Health Canada Santé Canada

Building a research ethics culture at Health Canada

Report of the
Health Canada Research Ethics Board
2003

June 10, 2004

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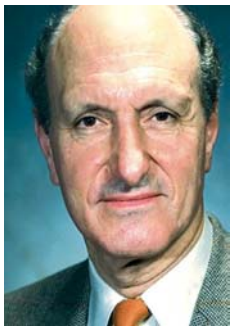
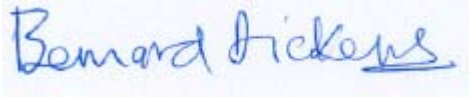


I am pleased to introduce the Health Canada Research Ethics Board report for 2003—our first since the board was formed in late 2002 to formalize the department's ethics review process.

It is fitting, therefore, that we have adopted a theme for this report: *Building a research ethics culture at Health Canada*. Many of our accomplishments profiled in this document are about getting the fundamentals right—establishing an all-new board, conducting in-depth training, and consulting our stakeholders during the course of our work. These steps have been crucial so that we can move ahead to meet our vital and challenging mandate.

The Research Ethics Board is always eager for comments and feedback, so be sure to contact us (our address is listed on the final page of this report) and share your thoughts about our work and on the contents of this report.



Bernard Dickens, LLB, LL.M., Ph.D, LL.D
Chairperson, Research Ethics Board

A message from the Chief Scientist, Dr. Kevin Keough

Since its inception, the Research Ethics Board has been supported by a secretariat, including resources from my organization, the Office of the Chief Scientist. It's a logical fit—both organizations are devoted to the pursuit of excellence in science.

Never before have the potential and the challenges posed by science been greater. In a range of research underpinning everything from biotechnology to health promotion, scientists today must contend with issues that generate debates extending well beyond the research activity itself. Research ethics are becoming part of our civic dialogue.

I commend the work of Health Canada's Research Ethics Board and thank them for their important work on behalf of the Department. Having developed the tools needed, the Board contributes greatly to a new culture of research ethics within Health Canada—and that's something that can benefit Canadians everywhere.

Kevin Keough, Ph.D.
Chief Scientist, Health Canada

Executive Summary

The purpose of this report is to inform Health Canada and other interested stakeholders about the roles, membership, activities, achievements and forward-looking plans of the Health Canada Research Ethics Board (REB). More than a summary of activities, this document demonstrates how the REB's efforts to date are helping to build a vital, vibrant research-ethics culture within Health Canada.

Prominently featured in this report are the profiles of REB members—unique, distinguished professionals who are making a difference in the pursuit and promotion of research ethics at Health Canada.

Getting the fundamentals right has been one of the key objectives of the board since its inception. With this in mind, the report identifies the following key achievements for the REB in 2002–2003:

- developing a formalized ethics review process at Health Canada;
- establishing the first-ever research-ethics training and orientation sessions for Health Canada researchers and managers;
- developing opportunities for REB members to ensure that their knowledge of research ethics is current; and
- consultations with REB members and Health Canada researchers on the function and performance to date of the REB.

Thanks to these achievements (among others), the REB is now ideally positioned to undertake further challenges in carrying out its mandate. In this regard, this report highlights key activities to be undertaken in 2004, including the development of an REB website, revised polices and procedures, as well as ongoing training for board members and for researchers and managers in the department.

About Health Canada's Research Ethics Board

Founded in 2002, the Research Ethics Board (REB) is an advisory body that helps contribute to ensuring that all human-based research carried out by Health Canada or associated investigators meets the highest scientific and ethical standards. Equally important, it also helps ensure that safeguards are developed to protect participants who serve as subjects in connection with research of this nature.

The scope of activities of the REB involves reviewing all human-based research:

- in circumstances of intramural study;
- carried out at Health Canada involving technical or consultation support, including equipment, laboratories or other facilities;
- undertaken in collaboration or partnership between Health Canada and external researchers;
- funded by grants and contributions; and
- conducted under contract.

The REB reports to Chief Scientist (Health Canada), and is supported by a secretariat located within the Office of the Chief Scientist, including a manager, a project officer and a part time administrative assistant. Complementing the review function served by the board, the REB Secretariat provides Health Canada with research-ethics training for departmental managers and researchers.

Background

Prior to the establishment of the REB, research ethics at Health Canada was addressed on an ad-hoc basis. While this approach was effective in addressing many key issues, by the late-1990s, the need for a formalized research ethics process as prescribed by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), was evident. The TCPS, prepared by Canada's three major research funders—the Medical Research Council (the predecessor of the Canadian Institutes of Health Research), the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council of Canada, is the governing standard for research ethics in Canada. The TCPS provides that an accountable, effective and efficient process of ethics review must accompany professional responsibility in science.

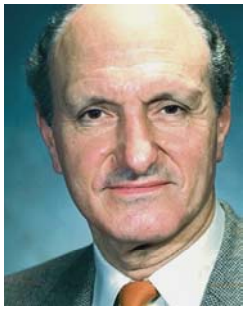
With an endorsement in 2000 by the Health Canada Science Advisory Board, a consultation process was begun in which departmental concerns about research ethics were examined. In particular, it explored the steps required to establish a permanent body to oversee research ethics at Health Canada. A final concept was approved in 2001 by the Science Advisory Board and by Health Canada's Executive Committee—paving the way for the establishment of the Research Ethics Board in 2002.

The REB guiding principles, based on the TCPS are attached to this report as *Appendix A*.

Membership profiles

The Research Ethics Board membership consists of eight expert representatives; one member has expertise in law, one member with expertise in bioethics, one member with expertise in human research ethics, one member is a researcher from outside Health, two members are researchers from within Health Canada and two members represent the community at large. Together, these members ensure that Health Canada applies a consistent approach to ethical reviews of research involving human subjects. Each member holds tenure with the REB for three years, up to a maximum of six years.

Chairperson



Dr. Bernard Dickens, LL.B, LL.M., Ph.D., LL.D.
In addition to serving as Chairperson of the Research Ethics Board, Dr. Dickens is the University of Toronto's Dr. William M. Scholl Professor in Health Law and Policy in the Faculty of Law, the Faculty of Medicine, and the Joint Centre for Bioethics. He is the author of over 300 publications primarily in the field of medical and health law. In addition, he is a Fellow of the Royal Society of Medicine (London) and Chairman of the Human Ethics Review Committee at the University of Toronto. From 1995 to 1999, Dr. Dickens served as Chair of the National Research Council of Canada's Human Subjects Research Ethics Committee. He became a Fellow of the Royal Society of Canada in 1998.

External researcher

Dr. Cornelia Wieman, B.Sc. M.Sc., M.D., FRCPC

Is Canada's first female Aboriginal psychiatrist. She attained an Honours Bachelor of Science degree and a Master of Science degree, both from the University of Waterloo. She graduated from the medical school and completed her specialty in psychiatry at McMaster University. She holds an academic appointment as an Assistant Clinical Professor in the Department of Psychiatry and Behavioral Neurosciences, Faculty of Health Sciences at McMaster University. Dr. Wieman currently works part time at the Six Nations Mental Health Services. She provides independent consulting services to various national agencies involved in the delivery of health care services to Aboriginal communities. In July 2001, she was appointed to the Suicide Prevention Advisory Group jointly by the Federal Minister of Health and the Assembly of First Nations National Chief. She won numerous research scholarships and awards, including a National Aboriginal Achievement Award that recognizes career achievement in the area of medicine (1998). She was the inaugural recipient of the University of Waterloo Faculty of Applied Health Sciences Alumni Achievement Award (2002). Her clinical and academic interests include Aboriginal health and mental health issues, Aboriginal health care policy and workforce. She takes a special interest in Aboriginal youth and, as a role model, tries to encourage young Aboriginal people to work towards and achieve their dreams.

Ethicist

Dr. George C. Webster

A Clinical Ethicist with the Health Care Ethics Service at St. Boniface General Hospital in Winnipeg, Manitoba. Dr. Webster is an Assistant Professor at the University of Manitoba in the Faculty of Medicine (Family Medicine and the Department of Anaesthesia). At the same University, he is also an Adjunct Professor in the Department of Philosophy and an Associate of the Centre for Applied and Professional Ethics. Dr. Webster has extensive experience with health care ethics committees and Research Ethics Boards. He is currently a member of and consultant to the Canadian Anaesthetists' Society's Committee on Ethics. He serves on the Manitoba Medical Association Ethics Committee, the Winnipeg Regional Health Authority, Steering Committee on Mental Health Ethics, and the Canadian HIV Trails Network (Vancouver, B.C.) National Ethics Review Committee. He has served on the University of Manitoba, Faculty of Medicine, Research Ethics Board and from 1998 - 2003 he chaired the National Research Council of Canada, Winnipeg Research Ethics Board. In 2003, he was appointed a member of the American Society for Bioethics and Humanities, Clinical Ethics Task Force.

Expertise in human research ethics

Dr. Michael Enzle, B.A., Ph.D.

Dr. Enzle has long been involved in the development and implementation of human research ethics policies at the University of Alberta, where he is currently a Professor of Psychology. Since 2003, he has been on secondment to the Office of Vice-President (Research) as a human-research policy advisor. Dr. Enzle has been the chairman of several research ethics boards. Currently, he is the Chair of the National Council on Ethics in Human Research Education Committee at the University of Alberta. His professional interests include scientific and scholarly integrity and conflicts

of interest and his academic research includes privacy issues, power relationships and motivation. In 2003, Dr. Enzle was appointed as Chair of the Canadian Institutes of Health Research Stem Cell Oversight Committee.

Community representatives

Ms. Monique Martineau

Ms. Martineau was nominated to Health Canada's REB by Lupus Canada. She worked for a legal firm in Montreal as a paralegal and manager of corporate services and is familiar with precedents and changing laws. For a period of 20 years, Ms. Martineau served in different capacities at the Provincial and National level of lupus organizations. She was on the Board of directors of Lupus Canada for several years; she served a 2-year term as Vice-President of Lupus Canada and served on the Strategic Planning Task Force for Lupus Canada. Ms. Martineau served as a member of the Board of Directors of Lupus Quebec as well and several terms as President; she edited the French version of "*Lupus-Disease of 1000 Faces*". She is familiar with the grants process as well as the communications and public relations areas. She speaks fluent French and English and has some knowledge of Italian and Spanish.

Me Susy Landreville, inf. B.Sc., LL.B

As a lawyer and nurse, Me Landreville has a wealth of experience in various areas of health services. As a lawyer (and member of the Quebec bar) she has been an advocate for a non-profit agency dealing with the rights of citizens when dealing with health care. Me Landreville has worked in hospitals and in schools in the public health area. She was nominated to the REB by the Conseil pour la protection des malades.

Health Canada researchers

Dr. Agnes Klein, MD, DPH

Currently the Manager of the Clinical Evaluation Division within Health Canada's Health Products and Foods Branch, Dr. Klein's professional interests include the ethical issues related to the design of clinical trials. Prior to joining the REB, she was the chairperson of Health Canada's ad-hoc research ethics group. Dr. Klein is also a founding member of the National Council on Ethics in Human Research, where she has played an active role both in the Clinical Trails Subcommittee and the Communications and Education Subcommittee. She is the author of two background papers prepared in 1986 for the Medical Research Council. Dr. Klein was also a member of the 1987 working group that drafted the Medical Research Council guidelines on research involving human subjects.

Dr. Tom Wong,[1] MD, MPH, FRCPC

Dr. Wong is the Director of Community Acquired Infections Division within Health Canada's Centre for Infectious Diseases Prevention and Control. Trained at McGill, Harvard and Columbia Universities, he is an infectious disease physician with a Masters Degree in Public Health. Dr. Wong has established an impressive career in public health, including authorship of various journal publications. He is an Assistant Professor at the University of Ottawa's Department of Medicine (Division of Infectious Diseases), and is an Adjunct Lecturer at the University of Toronto's Department of Public Health Sciences. Since 2003, Dr. Wong has been the Chair of the National Clinical SARS Working Group, and the Canadian Sexually Transmitted Diseases Guidelines Expert Working Group Committee, among various other committees.

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[1] Note: Dr. Wong replaced Dr. Sutherland, who left the Research Ethics Board in June 2003.

Dr. Donald Sutherland and Dr. John Last

Dr. Sutherland and Dr. Last were members of the REB until June 2003 and November 2002 respectively.

Ethics review process

In conducting its review of all human-based research at Health Canada, the REB has developed a process for examining each application it receives. Based on the REB's guiding principles (drawn from the TCPS), research involving humans can be ethically justified only when:

- the research is scientifically sound;
- the potential benefit significantly outweighs the potential for harm;
- there is an adequate process for informed consent, along with (when applicable) a child's assent to participate; and
- there is a just and fair selection of participants.

The REB meets monthly to review research projects. Health Canada research applications that are reviewed by the board will receive one of the following decisions:

Approval: Ethical approval is given in writing only. Research within this domain cannot commence until such approval is granted. Approval is given for one year and must be renewed annually until the research is complete. A copy of the Annual Progress Report application must be submitted to the REB Secretariat.

Approval with revisions: A study is given approval on the condition that revisions are made, as summarized in the letter from the Chairman of the REB. Approval will not be considered by the board until the revisions are Received by the REB Secretariat.

Not approved: If there are a significant number of outstanding issues, an application may not be approved. In such circumstances, the REB will assist a researcher to resolve these issues. If a satisfactory solution is not reached, a researcher may be invited to a subsequent REB meeting to further discuss the issues arising from the research application.

Board decisions are issued in writing to the applicant in accordance with established Health Canada procedures.

Achievements 2002–2003

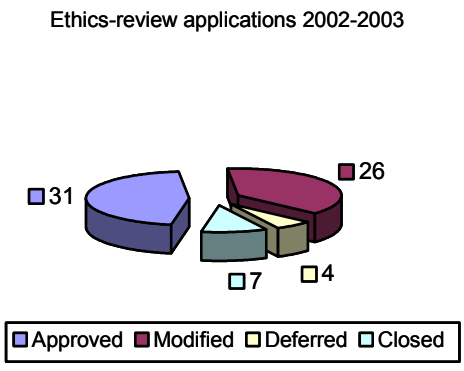
Since the REB's inception in 2002, the board has made steady progress in pursuit of building a research-ethics culture within Health Canada. Getting the fundamentals right has been one of the key objectives of the board, and with this in mind, it is proud to point to the following 2002–2003 achievements:

- undertaking the formal ethics review process at Health Canada;
- conducting consultations and obtaining feedback from REB members
- conducting consultations and obtaining feedback from Health Canada researchers and managers;
- establishing the research ethics training and orientation sessions for Health Canada researchers and managers;
- establishing ongoing opportunities for REB members to keep their skills current;
- developing procedural documents and key reference material; and
- additional key activities.

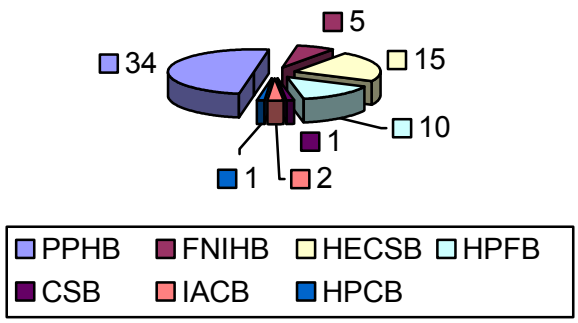
Establishing a formal ethics review process at Health Canada

Since the establishment of the REB in 2002, all research involving humans at Health Canada has had to be reviewed and approved by the Board. From September 2002 to December 31, 2003, the board received 68 applications for ethical review from various branches of Health Canada.

Of those applications: thirty-one were approved as submitted; twenty-six required certain conditions to be met or modified; four were deferred for additional information to be provided to the Board by the Principal Investigator; and seven were allowed to proceed without an ethical REB review.



PPHB	34
FNIHB	5
HECSB	15
HPFB	10
CSB	1
IACB	2
HPCB	1



A core component of the formalized ethics review process was the development of an REB meeting schedule. During 2002–2003, members of REB met monthly and in accordance with the group's workload to examine ethics-review applications. Applicants and investigators were invited to make brief presentations to the board, followed by question and answer sessions to assist members in their review.

The REB met eleven times at the following locations across Canada:

- Ottawa
- Edmonton
- Winnipeg

The meetings in Edmonton and Winnipeg provided opportunities for the REB to meet researchers in the regions and to gain a better understanding of the nation-wide range of Health Canada research activities and associated ethical issues.

Consultations and feedback from REB members

During 2003, the Research Ethics Board undertook a consultation exercise, in which it developed a survey to seek feedback from board members on the following areas: meetings, training, support, as well as priorities and impact of the REB. A copy of this report is attached as Appendix B).

All members completed the survey and the results overall were very positive. Board members were highly satisfied with their role and with the support provided by the REB Secretariat. In particular, the report cited satisfaction among members with protocol, preparations, and meetings conducted throughout the year, including the administrative support (e.g., travel arrangements and facilities).

The report also contended that members were satisfied with the training provided by the REB Secretariat in collaboration with the National Council on Ethics in Human Research (NCEHR) and that additional training opportunities were

appropriate. The board's approval process was credited for having an important, positive impact on research in the department.

The report also noted areas where there was some variability in responses. These included the geographic selection of meeting venues, training received to perform responsibilities, video conferencing support, and time devoted to policy development.

In addition to assessing the performance of the REB to date, the report also highlighted areas for growth within the REB, identified by its members:

- further training;
- service improvements;
- making policy development a priority; and
- improving the efficiency and effectiveness of the board.

Consultations and feedback from Health Canada researchers

Following the survey of REB members, an additional survey was undertaken to consult and obtain feedback from Health Canada researchers about their experiences working with the REB. A copy of this report is attached as Appendix C).

The response from the department was very impressive. Among researchers, 32 out of 40 questionnaires—80 percent—were completed by respondents. The REB was especially encouraged by the positive feedback from respondents concerning the following aspects of the ethics review process:

- the time it takes to receive information, documents and approval notification;
- services provided to researchers by the REB Secretariat;
- communication between the REB and researchers; and
- a perception that the process added value to a researcher's project.

The report also contended that researchers were interested in seeing improvements to the following aspects of the REB's work:

- providing clarification about documents and the ethics review process;
- enhancing perceptions within Health Canada of the overall value of receiving REB approval, especially in cases where such approval is being renewed; and

- exploring ways to speed up or streamline the approval process.

Additional areas for discussion were also identified. In particular, researchers called for:

- increased researcher attendance at orientation sessions and at short presentations conducted by the REB Secretariat;
- exploring suggestions by researchers for activities that could be undertaken to help them better understand research ethics issues; and
- reviewing researchers' suggestions for general improvements to the ethics review process.

The feedback received in this survey has been especially helpful to the REB and the recommendations in the summary report are being considered as the board undertakes its work for 2004.

Training and orientation opportunities provided

To assist with the orientation of the REB members and Health Canada researchers in the early months following the inception of the group, and later to assist board members in carrying out their work, the REB Secretariat developed a host training and orientation services. These were important achievements for the REB and for Health Canada: the first-ever research ethics educational programs undertaken within the department.

In October 2002, in collaboration with the National Council on Ethics in Human Research (NCEHR), the REB Secretariat began orientation sessions for Health Canada staff and managers. The session agenda included a broad scope of presentations:

- a history of research ethics;
- a review of violations, landmark cases, and codes of ethics;
- an introduction to the *TCPS*;
- an overview of the *Privacy Act* and of the collection and secondary use of personal information; and
- an examination of procedures for obtaining an ethical review by the REB.

A total of 72 participants attended sessions that took place at the following venues and dates:

- Ottawa (October 2002)

- Ottawa (March 17 and 18);
- Winnipeg (March 20);
- Vancouver (March 21); and
- Edmonton (June 13).

Session evaluation sheets were reviewed, and initial feedback suggests that the sessions are well received and appreciated by participants. Additional orientation sessions are being arranged to be held in Ottawa and at regional offices to increase awareness within Health Canada about research ethics issues. These sessions are also available to specific groups, upon request.

Procedural documents and key reference material developed

To support the Research Ethics Board in its work, the REB Secretariat developed various support and reference documents during 2002–2003. Key among theses were:

- Reference and guideline materials;
- criteria for expedited review;
- application forms for full and expedited review; and
- consent, assent, annual renewal, adverse-event reporting, and amendment request forms.

To support the REB with ample reference and guideline material, the REB Secretariat developed two key documents:

- the *REB Policies and Procedures Manual*—provides direction to Health Canada researchers who are doing research involving humans. It contains the forms that researchers must complete for all stages of an ethics review; and
- the *REB Operational Guidelines*—provides the rules under which the REB operates and reflects the standards established by the *TCPS*.

Reflecting the continually evolving nature of research ethics, these two publications are considered living documents—subject to ongoing revisions and review by the REB Secretariat.

Other key accomplishments

Other key accomplishments of the REB during 2002–2003 included:

- a Ph.D. student, Rodney Schmaltz of the University of Alberta, was hired for two months to assist the REB Secretariat. Mr. Schmaltz developed a procedure for dealing with time-sensitive reviews, which was adopted by the board;

- the REB members also participated in a joint dinner with Health Canada's Science Advisory Board;

- guest speakers were invited to REB meetings to give presentations on a host of topics. These speakers were: Dr. John Last of the University of Ottawa, and Dr. Francis Rolliston of the National Research Council's Research Ethics Board;

- branches of Health Canada were invited to give presentations to the REB describing their work and questions about REB reviews;

- training session was offered for REB members on September 17 and 18, 2002 with such key speakers as Mr. Pitseolak Pfeifer of the Nunavut Tunnqavik Inc., Dr. Connie Nelson of Lakehead University, Dr. Micheal Enzle of the University of Alberta, Dr. Paddi O'Hara of Saint Vincent Pavilion, Ms. Inieke Neutel of the University of Ottawa and Mr. David Wiwchar of the Nuu-chah-nulth Tribal Council; and

- representatives from other federal departments attended REB training sessions to learn about how an ethics review is carried out.

Looking ahead

Just as the Health Canada's REB can look back with pride at its record of achievement in 2002–2003, the members and its Secretariat are looking forward to 2004 and beyond with much anticipation. Having worked hard to ensure that the fundamentals were in place for a formalized research ethics review process at Health Canada, the REB Secretariat is now poised to refine the board's review processes and ensure that the learning tools its members need remain relevant and effective.

Key activities planned for 2004 include:

- revising the *REB Operational Guidelines* and the *REB Policies and Procedures Manual* ;

- developing a research ethics review appeal process and designing a compliance plan to ensure that all human-based research at Health Canada is subject to REB review;

- identifying a roster of alternate REB members, and recommending their appointment to the board by the Deputy Minister of Health Canada;

- sustaining ongoing work with the NCEHR to provide training to Health Canada researchers and managers;

- continuing to provide presentations on the REB to groups within Health Canada;

- ensuring ongoing training of REB members to ensure they remain current on the latest issues concerning research ethics within Health Canada and in the broader science and research communities;

- developing an REB website;

- investigating options for allowing researchers to submit electronically their research ethics applications; and

- participating in Health Canada committees in such areas as privacy and REB governance.

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Appendix A
Research Ethics Board guiding principles

Health Canada's Research Ethics Board (REB) follows the ethical principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. These principles have been widely adopted by diverse research disciplines and express common standards, values as well as aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics. This principle aspires to protect the multiple and interdependent interests of the person—from bodily to psychological to cultural integrity. In certain situations, conflicts may arise from application of these principles in isolation from one other. Researchers and the REB must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons—to those whose diminished competence and or decision-making capacity make them vulnerable. Children, institutionalized persons or others are entitled—on grounds of dignity, caring, solidarity and fairness—to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. Such standards help to protect mental or psychological integrity and are consonant with values underlying privacy, confidentiality and anonymity.

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process has fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. Yet distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance—that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities and the principle of respect for human dignity impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-malfeasance, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

Appendix B
Health Canada Research Ethics Board Board Survey 2004

Appendix C
Health Canada Research Ethics Board Researcher Survey 2004