategy.

The next steps will be to revise the draft privacy best practices in light of comments received, with the advice of the Privacy Advisory Committee. A phased implementation strategy, including an ongoing evaluation process, will be further refined in collaboration with the broad research community.

Introduction

The Canadian Institutes of Health Research (CIHR) is Canada's major federal health research funding agency, and has a mandate to promote health research that meets the highest standards of scientific excellence and ethics. CIHR-funded health research involving human subjects is subject, at a minimum, to applicable legislation, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*-1998 (with 2000, 2002 updates)[2], and other funding policies[3]. One of the key ethical challenges facing CIHR and others in the broad research community (including ethics review and oversight bodies) is how best to protect privacy while enabling valuable research and evidence-based decisions that will maintain and improve peoples' health.

Privacy concerns have come increasingly to the attention of the research community as technological advances in information technology and the advance of genetic research challenge existing ways of protecting privacy. In addition, privacy laws and policies within and beyond Canada's borders have multiplied in sheer number and complexity, raising calls for clarification and harmonization of the legal and policy framework for health research. The Tri-Council Policy Statement (TCPS) provides an ethical framework for health research. This framework includes respect for privacy and confidentiality among other fundamental guiding ethical principles. However, there is general acknowledgement that the TCPS needs further clarification in this area.

CIHR has responded to these challenges by investing in research on privacy and other ethical issues, working collaboratively with policy makers towards common privacy standards and practices for the Canadian health research community, and engaging a broad range of stakeholders in constructive dialogues around privacy concerns. In particular, a CIHR-hosted multi-sectoral conference entitled "Privacy in Health Research: Sharing Perspectives and Paving the Way Forward" (November, 2002, Ottawa) led to a recommendation to develop privacy best practices for health research.

In response to the recommendation from the 2002 privacy workshop, CIHR established a multi-sectoral Privacy Advisory Committee (PAC) in June 2003[4] to provide advice on the development of privacy best practice guidelines for health research and on an associated communication and knowledge translation strategy. According to their terms of reference, PAC members are to bring their particular perspectives to the table but do not need to obtain formal approval from their respective organizations. PAC members voted to have the CIHR Ethics Office act as chair of the committee in a facilitator role.

Early discussions with PAC raised the possibility that the best practice guidelines could eventually be incorporated in some form into the TCPS, so that compliance would be a mandatory condition for receiving federal research funds from the three research funding councils (CIHR, the Social Sciences and Humanities Research Council of Canada and the Natural Sciences and Engineering Research Council of Canada). Any such incorporation would be determined upon advice to the Councils from the Interagency Advisory Panel on Ethics (PRE) which is charged with overseeing the further evolution of the TCPS. PAC also agreed that the guidelines will need to be continually revised and updated as current best practices are tested and new best practices emerge.

[2] The TCPS is accessible on the web site of the Interagency Advisory Panel on Research Ethics (PRE) at: http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm. An on-line TCPS tutorial can be accessed on PRE's site at: http://www.pre.ethics.gc.ca/english/tutorial/.
[3] Information on CIHR funding policies is accessible at: http://www.cihr-irsc.gc.ca/e/204.html.
[4] Privacy Advisory Committee members are listed in Appendix A.

Consultation Process

PAC advised CIHR to conduct a broad consultation process on a draft set of best practice guidelines to enable wider participation and input from all interested parties, particularly important if the best practice guidelines might eventually be incorporated into the TCPS. It was agreed that the consultation process should endeavour to satisfy the three principles for consultation set out by PRE, namely 1) transparency, 2) inclusiveness, and 3) fostering of critical dialogue[5]. To further these objectives, a consultant was hired to assist in the design of the consultation process, to facilitate all workshops and citizen dialogue sessions, and to put in place a mechanism to evaluate the process.

The consultation period extended from March to September, 2004, with some written comments being received through mid-October. There were three streams for obtaining feedback: (1) written comments received in response to invitations sent to key stakeholders, and through an on-line feedback questionnaire; (2) three multi-stakeholder workshops on key themes where potential gaps in coverage had been identified; and (3) two small group dialogue sessions with citizens. In addition, community outreach efforts were made to notify the broad community about the consultation, through association list-servs, informal networks, conference presentations, and other available means.

About 200 organizations were invited by letter to provide written comments, and CIHR received close to 70 written submissions[6]. A small number of people used the on-line questionnaire to provide feedback, but the web site received over 8,000 hits. People and organizations from the following broad stakeholder groups provided feedback:

- researchers;
- patients/consumers;
- clinical research nurses;
- research ethics board members;
- institutional privacy officers;
- universities;
- private industry;
- data custodians;
- research funders;
- non-governmental health organizations;
- health care providers;
- health professional associations;
- privacy commissioners/ombudsman; and
- governments.

Multi-stakeholder workshops focused on identifying any gaps in coverage of privacy issues related to:

- genetic research (March 26, co-funded by Health Canada);
- Tri-Agency funded research involving personal information (May 20, co-funded by PRE);
- research involving the health care context (August 24, co-funded by Heenan Blaikie LLP).

About ninety people in total participated in the workshops, bringing wide-ranging perspectives to discussions on these themes[7].

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[5] PRE's consultation principles are outlined in *Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans – April 2002*, pg. 2-3, posted on PRE's web site at: http://www.pre.ethics.gc.ca/english/policyinitiatives/governance01.cfm#S08.

[6] For a list of those who provided written comments see Appendix B. For selected feedback on specific sections of the draft text see Appendix C.

[7] For workshop participant lists and issue summaries see Appendix D (March workshop), Appendix E (May workshop) and Appendix F (August workshop).

Two small group dialogue sessions with a roughly representative sample of the adult population were designed to probe, in a qualitative and preliminary fashion, privacy issues around recruitment practices and informed consent for general research purposes.[8] At least half of the participants had had experience with health research, either personally or through a family member's participation. Participants discussed scenarios based on relevant sections of the best practice guidelines. A total of thirty-six people attended these sessions, in Ottawa or Toronto.

[8] For a description of the method and materials used for the small group dialogue sessions see Appendix G.

Overview of Feedback

Do the privacy best practice guidelines respond to the needs of the broad research community?

Many comments indicated that the best practice guidelines were a useful and value-added resource. Comments including the following: "*Useful adjunct to TCPS*"; "*Guidelines are appropriate and helpful*"; "*Stimulated discussions with research ethics boards and the research community*"; "*Provides valuable advice*"; "*A principled approach, practical, comprehensive, provides reasonable balance*". While many praised the comprehensiveness of the best practice guidelines, some wanted a shorter more streamlined document and others identified gaps in coverage (highlighted later in this section).

There were also requests for more practical advice for researchers (such as a template for a consent form or a privacy impact assessment) and for research ethics boards (such as standard algorithms and operating procedures). Along the same lines, the use of real-world case studies was recommended. There were also suggestions that the document could feature more efficient reader-friendly ways of navigating through the document, such as by flagging sections relevant to particular research methods or types.

A number of comments related to how well the best practice guidelines dealt with the key goals of protecting privacy **and** enabling health research. Views ranged between and within stakeholder groups as to whether the draft guidelines were too privacy-protective or too research-enabling. On the one hand, many thought that the best practice guidelines should provide greater recognition that consent is required for health research, with no or rare exceptions, and that the "impracticability" justification for the waiver of a consent requirement should be more restrictively formulated. Others commented that the guidelines should do a better job of recognizing that a consent waiver for some research is acceptable if approved by a research ethics board, such as for the secondary use of anonymized data or of administrative data in population-based research, where seeking consent is impracticable.

Many were concerned about the potential impact of the guidelines with respect to resources. For example, questions were raised about whether research ethics boards are being provided with sufficient training and resources to fulfill expectations, and whether research funding agencies are willing to support researchers and institutions in meeting requirements for privacy protections.

General concerns were raised around how to deal with privacy issues arising from international, national and cross jurisdictional studies; from research in the field of genomics and genetic/environmental interactions; and emerging standards for Aboriginal research. Some noted that the impact of electronic health records on privacy protection and research was still unknown but could be substantial.

Do the best practice guidelines have the right scope? Are there areas for further work?

The introduction to the best practice guidelines stated that this document was limited in scope to the Canadian context (not international), to personal information (including genetic information but not human biological materials); and to health research (not surveillance or other health information related activities). During the consultations, people were invited to comment on these boundaries: Did the document cover well what it was intended to cover? Should new sections or complementary policies be developed to address areas not yet covered?

As previously noted, many praised the draft guidelines for being comprehensive. However, some wanted a narrower scope and others identified gaps needing expanded treatment. In particular, respondents from a variety of perspectives requested greater clarity on the Canadian legal and policy framework for health research, such as on how the best practice guidelines would interface with the TCPS, applicable legislation, codes of professional ethics, and institutional policies. Some recommended that there be links in the guidelines to relevant information in the TCPS wherever possible. It was also suggested that any

overlaps or inconsistencies between the two documents should be identified, and it should be clear which policy "overrides" the other. Some commented that applicable laws may have more rigorous privacy requirements than those of the best practice guidelines, and that these differences should be identified. It was pointed out that clinical trials are subject to the *Food and Drug regulations* and the *International Conference on Harmonization Guidance E6: Good Clinical Practice: Consolidated Guideline*, and that these regulatory requirements should be referenced in the CIHR document.

The consultation workshops constituted an opportunity to focus on how well the draft guidelines covered privacy issues associated with genetic research, the spectrum of research involving personal information funded by the three main federal research funding agencies, and research involving the health care context such as clinical research and research requiring analysis of patient records.

In the area of genetic research, many thought the draft privacy guidelines applied reasonably well and there was general agreement at the March workshop that genetic data should be included in the scope of "personal data". Many pointed out that privacy issues related to implicated family members and communities (e.g. issues around group consent, duty to warn, the right not to know, and potential for identification and stigmatization) needed to be better articulated. With regard to human biological materials, there was general agreement that these should be covered by the best practice guidelines, but that there were unique issues (e.g. commercialization, ownership, retention periods, storage, and anonymization) that warranted further thinking about how to do this.

With respect to coverage of Tri-Council funded research, some commented that the draft guidelines did not adequately reflect the privacy issues and challenges that arise in population-based research involving secondary use of data, and in emergent (inductive) research and qualitative research methods.

For research involving the health care context, some commented on the need for greater recognition of health care providers' responsibilities to comply with their professional codes of ethics, as well as the need for more detail on privacy issues associated with specific methods, types and contexts of research. For example, some participants wanted more attention to privacy issues arising from public health research, long-term research databases, research conducted within institutions, invasive as compared to non-invasive research, and research funded partially or entirely by private industry.

From various sources we heard requests for more consultation with particular sectors to better address their privacy issues, including with:

- the Aboriginal community;
- the social science and humanities community;
- research ethics boards;
- physician regulatory authorities; and
- pharmaceutical companies and other private sector interests.

How did citizens respond to the recruitment scenarios and options for consent for future research?

Participants in the small group dialogue sessions discussed scenarios involving recruitment for health research and informed consent for future research involving linked databases. In general, participants were supportive of health research and of the recruitment scenarios and informed consent options presented.

Many participants preferred recruitment methods that gave them the most control over whether they could participate in the research and over what information was provided about the research. Also, there were

concerns about researchers having access to personal health records for recruitment purposes without the data custodian having first obtained consent from individuals.

Many participants would agree to be included in a database for general research purposes (ranging from a majority of participants in one session, to about half in the other session); and of those, about half would agree to the linkage of their data from various databases. The majority who would agree to be in the database wanted to be re-contacted to ask consent for future studies. However, participants did not want to be contacted too often. Suggested ways of minimizing the need for re-contact included having re-contact at periodic intervals, or limiting the kinds of research that could be done with the information. There was agreement that people generally want to be told the results of research in which they have participated.

Another key finding in these sessions was that most participants were not aware of the use of government databases for research, nor of the existence of research databases with linked information on individuals from various sources.

In general, participants wanted assurances that their personal information would not be used in ways that could harm them or for particular research studies they did not agree with.

How should these privacy best practices be implemented?

We heard a range of views on a compliance and implementation strategy for the guidelines. Some wanted the guidelines to have "teeth" and others recommended that they be voluntary, at least initially, to gain buy-in from the research community. Also, some expressed the view that compliance with the guidelines could not be a mandatory condition for receiving federal research funds unless more money were given to cover the costs of compliance.

Those advocating an initial period of voluntary compliance, for periods ranging from two to ten years, also recommended pilot-testing the guidelines so that feedback could be gathered on their usefulness and impact. Suggested mechanisms for pilot-testing included establishing a representative sample of research ethics boards to provide feedback; conducting a survey of researchers; and setting up a web-based feedback tool. After the initial period of assessment and revision, compliance with the privacy best practices could become mandatory for CIHR funding, and eventually also for Tri-Council funding once the privacy best practices are "rolled into" the TCPS.

There was some confusion over the inclusion in the title of both "best practices" and "guidelines" as if these terms have the same meaning, alongside the use of the word "manual" in the text. It was noted that these terms all mean different things with respect to their implicit authority and moral weight and the rigor in their development (guidelines being more systematically developed and having more authority than best practices). It was suggested that the term "manual" be dropped because there is no ethical obligation to read a manual, and that there be consideration of how to appropriately use the terms "best practices" and/or "guidelines".

Overall there was general support for releasing the privacy best practices as voluntary guidance initially, accompanied by active pilot-testing and a long term education and training strategy.

Conclusion

CIHR, with the advice of its Privacy Advisory Committee, undertook public consultations to foster transparency, inclusiveness and critical dialogue in the development of privacy best practice guidelines for health research. The breadth and depth of comments received demonstrated a high level of interest within the broad research community. We heard a range of viewpoints on such things as how best to protect privacy and promote health research, on how extensive the scope of the best practice guidelines should be, and on how to implement the guidelines and promote compliance.

With the advice of the CIHR Privacy Advisory Committee, the next steps are to revise these privacy best practices in light of feedback received. We will also establish a process for their ongoing revision as current best practices are refined through experience and as new best practices emerge. Supported by a phased implementation strategy that includes education and training, CIHR's privacy best practices have the potential to assist researchers, research ethics boards, institutions and others in protecting privacy in health research in more consistent and effective ways. These best practices could also help to inform the public about procedures in place to protect their privacy interests.

APPENDIX A - Privacy Advisory Committee (PAC)

Privacy Commissioners

David Loukidelis
Information and Privacy Commissioner of British Columbia

(Privacy-enhancing Technologies)
Debra Grant
Senior Health Privacy Specialist
Information and Privacy Commissioner/Ontario

Research Ethics Boards (REBs)

Sharon Buehler
Co-Chair, Research Ethics Board, Memorial University

Don Willison
(CIHR-funded research on REBs)
Scientist, Centre for Evaluation of Medicines, McMaster University

Health Researchers

Charlyn Black (Health Services Research)
Director, BC Centre for Health Services and Policy Research

Colin L. Soskolne (Epidemiology)
Professor, Department of Public Health Sciences, University of Alberta

Voluntary Health Organizations

Roy West
Co-Chair, Science and Research Committee, Health Charities Council of Canada

Patients/Consumers

Mary Vachon
Psychotherapist and Consultant in Private Practice
Professor, Depts. of Psychiatry and Public Health Science, University of Toronto
Clinical Consultant, Wellspring

Phil Upshall
Chair, Canadian Alliance on Mental Illness and Mental Health
President- The Mood Disorders Society of Canada

Policy-makers

Heather McLaren
Director, Legislative Unit
Manitoba Health

Data Producers/Custodians

Joan Roch
Former Chief Privacy Officer, CIHI
Privacy Consultant

Michael Wolfson
Assistant Chief Statistician
Statistics Canada

Aboriginal Interests

Bronwyn Shoush
CIHR Institute Advisory Board Member- Institute of Aboriginal People's Health,
Director, Aboriginal Justice Initiatives Unit, Alberta Solicitor General

Health Service Providers

Denis Cournoyer
Associate Physician, McGill University Health Centre
Associate Professor, Dept. of Medicine and Oncology
McGill University

Ethics/Law

Brent Windwick
Partner, Field LLP
Former Executive Director, Health Law Institute

Bartha Maria Knoppers
Canada Research Chair in Law and Medicine;
Professor, Public Law Research Centre, Faculty of Law, University of Montreal

Ex Officio Members

Interagency Panel on Research Ethics (PRE):

Pierre Deschamps, PRE member
Member of the Canadian Human Rights Tribunal

Social Sciences and Humanities Research Council (SSHRC)

Christian Sylvain (alternate: Jocelyn Girard)
Director, SSHRC Corporate Policy and Planning

National Council on Ethics in Human Research (NCEHR)

Fern Brunger, NCEHR Member
Assistant Professor, Health Care Ethics, Faculty of Medicine
Memorial University

Health Canada

Ross Hodgins/John Horvath
Privacy Division
Information, Analysis & Connectivity Branch, Health Canada

International Advisor

William W Lowrance
International Consultant in Health Policy and Ethics, Geneva, Switzerland

Canadian Institutes of Health Research – Ethics Office

Patricia Kosseim - **Chair**
Former A/Director, Ethics Office
General Counsel, Office of Privacy Commissioner of Canada

Sheila Chapman
Senior Ethics Policy Advisor

Mylène Deschênes
Senior Ethics Policy Advisor

Sylvie Burion
Project Officer

APPENDIX B - List of those who provided written comments

Organizations:

- National Council on Ethics in Human Research
- Social Sciences and Humanities Research Council of Canada
- Interagency Advisory Panel on Research Ethics- Social Sciences and Humanities Research Ethics Special Working Committee
- CIHR Institute of Population and Public Health- Institute Advisory Board
- Sir Wilfred Laurier University
- University of British Columbia
- University of Saskatchewan
- University of Manitoba
- Concordia University
- Ryerson University
- Queen's University
- University of Guelph
- Memorial University
- York University
- University of Regina
- University College of the Cariboo
- Manitoba Centre for Health Policy
- Newfoundland and Labrador Centre for Health Information
- Cancer Care Ontario
- Fonds de la recherche en santé, Québec (FRSQ)
- Community Research Ethics Board of Alberta
- West Park Health Care Centre, Toronto
- Winnipeg Regional Health Authority
- British Columbia Regional Health Services Authority
- Hospital for Sick Children, Toronto
- Sunnybrook and Women's College Health Sciences Centre, Toronto
- Pfizer Canada Inc.
- N2N Privacy Solutions Inc.
- CGI Information Systems and Management Consultants Inc.
- Canadian Council of Cancer Registries
- Canadian Institute for Health Information
- Canadian Blood Services
- Canadian Public Health Association
- Canadian Medical Association
- Canadian Dental Association
- National Aboriginal Health Organization
- Office of the Ombudsman of Manitoba
- Office of the Privacy Commissioner of Canada
- Office of the Information and Privacy Commissioner of Alberta
- Canadian Biotechnology Advisory Committee
- Ministère de la Sante et des Services Sociaux, Quebec
- Prince Edward Island Department of Health and Social Services
- Manitoba Health
- Northwest Territories Department of Health and Social Services
- Saskatchewan Health
- Ontario Ministry of Health and Long-term Care
- British Columbia Ministry of Health Services
- Health Canada
- Department of Justice Canada
- USA National Academies of Medicine-Panel on Data Sharing

Individuals associated with the following perspectives:

- Researchers
- Clinical research nurses
- Research Ethics Board members
- Patients/Consumers
- Health care providers
- Health lawyers
- Institutional privacy officers

APPENDIX C - Selected Section-by-Section Feedback

The table below provides a listing of key comments on specific sections of the draft text.

SECTIONS	SELECTED FEEDBACK
Goals	- Add: guidance for data custodians - Add: resource for research participants - Indicate that the goals apply to privacy, confidentiality and security of "personal information" only
Statement of Values	- More emphasis on public good of research; recognize health as a human right (e.g. support for broad research) - State that privacy is a moral and legal right; add concept of autonomy - Clarify meaning of "social value of health research"; note that peer review committees make this determination, not Research ethics boards; note the social value of basic, applied and social sciences research - Recognize individual's choice to not be anonymous, e.g. in ethnographic research - Recognize cultural context of some research and "community privacy" concept (e.g. in Aboriginal communities); recognize potential harm to groups - Recognize that ethical issues in research go beyond privacy and confidentiality (e.g. include issues of power inequities; harms to groups)
Scope of Application	
Health Research	- Need more holistic definition of "health" (e.g. WHO definition) - State what it doesn't cover: D of Rx& D - Cannot apply medical model to social sciences and natural sciences - Clarify that it does not just apply to health care research but to biomedical, clinical, health systems and services, and population and public health research. - Include basic science and social sciences
Personal Information	- Issues identified at the March workshop (e.g. sensitivity of genetic data, implications for family/communities, reporting back of research results) - Distinguish data relating to a person (personal data) vs. data that identifies or potentially permits the identification of a person (personal identifiers)
Canadian Context	- Clarify guidance on when law takes precedence - Clarify if apply to non-federally funded institutions conducting health research (e.g. provincially funded); or to privately funded research (and if so, how?) - Clarify that these are not mandatory - Make explicit reference to primacy of legal and professional obligations on physicians (and other health professionals) [re collection/use/disclosure of patients' health information for research] : reference CMA *Code of Ethics* (update 2004); CMA *Health Information Privacy Code* - Reference examples of policies/codes related to private sector research of which researchers need to be aware: for researcher involving health care context: CMA's *Physicians and Pharmaceutical Industry* (Update 2001); for researchers requesting data from Manitoba Centre for Health Policy: *Guidelines for Private Sector Sponsorship- Projects accessing the Manitoba Population Health Research Data Repository* - Recognize the unique status of Aboriginal peoples in Canada; and the need to consult with Aboriginal communities in research that has an impact on them or involves their members; reference OCAP policy; reference work underway to revise TCPS Section 6- Research involving Aboriginal Peoples

SECTIONS	SELECTED FEEDBACK
	- Recognize need for PIAs in some jurisdictions - Provide more information on PIPEDA
Commitment to Continuous Learning and Review	- CIHR needs to commit resources to this - Develop web-based mechanism
Overview of the Current Landscape of Research	- Add: "Aboriginal jurisdictions" in addition to FPT (e.g. research projects may cross cultural, provincial, territorial or national boundaries") - Add longitudinal survey panels as example of long-term research database - Address chart reviews - Add international research - Add industry sponsors to the list of data holders, for clinical research databases - Re-define "registries"
Future Considerations: Changing Landscape of Health Research	- Re: Aboriginal: Add "emerging standards for Aboriginal research and Aboriginal collective privacy rights and interests" (e.g. "articulation and application of First Nations' principles of Ownership, Control, Access and Possession (OCAP) and other Aboriginal ethical considerations is rapidly reshaping research in Aboriginal settings"). - Consider new and emerging research: including genomics and genetic/environmental interactions - Electronic health records: clarify that much is unresolved for care providers; and with respect to access for research purposes - Privacy issues and the use of data system for multiple purposes, e.g. for individual patient care and management, programme management, public health services (e.g. cancer screening, vaccinations), and research. - Put more emphasis on harmonization - Consider the impact of new computer systems to control data access

ELEMENTS	SELECTED FEEDBACK
1. Determining research objectives	- Objectives not always known at outset (e.g. emergent (inductive) research methods) - Difficult/futile to try to anticipate all future questions/uses
2. Limiting collection of personal data	- Don't always know what is needed at outset - Need to collect more information and then control future access - Anonymization terms are not consistent with the TCPS
3. Determining if consent required	- Address chart review (consent waiver?) - Recognize pilot and preliminary studies - Recognize different rules for invasive vs. non-invasive research - Recognize clinical trials- need for written consent - Recognize legal requirements (e.g. Alberta) - Need more details on when consent is impracticable - Need for consent waiver for: population-based research (e.g. health services); secondary use of administrative data for research; deceased subject; denominalized or anonymized data; discarded human tissue Also contrasting views: - Maximize opportunities for consent (express or opt-out) in prospective collection of data– e.g. for registries— with possible individual authorization of future studies subject to procedural safeguards such as ongoing monitoring by an REB and (if desired) notification of the addition of new projects with secondary access - Limit secondary uses without consent

ELEMENTS	SELECTED FEEDBACK
	- Recognize concept of community/collective privacy
4. Recruiting participants	- What does "undue pressure" mean? - Operational difficulties in long term care institutions (physicians don't have time to discuss questions) - Differentiate "finder's fees" from pecuniary interest - Recognize clinical research team's role in obtaining consent, not only "researcher" - Provide more on recruitment for longitudinal surveys - Provide individuals with varied opportunities to be recruited; emphasize freedom from undue pressure to consent; general trust in doctor to explain risks
5. Informing participants	- Recognize need for layers of information (consent form not too lengthy; opportunities to get more information) - Should Research ethics boards consult with affected individuals? - Define "general research purposes" - Provide prospective participants with sufficient information (and varied sources of information) to make up own mind; - Provide participants with opportunities to control future uses of information in general research database, without re-consent being overly-intrusive; recognize lack of public awareness of data linkages and use of a government databases for research, along with some support/concern over long-term linked databases.
6. Managing and documenting consent	- Recognize that consent is a process (e.g. children become "competent") - Clarify term: "authorized third parties" - Clarify terms (implied, express, opt-out, by conduct) - Need to not document consent sometimes (could put informants at risk) - Documenting opt-out may be a disincentive - Collect information on non-participants or those who withdraw: contrasting views on acceptability - Need more information on consent with children, elderly, immigrants, those with diminished or fluctuating competence - Address genetic issues: implicated family members- consent, right not to know, duty to warn
7. Safeguarding data	- Reference COACH Guidelines? - Note potential gap: new media - Need more information for researchers who switch institutions or have cross-appointments - Need more information on residual disclosure - Need culture shift; resources; raise standards - "Risk management" is a low standard - Need to recognize reality of "distributed networks" - Audit/monitoring system hard to set up/validate - Recognize difficulty in anonymizing data
8. Limiting access to data	- Need more on roles of data holders in restricting data access and safeguarding data - Option D- offsite data linkage—how to protect data?
9. Retaining, destroying and archiving data	- Social sciences generally support archiving; need to protect personal privacy - Define "socially valuable research" - Clarify what is being archived—raw data? Results? - Fostering availability of data is inconsistent with limiting access - Need data subject's consent and/or awareness before archiving personal data - Need to archive scientifically useful data (may include identifiers)

ELEMENTS	SELECTED FEEDBACK
	- Need to promote diversity in research (not concentrate data in established data centres) - Whose responsibility is it to maintain archived data sets? - Who has authority over databases created from patient records? - Clarify if archived datasets includes human tissues and blood
10. Ensuring accountability and transparency	- Could be first element - Could be more comprehensive (include industry sponsors, the public, etc.) - Title should reflect that it only deals with “management of personal data” - What is expected from Research ethics boards seems unrealistic considering human and financial constraints
Glossary	- Expand the glossary
Appendix	- Indicate legal requirements - Include privacy impact assessment template & consent form template

APPENDIX D - “Genetic Research” Workshop: Issue Summary

Date: March 26 2004 Workshop co-funded by Health Canada and CIHR
Theme: How well do these draft guidelines address genetic privacy issues?
City: Ottawa
Facilitator: Jacquie Dale, One World Inc.

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ISSUE SUMMARY

Overall message regarding how well the guidelines apply to genetic research

- The majority of participants thought the draft privacy guidelines applied reasonably well to genetic research, with some gaps. There was general agreement that genetic data should be included in the scope of "personal data" covered by the guidelines.
- One group was very concerned about having yet more "hoops" to jump through, and wanted the guidelines to be a more practical document.
- Regarding human biological materials, there was general agreement that "materials" should be added to the best practice guidelines, but that there were unique issues (e.g. commercialization and destruction) that warranted further thinking about how to do this.
- Various complementary instruments for addressing issues around human biological materials were suggested, including federal norms (policies), Provincial laws, institutional policies, and health professional codes.

General issues raised

Definitions and Scope in Guidelines:
- Recognize different types of genetic information
- Do we need to clarify "data", e.g. does it include specimens?

Question of Uniqueness of Genetic Information:
- Is genetic data more sensitive? Are more stringent principles needed? Consider: Implicated family members. Quantifiable risk of future health problems.
- Genetic research raises the need for a range of protection (beyond the individual) for:
  - Individual
  - Families
  - Geographic communities
  - Racial groups

Consent:
- What is "anonymous" genetic data? Should anonymous genetic data be shared between researchers without consent?
- Need to consider informed consent by individual vs. secondary consent by family.
- Need a reasonable approach to collecting family histories.
- Is blanket consent for future uses of genetic information acceptable? With opt-out and notification?

Confidentiality and Security:
- Levels of access not captured e.g. physicians, PIs, others.
- Potential sharing internationally (Do the guidelines apply to international research with different sites, including Canada?)
- Increase clarity around auditors and what data they have access to
- Differences between ethicists and patients about the right balance between research and privacy; patients are concerned about **abuse** of information—address this concern.

Obligations on Researchers:
- Duty to "warn" implicated family members/relatives
- There may be different obligations for physician-researchers with responsibilities for clinical care vs. researcher (e.g. doing population research).

Format/Content:
- Not a practical document/manual, e.g. in Appendix: if you are doing genetic research, this is how to write a consent form (a template in guidelines); this is how to meet legal requirements (e.g. look at CSA principles in PIPEDA).
- Need a balance between guidelines and feasibility to do the job.
- Are all the guidelines needed? Do some dilute the focus on privacy?

Issues raised relating to human biological materials

Ownership:
- Who owns the sample (donor, the PI, scientific body)? Who guides the sample for research?

Destruction:
- Cannot clearly map "material" onto anywhere in the guidelines where you see "data", e.g. destruction---one can more readily destroy data than material (Is biological material effectively "irreplaceable" and therefore should not be destroyed?)

Anonymization:
- Can't permanently anonymize material
- Shouldn't strip data of identifiers (use encryption tools)—"duty to warn" individual and family members.

Resources/Maintenance:
- Resource issues around maintenance of biobanks
- Storage issues: coded first, locked in freezer

Consent:
- If the sample is not used for intended consent are we obligated to inform donor?
- What about material from "control subjects"—can control material be used for other studies? Should access to samples be with consent, e.g. from relatives if subject deceased?

Commercialization/Privatization:
- This is the big patient issue—privacy is secondary.
- What about material obtained for commercial purposes—do we need separate consent if access to collections for commercial bodies is envisaged?
- Is "collecting" different from "banking" (e.g. a formal system for access)

Various views on a mechanism to address issues of research using human biological materials

- An overarching "umbrella" set of guidelines for research on humans (including genetic data and biological samples): the lens of "privacy" misses unique issues around biological materials; and the lens of "materials", misses issues of privacy. For example: replace Tri-Council Policy Statement and have a federal regulator.
- Multiple prisms (complementary instruments: Provincial tissue laws; health professional codes, institutional policies, complementary federal norms (e.g. Health Canada policy, etc.)

Various views on how enforceable the guidelines should be

- Depends on the final document and how practical it is to enforce it—but possibly rolled into TCPS; need to recognize what is already covered by legislation

- Should be voluntary regulations for federally-funded institutions, but questions about how effective a self-regulating model is; might need to move to a regulatory model with third party monitoring
- Should be regulatory model if private sector involved; guidelines should be mandatory funding criteria (rolled into TCPS), but need a mechanism for oversight of local Research ethics boards
- Should be free-standing voluntary guidelines (not rolled into TCPS); genetic researchers need guidance, not more regulation; institutions are bound by TCPS -- let's evolve TCPS, its process and substance.

APPENDIX E - “Tri-Council Research” Workshop: Issue Summary

Day: May 20, 2004 Workshop co-funded by the Interagency Advisory Panel on Research Ethics and CIHR
Theme: How well do these draft guidelines apply across the spectrum of research involving personal information funded by CIHR, SSHRC or NSERC?
City: Ottawa
Facilitator: Jacquie Dale, One World Inc.

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ISSUE SUMMARY

Regarding how well the guidelines apply across the spectrum of research involving personal information

Clinical research perspective:
- On the positive side, the guidelines would improve adherence to common standards, with researchers and Research ethics boards using the same rule book.
- On the negative side, the guidelines would require additional steps in the protocol approval process, which may require additional staff/time.

Social Sciences perspective:
- The guidelines would improve accountability, by having similar requirements across the three federal funding councils.
- However, before the guidelines can apply to Tri-council research, more text/explanation is needed for issues related to qualitative and emergent research methods. These methods are also used by CIHR-funded researchers.

Health services and policy research perspective:
- Need to recognize that the "social value' of the research is decided through the peer-review process, not the REB process (i.e. need to distinguish in the guidelines between scientific and ethics review processes).
- Not a good fit for large database research (e.g. population-based research, secondary use of administrative data for research); for example, the document is too "consent-based" and uses pejorative language in the consent section such as "normal", "exceptions"; and regarding security, need more attention to qualitative differences of different databases (e.g. security measures for large databases vs. for small number of records).
- Not enough attention to roles of different custodians.
- Instead of being based on the four "pillars" of health research, might be a better taxonomy to focus on approaches to research, e.g. hypothesis testing, hypothesis generating, secondary analysis, and direct collection.
- Structure the document based on research contexts (colour-coded), with information for research ethics boards in checklists/boxes.

New content/modules

- Emergent research and qualitative research methods (before the document can be "rolled" into TCPS)
- Large database research (e.g. population-based, secondary use of administrative data)
- Roles of data custodians
- Scientific vs. ethics review processes (clarify the meaning of "socially valuable research")
- More structured information for Research ethics boards, related to specific kinds/phases of research.

Various views on implementation strategy

- Should begin as voluntary guidelines and then move into institutional accreditation standards, with funding incentives to institutions.
- Promote an educational model: CIHR should provide teaching sessions, web-based tutorial, and standard forum for use by Research ethics boards.
- Should be voluntary for two years, review/adjust, and then be integrated into the TCPS.
- Should remain voluntary standards for at least 10 years (and then possibly folded into the TCPS); meanwhile, collect case studies on actual use and implications of the guidelines at the REB level for CIHR-funded research.

APPENDIX F - “Health Care & Research” Workshop: Issue Summary

Date: August 24, 2004 Workshop co-funded by Heenan Blaikie LLP and CIHR
Theme: How well do these draft privacy guidelines apply to research involving the health care context?
City: Toronto
Facilitator: Jacquie Dale, One World Inc.

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ISSUE SUMMARY

Overall message regarding how well the guidelines apply to research involving the health care context

Workshop participants came from a range of perspectives—researcher, patents/consumers, health care providers, health professional associations, research ethics boards, health law, government, and private sector. A range of sometimes contrasting viewpoints, within and between stakeholder groups emerged in discussions. Participants' views regarding how well the guidelines apply to research involving the health care context, included comments that the guidelines:

- provide best practices (a reference document), more transparency and standardization of REB processes;
- have a heavy clinical focus but not enough on public health;
- cover small neat studies better than long-term and institutional research;
- has obvious conflicts with other guidelines and laws, which need to be referenced;
- don't address research in the office setting (and how can this be monitored?);
- will discourage small research projects, because health care providers can't afford all of these processes when conducting research;
- very helpful information in the guidelines, but how can institutions use it while facing restraints and meeting Bill 31? and
- are better suited to publicly funded research than privately funded research or public-private partnerships.

Various views on implementation strategy

- The guidelines should have "teeth", and the role of research ethics boards is critical.
- The guidelines should be voluntary-- need to get buy-in from the research community, and do pilot testing with researchers and research ethics boards, to assess the guidelines' practicality and their effect on researchers.
- There was general agreement that the guidelines should be value-added—not "just another document". Some comments indicated that the guidelines should eventually become incorporated into the TCPS, accompanied by an educational strategy.
- Implementation challenges included:
  - providing education, common standards, resources, accreditation for Research ethics boards; and
  - raising public awareness and ensuring a consumer voice is reflected in the guidelines (e.g. How much does the public know or need to know?).

General issues raised

New content/modules:

- Different rules for invasive/non-invasive research
- Private sector research and public/private partnerships or only cover public research
- Secondary use of data for research (e.g. chart reviews).
- Genetic research
- Large institutions vs. small studies
- National and cross jurisdictional studies
- Reference Provincial/Territorial laws
- Consistency with/reference to TCPS
- Emerging context of electronic health records
- Case reports/case series
- Public health.

Consent:

- Provide a more focused and detailed treatment of waiver of consent. Various views were expressed on the acceptability of a waiver of consent for secondary use; and on the acceptability and logistics of an opt-out mechanism. Contrasting views on consent were:
  - consent should never be waived— in some circumstances it may be presumed or implicit;
  - if there is no opt-out consent, consent is being waived; need to clarify what form of consent is being waived and under what circumstances;
  - patients' right to know is paramount-- need truly informed consent, with a higher onus for genetic research; and
  - need to include the concept of collective privacy.
- There was concern about anonymized data— need for more protections vs. the acceptability of a consent waiver.

APPENDIX G - Small Group Dialogue Sessions with Citizens

Dates: June 19, 2004 Ottawa and August 23, 2004 Toronto
Facilitator: Jacquie Dale, One World Inc.

SUMMARY REPORT

Purpose

Two small group dialogue sessions were conducted with citizens, many of whom were former research participants, as part of a multi-stakeholder consultation on CIHR's draft privacy guidelines. These sessions were intended to test, in a qualitative and preliminary way, the acceptability to the general public of selected recruitment and informed consent "best practices".

Process

The sessions were conducted in two cities, Ottawa and Toronto, with a roughly representative mix of the adult population. Each dialogue session took place over one three-hour period and was led by the same trained facilitator. Participants were seated in pre-assigned groups and provided with a discussion workbook.

The workbook[9] contained four scenarios, based on sections of CIHR's draft privacy guidelines (see Box). The scenarios addressed issues around recruitment and the informed consent process, and led participants to discuss such questions as:

- Who should have access to personal information for screening purposes (to determine eligibility for research)?
- Who should make the initial contact with prospective participants?
- Who should conduct the informed consent process?
- What options should participants be given to control future uses of their information in a general research database?

[9] See the Supplementary Materials at the end of this report for a copy of the workbook used in these sessions.

Workbook scenarios and links to the privacy best practice guidelines

WORKBOOK SCENARIOS	GUIDELINES ELEMENT (EL)
1. Screening and initial contact by the data holder (a physician or his assistant); informed consent process by researcher	EL #4, Scenario 2 (b) (i)
2. Screening, initial contact, and informed consent process by data holder (the physician/researcher)	EL #4, Scenario 2 (b) (ii)
3. Initial screening by data holder (government); initial contact by researcher. Follow up option: Initial screening by researcher with access to government database.	EL #4, Scenario 3 (a)
4. Informing people about how to control future research uses of their data in a database created for general research purposes.	EL #5, 5:3

Description of Participants

Participants were recruited by professional recruitment services. The objective was to recruit a roughly representative sample of the adult (18 + years) Canadian population, excluding researchers or health professionals. Additional criteria were the ability to read and speak English and, for at least half of each group, some experience with health research.

In total, 36 people participated in these session-- 21 people in one session, and 15 in the other. The demographics of the 36 participants were as follows:

- approximately equal numbers of males and females in each session;
- ages ranging from 19 to 73 years;
- education ranging from high school to post-graduate degrees;
- mix of occupations and income levels, with some retired or on disability;
- 50% of participants in one session were from visible minority groups; and
- about 70% had had experience with some kind of health research, either through personal participation or through a family member.

Feedback

In participants' comments physicians were generally portrayed as trusted figures in the recruitment process for clinical research, primarily because this offered the greatest assurances of confidentiality for personal health information. However, some participants were concerned about physicians having a conflict of interest between caring for patients and conducting research. Some were also concerned that the doctor might have too much control over who was eligible for the research and over information provided about the research.

Many participants preferred recruitment methods that gave them the most control over whether they could participate in the research, such as self-selection recruitment methods (e.g. by answering advertisements or posters), and over what information was provided about the research (e.g. by supplementing information from the physician with other sources, such as voluntary public information sessions).

Most participants did not think a researcher should have access to personal information from a government database without prior consent, to make initial contact with prospective participants. The masking technique of mixing 80% of people with the condition under study and 20% without the condition

on a recruitment list was criticized for not protecting the privacy of the 80% and for potentially and unnecessarily harming the 20%. Most would not permit a researcher to access the government database to produce a list of eligible people for a study —although some would permit it with strict supervision or for very valuable research.

Most participants were not aware of the use of government databases for research or of the existence of research databases with linked information on individuals from various sources. People expressed concern about the possibility of pharmaceutical companies and insurance companies gaining access to government-held personal information, as well as potential identity theft.

Many participants would agree to be included in a database for general research purposes (ranging from a majority in one session, to about half in the other session); and of those, about half would agree to the linkage of their data from various databases. The majority who would agree to be in the database wanted to be re-contacted to ask consent for future studies. However, participants did not want to be contacted too often. Suggested ways of minimizing the need for re-contact included: having re-contact at periodic intervals, or limiting the kinds of research that could be done with the information.

Conclusion

In general, participants were supportive of health research and of the recruitment scenarios and informed consent options presented. However, there were concerns about researchers having access to personal health records for recruitment purposes without the data custodian having obtained prior consent from the individuals whom the information was about. Another key finding was that most participants were not aware of the use of government databases for research, nor of the existence of research databases with information relating to individuals from various sources. Overall, people wanted assurances that their information would not be used in ways that could harm them or for particular research studies they did not agree with.

Supplementary Materials

SMALL GROUP DIALOGUE WORKBOOK

SECTION A: Recruiting People for a Research Study

BASIC STEPS

Recruiting people for a health research study involves three basic steps:

1. **Determine who should be eligible for the study.** For example, researchers may be investigating the cause and treatment of a particular medical condition and therefore need to recruit only people who are affected by this condition and who are currently under a doctor's care.

2. **Reach these people, through direct personal contact (by mail, phone or in person) or indirectly (through posters, newspaper advertisements, etc).**

3. **Inform people** about the details of the research**. Ask if they will consent** to participate**.**

GENERAL PRINCIPLES

- When recruiting people, researchers should not invade people's privacy or interfere in their lives more than is necessary. For example, if recruitment is through direct contact, people should be contacted by someone whom they would expect to know them and the reason why they are eligible for the study.

- People should be aware of the risks and benefits of the research to themselves so that they can make a decision about participating based on their own best interests.

- Consent should be voluntary. This means that people should not feel pressured to participate in the research. They should know that they can withdraw from the research at any time. They should not feel that they will be penalized if they do not participate. (For example, they should not feel that their health care will suffer if they do not agree to participate in a research project).

- A research ethics board should approve the proposed recruitment procedure.[10]

Scenario #1

Doctor A is a family doctor. He is part of a research team that is planning to investigate how adults cope with asthma.

Doctor A wants to give his eligible patients the option of participating in the research, but he is concerned that his patients might feel that they have to agree to participate in the study if their health care provider makes the request.

As part of his submission to the research ethics review board, Doctor A proposes the following recruitment procedure:

[10] Research ethics boards are set up by universities and other research organizations to review, approve or reject research proposals, according to national research ethics guidelines. Research ethics boards should have at least five members, including men and women, experts and community representatives.

- He will review the charts of his patients and make a list of those patients who are eligible for this study.

- He or his assistant will contact the patients on his list and inform them that there is a study that they might want to participate in. If they are interested in hearing more about the research, they will be told that a research nurse will contact them.

- The research nurse will contact interested patients and provide details of the research, including any risks and benefits of the research to patients.

- The research nurse will make it clear to patients that whether or not they agree to participate in the research will have no effect on the quality of the treatment they receive. And, if they agree to participate, they can withdraw at any time.

WORKSHEET 1:

SCENARIO #1 - questions

1. Do you think this scenario measures up to the general principles? Why or why not?
2. Are there other principles that you think should be considered? If so, what are these?
3. Do you think the scenario measures up to these other principles? Why or why not?
4. Are there other issues that occur to you as you discuss this scenario?

Scenario #2

Doctor B is part of a research team that is planning to investigate the effectiveness of a new therapy for people with severe asthma that in previous research has shown better results for some patients than have standard therapies. For some participants, this will mean switching medication for the period of the research project.

Doctor B wants to give his eligible patients the option of participating in the study but he is concerned that patients might decide about participating in the study without a full understanding of the risks and benefits of the research to themselves. Because he has detailed knowledge of his patients' cases, he believes that his patients would expect and trust him, rather than a research nurse or another doctor, to give them an accurate description of the risk and benefits of the research in their particular cases.

In his submission to the research ethics review board, the doctor proposes the following recruitment procedure for his patients:

- He will review the charts of his patients and make a list of those patients who are eligible for the research.

- He or his assistant will contact and inform the patients on his list that there is a study that they might want to participate in. If patients are interested in hearing about the research, the doctor will inform them of the risks and benefits of the research in their particular cases.

- The doctor will make it clear to the patients that whether or not they participate in the research will have no affect on the standard of care that they receive at his clinic. And, if they agree to participate in the research, they can withdraw at any time.

WORKSHEET 2:

SCENARIO #2 – questions

1. Do you think this scenario measures up to the general principles? Why or why not?
2. Are there other principles that you think should apply in this situation? If so, what are these?
3. Do you think the scenario measures up to these other principles? Why or why not?
4. Are there other issues that occur to you as you discuss this scenario?

Scenario #3

A researcher is planning a study to investigate the effect on people with asthma of a Ministry of Health decision to remove an "old" type of asthma treatment from provincial health care coverage, and replace it with a "new" treatment. Research has shown that the new treatment is more effective for most people and cheaper to supply than the old one. The policy will take effect in some regions of the province before others.

The researcher proposes to give a quality of life survey to people with asthma who switch to the new treatment and to those who continue to use the old treatment in regions where the policy is not yet being applied. Her research results will provide information to the Ministry about the benefits and costs of the policy.[11]

For the recruitment process, the Ministry of Health is willing to assemble a list of eligible people for the research. However, the Ministry does not have the resources to contact each person to ask them if they will permit their names to be given to the researcher who would then contact them to ask if they want to participate.

In her submission to the ethics review board, the researcher proposes the following recruitment procedure:

- She will sign a confidentiality agreement with the Ministry of Health. This agreement will state that she can only use contact information to ask people if they want to participate in her research project.
- The Ministry of Health will then provide the researcher with the contact information of eligible people without getting their consent first. However, to provide some privacy protection, the names of people with asthma will be "camouflaged" (mixed in) with the names of people who do not have asthma. 80% of the names on the list will be of people with asthma, and 20% will be of people who do not have asthma. The researcher will not know who has asthma and who doesn't.
- The researcher will mail to everyone on the list her survey and a more general Ministry survey (applicable to everyone registered under the provincial health care plan). The mailed package will include a cover letter from the Ministry and the researcher explaining how the list was compiled and that the researcher does not know the health status of anyone on the list. She will only know the health status of those people who voluntarily fill out her survey and return it to her.
- The cover letter also explains the research purposes for the two surveys and any risks and benefits of the research. The letter states that participation in either survey is voluntary.

WORKSHEET 3

SCENARIO #3 - questions

1. Do you think that this scenario measures up to the general principles? Why or why not?
2. Are there other principles that you think should be considered? If so, what are these?
3. Do you think the scenario measures up to these other principles? Why or why not?

[11] One type of health research compares two groups of individuals-- those who receive a new treatment (called the "experimental group"), and those who don't receive the new treatment (called the "control group"). The two groups should be similar except for the difference in treatment so that any changes in the experimental group can be attributed to the effect of the new treatment.

4. Are there other issues that occur to you as you discuss this scenario?
5. If the Ministry of Health does not have staff time to assemble a list of people to give the researcher:

   Do you think the researcher should be permitted to go the Ministry office, access the health database and run the computer program to produce a list of eligible people for her study? Why or why not?

   Would you consider it acceptable under certain conditions—if so, what conditions?

SECTION B: Informing People about Future Research Uses of Their Data

COLLECTING RESEARCH DATA FOR GENERAL RESEARCH PURPOSES

Some health research projects are conducted over a long period of time. A research institution will set up a research database to be used for many different research projects over years or decades. Researchers must apply to the institution for access to the data. When a database is being set up for general research purposes, it is not known what particular research projects will use the information in the future or what future research questions will be.

GENERAL PRINCIPLE

When research participants are informed that a research database is being set up for general research purposes, they should be given options to control future uses of personal information in the database.

Scenario #4

A university health sciences institution is planning a long-term research project. The general purpose of the research is to investigate:

- causes of asthma (lifestyle, genetic, environmental, social, etc.),
- effectiveness of treatments, and
- impact of the condition on people and the health care system.

Potential public benefits of the research include improved medical treatments and health services, more effective promotion of healthy lifestyles and a better understanding of how to prevent environmental triggers for asthma.

Research participants will be asked to:

- answer a health and lifestyles survey;
- give a blood sample for genetic analysis; and
- allow their survey data to be linked to data about them from other sources (genetic analysis, physician billing data from provincial health insurance records, hospital records, and provincial births and deaths records). These other data sources will provide additional information about participants' medical histories.

Researchers from outside the centre will be able to submit proposals to use this data. The proposals will have to be approved by an institution research review committee and by a research ethics board before the researchers are permitted to access any data.

In the submission to the research ethics board, the Research Director at the institution explains that their proposed informed consent process does not include details about all future uses of participants' data, because they do not know what specific studies will be done. Therefore, they propose to give participants general information about the research and offer them some choices about how their data could be used in the future.

WORKSHEET 4

Scenario # 4 - questions

The table below suggests a series of different options that researchers could give research participants so that they have some control over future uses of their data.

1. Are these the right options to give to research participants?

OPTIONS FOR FUTURE USES OF DATA

Do you want to be contacted in the future every time a researcher wants to use your data?	(Check one)
A. Yes.	
B. Yes, but only for certain types of research. Otherwise I don't want my data used.	
C. No, but any future uses must follow my instructions.	

If you chose Option B or C: **For what purposes can your data be used in the future?**	(Check one)
D. Only for approved research projects on certain topics related to asthma. The researcher and I will decide on the topics during the consent process.	
E. Only for approved research projects related to the general purpose for establishing this research database (which is to investigate the causes, treatment and impact of asthma).	
F. For any approved research project, including new areas that do not directly relate to asthma. But not for employment or insurance purposes, or to make any administrative decisions directly related to me.	
Will you allow your data from different sources to be linked together for research purposes, over a number of years? This means linking information about you from the health survey, genetic analysis, and physician billing records, hospital records, and provincial births and deaths records.	(Check one)
G. Yes.	
H. No.	

Who should be allowed to access your name and other directly identifying information? Any directly identifying information would be stored in a separate database and only accessed when necessary to contact you, or to do data linkages for research purposes.	(Check one)
I. No one. My name and other directly identifying information are to be permanently removed from the research database. This means that I cannot be contacted about the research for any reason. Also, I will not be able to ask for the	

	rest of my data to be removed from the database in the future. If I have allowed data linkages to be done (in Option G), they will be done using other pieces of information in my records. [12]	
	J. Institution staff only, on a need-to-know basis. Institution staff should conduct any data linkages for outside researchers. No outside researchers are allowed to see my directly identifying information.	
	K. Institution staff and outside researchers, on a need-to-know basis. If necessary, I will permit outside researchers to access my directly identifying information to do data linkages and then destroy or return this information to the institution as soon as possible.	

2. Are there other options that you think should be offered? Why?

3. Which options would you choose? Why?

4. Are there other issues that occur to you as you discuss this scenario?

[12] Data linkages are generally most accurate when done by matching directly identifying information (such as names, addresses, etc.) on different records. Data linkages can sometimes be done by matching other pieces of information (such as a combination of postal code, birth date, etc.). For this kind of data linkage, there may be some loss of accuracy, meaning that records for different people may be incorrectly matched as coming from the same person. The accuracy of the research results will depend in part on how many inaccurate data linkages are made.