Health Canada's Research Ethics Board

Annual Report 2007-2008

Continuing to build a culture of research ethics

June 2008

Canada

ABOUT HEALTH CANADA

Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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ABOUT THIS REPORT

This Annual Report of Health Canada's Research Ethics Board (REB) covers the fiscal year 2007–2008 and includes plans for 2008–2009. It is published as part of the Office of the Chief Scientist's ongoing efforts to inform senior decision-makers, the science regulatory and policy communities within Health Canada, PHAC and other partners and stakeholders about the work of the REB.

This report describes the mandate of the REB, key results achieved and also the activities of the REB Secretariat in the Office of the Chief Scientist, Health Policy Branch of Health Canada. Also featured in this report is a summary of the REB's role, future goals, and profile of members of the Board.

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MESSAGE FROM THE CHAIR

I am pleased to introduce to you the Health Canada Research Ethics Board's Annual Report for fiscal year 2007–2008.

This report marks a further year of progress in achieving the Board's mandate. It also recognizes the growing role of ethical reflection, analysis and observance in the research cultures among investigators and others working in Health Canada and the Public Health Agency of Canada (PHAC).

A gratifying feature of the past year has been the more profound ability within the Board to address some of the more distinctive ethical issues presented by research with human population groups, and of contributions to the Board's capacity due to its expanding familiarity with public health studies. The Board has also grown through its appreciated collaboration with the National Council on Ethics in Human Research (NCEHR), including hosting a site visit by a distinguished review team from NCEHR.

During the fiscal year in review of this report, there were new advances in ethical insight and sensitivity and these were taken into account by investigators from both Health Canada and the PHAC when preparing and presenting their research proposals to the Board. The year also witnessed how some ongoing projects that had initially come to the Board as research, subject to at least annual reporting, review and renewed approval, have achieved the transition out of research into routine practice that has proven effective and valuable.

Members of the Board are, as ever, grateful for the comprehensive, facilitative support provided by Health Canada's Office of the Chief Scientist and its excellent REB Secretariat.

The forthcoming fiscal year 2008-2009 will be a year of transition, both in terms of the position of the Office of the Chief Scientist within Health Canada, and as well as in terms of the membership and Alternate Membership of the Board.

I have greatly enjoyed the privilege, opportunity and friendship of working with Members and Alternate Members of the Board since its founding in 2002 and with its admirably accomplished Secretariat.

As of July 2008, Professor Janet Storch will assume the REB Chair. I am proud of what the REB has achieved since 2002, and anticipate the Board's continuing advance under the experienced leadership, vision and wisdom that Professor Storch will bring.

Bernard M. Dickens
Chair, Health Canada Research Ethics Board

HOW HEALTH CANADA'S RESEARCH ETHICS BOARD WORKS

Health Canada's Research Ethics Board (REB) was founded in 2002 by the Deputy Minister of Health Canada as an independent advisory body that helps ensure that all research involving human subjects carried out or funded by the department and/or by the Public Health Agency of Canada (PHAC) meets the highest scientific and ethical standards. Equally important, the REB helps ensure that safeguards are developed to protect participants who serve as subjects in research of this nature.

Guiding Principles

The REB's guiding principles are based on the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) authored by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada. The TCPS states that professional responsibility in science must be accompanied by an accountable, effective and efficient ethics review process. The TCPS's guiding principles can be found under Appendix A in this report.

Authorities

Empowering Authority

The Deputy Minister of Health Canada empowered the REB to assure its legitimacy within Health Canada, while ensuring its independence. The Deputy Minister is not directly responsible for setting research priorities, developing research protocols nor with funding decisions linked to the research. The REB's independence is further strengthened by ensuring that the Board's terms of reference, membership and operating procedures are made public.

Reporting Authority

Under a Delegation of Authority Order, the Deputy Minister of Health Canada delegated his reporting authority functions to the Chief Scientist of Health Canada, who is referred to as the Reporting Authority throughout this document.

Authority of the REB

The REB recommends to the Reporting Authority on whether to approve, reject, modify or terminate any proposed or ongoing research involving humans, conducted by or on behalf of the department and/or PHAC. The REB reviews applications of proposed research projects in accordance with the considerations set forth in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (*TCPS*) as the minimum standard.

Scope of the REB

The scope of activities of the REB involves reviewing all research involving human subjects that are:

- Intramural studies (i.e., occurring within the limits of Health Canada/PHAC);
- Carried out at Health Canada/PHAC involving technical or consultation support, including equipment, laboratories or other facilities;
- Undertaken in collaboration or partnership between Health Canada/PHAC and external researchers;
- Funded by Health Canada/PHAC grants and contributions; and/or
- Conducted under contract with Health Canada/PHAC.

Fulfilling a Mission

Since its inception in 2002, the REB has made steady progress in fulfilling its mission. In doing so, it has helped to ensure that the research ethics culture within Health Canada and PHAC continues to flourish and grow. This is very important to Health Canada and PHAC as federal organizations that base their decisions and policies on sound and ethical science.

In fiscal year 2007-2008, the REB reported directly to the Reporting Authority of Health Canada and made recommendations on the ethical reviews of proposed research projects undertaken by the members of the REB. The Board is supported by an REB Secretariat located within the Office of the Chief Scientist in the Health Policy Branch of Health Canada.

The REB considers Health Canada/PHAC research to be ethically sound when:

- The potential benefits of the research project significantly outweighed the potential for harm or other risks;
- The research projects are scientifically sound;
- There are adequate processes for informed consent and—where applicable—an assent to participate in the research; and
- The selection of participants is fair.

REB MEMBERSHIP

The REB membership structure is designed to meet the requirements of the TCPS and to ensure the expertise and independence essential for competent research ethics reviews by the Board.

Full Membership

Currently, the REB membership consists of eight expert representatives:

- One member with expertise in law,
- Two members with expertise in bioethics,
- A researcher from outside the department,
- A researcher from within Health Canada,
- A researcher from PHAC,
- Two members representing the community at large.

Together, these members ensure that Health Canada/PHAC applies a consistent approach to ethics reviews of research involving human subjects. Members were appointed by the Associate Deputy Minister of Health Canada.

Alternate Membership

The *TCPS* provides that institutions should also consider the nomination of substitute REB members so that the REB is not hindered by illness or other unforeseen circumstances. The use of alternate members is not to alter the membership structure as outlined in the *TCPS*.

The REB membership includes alternate members comprised of:

- One member with expertise in law;
- An ethicist;
- A researcher from outside the department;
- A researcher from Health Canada;
- A researcher from PHAC; and
- One member representing the community at large.

Alternate members ensure that the REB always has the adequate expertise to hold an ethical review and uphold the ethical guidelines elaborated in the *TCPS*. The Board's current alternate members were appointed by the Associate Deputy Minister and will hold tenure with the REB for three years.

Revised Membership Structure

Given the increasing number of research protocols involving subjects from Aboriginal communities, and in light of Health Canada's responsibilities regarding First Nations and Inuit people, the Office of the Chief Scientist recommended to the Associate Deputy Minister of Health Canada to designate one of the two existing community representative positions on the REB specifically for Canada's Aboriginal communities. Furthermore, the Office of the Chief Scientist recommended that a new alternate member position be created to represent Aboriginal communities.

The Associate Deputy Minister of Health Canada agreed with these recommendations and in March 2008, appointed two individuals representing Aboriginal communities —one as a full member to the REB and another as an alternate member.

These revisions to the REB membership structure will improve the Board's ability to ensure that a representative of Canada's Aboriginal communities can participate in deliberations on protocols involving Aboriginal subjects.

Appointment of REB Members

With the scheduled tenure of certain REB members coming to a close in 2008, the Office of the Chief Scientist, as per usual practice, consulted with the REB Chair, other REB members and the National Council on Ethics in Human Research to identify suitable replacement candidates:

- **Full members—**a researcher from outside the Department, a researcher from PHAC, two ethicists and a legal expert; and
- **Alternate members—**a researcher from PHAC, an ethicist, a legal expert and two community representatives (i.e., Aboriginal and general population).

On March 25, 2008, the Office of the Chief Scientist recommended to the Associate Deputy Minister of Health Canada the appointment of new members, all of whom were subsequently nominated to the Health Canada REB. A listing of the revised Health Canada REB membership can be found under Appendix B in this report.

Responsibilities of REB Members

The REB is responsible for advising and making recommendations to the Reporting Authority at Health Canada on policies and procedures to be established or modified, ensuring that all research involving human subjects was carried out in a manner consistent with the highest ethical standards. The REB members monitor actively compliance by researchers to the Board's policies and procedures, the *TCPS*, federal and provincial regulations, and all other applicable guidelines.

The REB is responsible for:

- Reviewing research projects involving human subjects in a manner consistent with the TCPS, and/or the REB Policy and Procedures;
- Meeting face-to-face on a monthly basis, with the exception of July and August;
- Conducting the continuing review of ongoing research projects;
- Reporting promptly the suspension or termination of approval of a research project to the Principal Investigator (and to other institutional officials as deemed appropriate by the REB), providing a statement of the reasons for the action taken; and
- Reporting on REB activities to the Reporting Authority of Health Canada.

The REB members are responsible for reporting to the REB Chair any real, potential or apparent conflict of interest they may have before the beginning of the ethics review. In such circumstances, the member recuses himself/herself from the review, if deemed necessary by the Chair.

REB OPERATIONS

Face-to-face meetings are essential for adequate discussion of research proposals, and for the collective education of the REB members. The REB Secretariat posts on its website a schedule of upcoming meetings so that researchers can plan their schedules accordingly. Quorum for a Board meeting requires that five of eight members be in attendance. Recommendations requiring full review are adopted only if the members attending the meeting possess the range of background and expertise required by the *TCPS*.

During fiscal year 2007–2008, alternate members were asked to attend meetings to ensure that the required range of background and expertise were met. Furthermore, REB meetings were planned in accordance with the workload of its members and took place on a monthly basis with a pause during the summer. REB members were given notice two weeks in advance of a meeting to review the application documents. Minutes of meetings were produced and approved by the REB. The minutes of the discussions and the record of recommendations taken at REB meetings have been maintained in a confidential manner.

Ethical Review Process 2007-2008

During fiscal year 2007–2008, all research projects involving human subjects carried out for or by Health Canada/PHAC were subject to an ethical review by the Health Canada REB.

The REB undertook a review of each proposed research projects submitted to the REB Secretariat and provided one of the following recommendations to the Reporting Authority of Health Canada:

- approved as submitted;
- approved with minor modifications; and/or
- proposed modifications to the proposed research project.

Reporting of REB Ethical Decisions

As per the REB Policy and Procedures, the REB recommendations are communicated to the Principal Investigators by the Reporting Authority of Health Canada within 10 days of the meeting at which a decision was reached. When additional information is required from the Principal Investigator to conclude the ethics review of their application, a summary of the decision is communicated to the Principal Investigator by the REB Secretariat within five days of the meeting.

Health Canada/PHAC researchers were asked to attend REB meetings to participate in the discussion and review of their proposed research projects, but were not present when the REB made its final recommendation. When considering a recommendation to modify or reject a research project, the REB provided the researcher with written reasons for doing so, and gave the researcher an opportunity to reply before rendering its final recommendation.

The REB had ten face-to-face meetings in 2007–2008, during which the members:

- Undertook a timely review of all research protocols
- Reconsidered recommendations affecting a research project when requested by researchers; and
- Offered clear suggestions for revisions as well as a procedure for having an application reviewed again in cases of conditional recommendations.

KEY INDICATORS AT A GLANCE

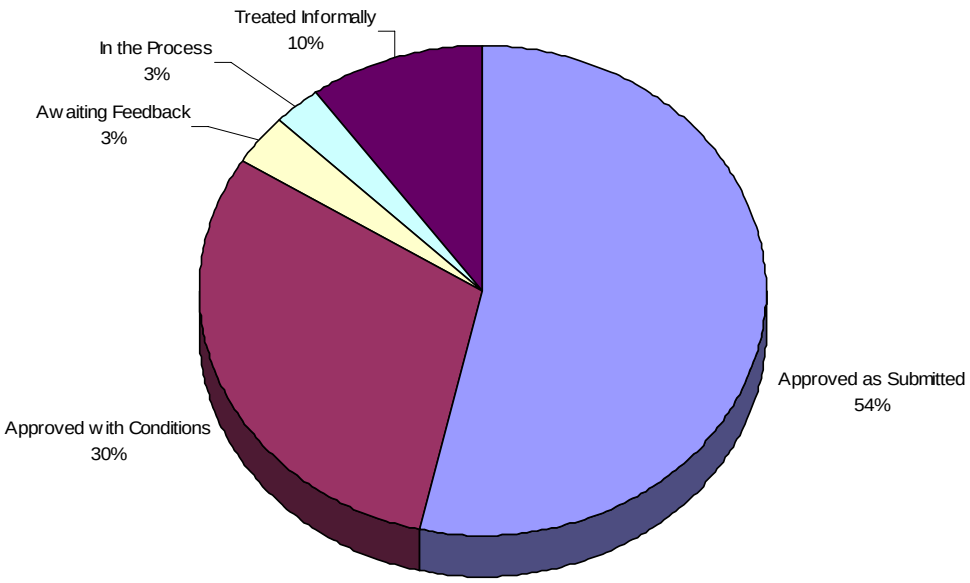
During fiscal year 2007–2008, the REB received 149 applications from researchers from Health Canada and from PHAC for an ethical review by the members of the REB. Of these applications, the Board reviewed: 44 new research proposals; 27 amendment reports; 78 annual progress reports; and 43 completion reports.

Of the 44 new research proposals received by the REB, 50% representing 22 applications were considered as requiring an expedited review by the Chair of the REB. All other research projects received a full ethical review by the REB.

As illustrated in Figure 1, of those 149 applications received by the REB in 2007–2008:

- 80 (54%) applications were approved as submitted;
- 45 (30%) applications were approved once certain REB-mandated conditions or changes had been satisfied;
- 5 (3%) applications remained outstanding pending additional information to be provided to the REB by the Principal Investigators;
- 4 (3%) applications remained outstanding pending a response from the REB; and
- 15 (10%) applications were considered by the REB Chair or REB Secretariat as not requiring an ethical review.

Figure 1: Action Taken by REB on Applications for Ethics Review



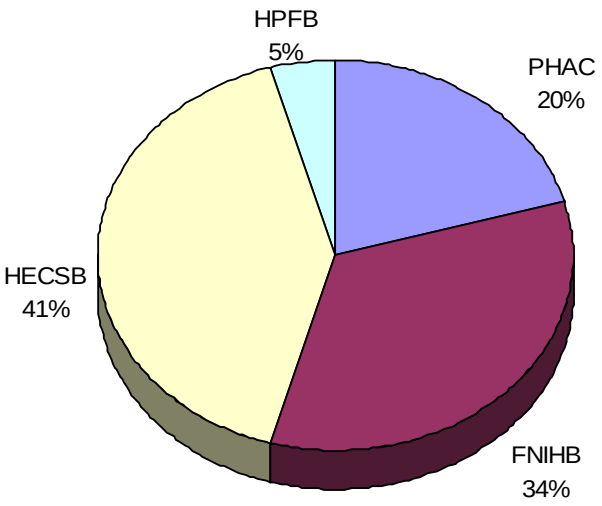
As illustrated in Figure 2 (below), of the 44 new research projects received by the REB Secretariat during fiscal year 2007–2008:

- 9 requests applications were from PHAC; and
- 35 requests were from Health Canada.

Of these 35 new research projects received from Health Canada researchers:

- 15 requests were from the First Nations and Inuit Health Branch (FNIHB);
- 18 requests were from Healthy Environments and Consumer Safety Branch (HECSB); and
- 2 requests were from the Health Products and Food Branch (HPFB).

Figure 2: Origins of Requests for Ethics Review



FEEDBACK FROM RESEARCHERS

Praxis Survey

The REB Secretariat contracted Praxis Research Inc. in 2007 to undertake an independent survey of all researchers that had an ethical review of a research project undertaken by the REB during the fiscal year 2007–2008. The researchers were requested to comment on the efficiency and effectiveness of the Board, of the research ethics review processes and of the performance of the REB Secretariat in providing guidance and timely service. The response rate of the survey administered online to the researchers was higher (50.6%) than the previous fiscal year, and the feedback received was quite positive.

The Praxis Report can be viewed under *Appendix C – Health Canada Research Ethics Board Researcher Survey 2007–08*.

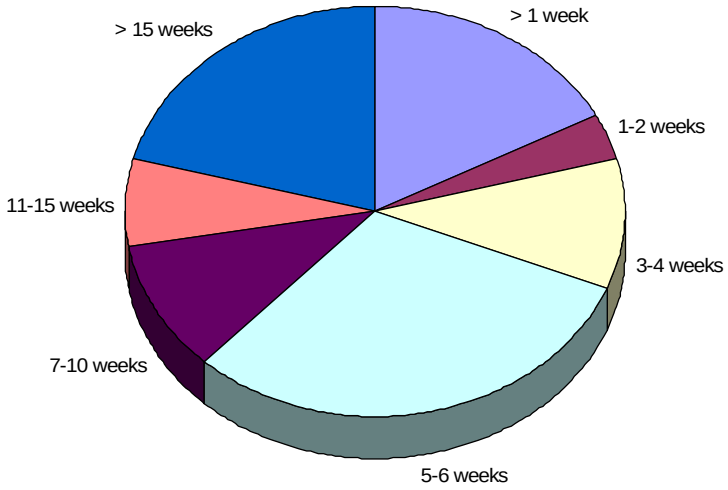
Seventy percent or more of the respondents indicated in the survey that they were satisfied or agreed with the following:

- The process of preparing a REB application—the clarity or the thoroughness of the electronic resources (78%) and of the printed resources (72.5%) produced by the REB Secretariat;
- The amount of time required to perform steps involved in the REB process—time required to obtain application forms (78.4%), notification of additional requirements (71.4%), supporting documents (76.5%), and reply to questions about the application (81.1%);
- Support from the REB Secretariat—being accessible (97.6%), being helpful in answering questions and providing clarifications (97.6%), and accommodating requests for time-sensitive reviews (89.5%);
- Time consideration—that the REB review gave adequate time to discuss a given application during its meeting (97.3%), communicated its decisions in a timely manner (90.2%), communicated its decisions in a clear manner (95.1%) and accommodated time sensitive reviews (80.6%);
- The perceived value of the ethics approval process—that this process was necessary to publish their research (92.8%), and that it raised level of awareness about ethical issues (73.1%); and
- The overall satisfaction with the review process (75.7%).

As illustrated in Figure 3, the responses received from the respondents indicate that:

- 11.9% indicated their application was approved in less than 1 week;
- 2.4% indicated within 1 to 2 weeks;
- 7.1% indicated within 3 to 4 weeks;
- 21.4% indicated within 5 to 6 weeks;
- 7.1% indicated within 7 to 10 weeks;
- 4.8% indicated within 11 to 15 weeks;
- 14.3% in more than 15 weeks; and
- 31% did not respond to this question.

Figure 3: REB Performance and Response Time



Additional Feedback from Researchers

During fiscal year 2007–2008, the REB Secretariat received numerous emails from researchers within Health Canada and PHAC, in which they expressed their gratitude for the support and assistance provided by the REB Secretariat in the preparation of their applications to obtain an ethical review by the Board.

REB TRAINING ACTIVITIES & ORIENTATION SEMINARS

The REB Secretariat undertook training sessions for researchers and managers at Health Canada and PHAC to raise awareness about research-ethics related issues faced by both organizations. In collaboration with the National Council on Ethics in Human Research, two orientation seminars were organized in the spring of 2008 for Health Canada and PHAC researchers and managers.

Ongoing Communications

As part of its support to researchers, the REB Secretariat maintains the REB website at Health Canada, which includes:

- A list of ethics resources;
- Application forms, consent and assent templates;
- Policies and procedures, consent requirements procedures;
- Biographies of all the REB members; and
- REB annual reports.

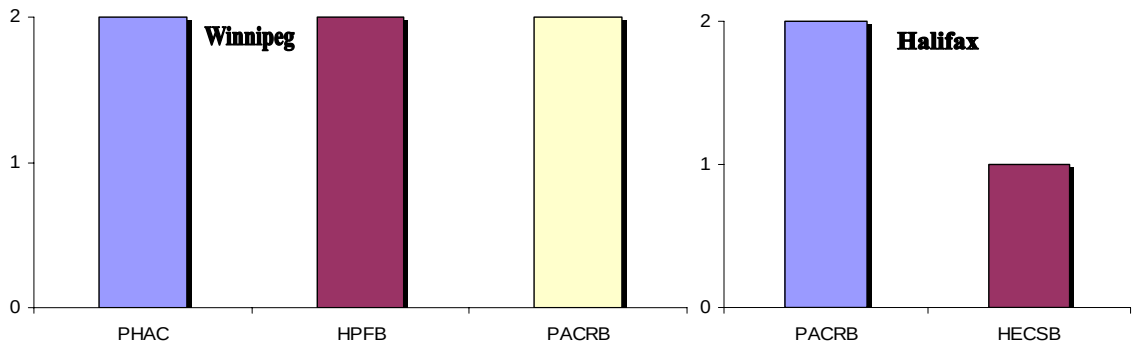
The session agendas included presentations on:

- A review of landmark cases and codes of ethics;
- An introduction to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*; and
- The policy and procedures for obtaining an ethics review by the Health Canada REB.

A total of nine participants attended these sessions, which were held in Winnipeg (six participants), and in Halifax (three participants). In Winnipeg, two participants were from PHAC, two were from the Health Products and Food Branch (HPFB), and two were from the Public Affairs, Consultation and Regions Branch (PACRB). In Halifax, Nova Scotia, two participants were from PACRB and one participant was from Healthy Environments and Consumer Safety Branch (HECSB).

Figure 4 provides a breakdown by branch of employees who attended these sessions. Some participants were responsible for advising other colleagues in their organizations which led to a multiplier effect.

Figure 4: Breakdown by Branch of Attendance at REB Information Sessions in 2008



National Council on Ethics in Human Research Site Visit

In January 16, 2008, the National Council on Ethics in Human Research (NCEHR) Site Visitors met with the Director of the Health Research Secretariat and the A/Manager of the REB Secretariat to obtain an overview of the operational structure of the Research Ethics Board and of the reporting relationship with Health Canada. On January 17, 2008, the NCEHR Site Visitors met with the REB members while attending the scheduled January REB meeting.

The objectives of the NCEHR site visit to the Health Canada REB were to:

- discuss the process of ethics review with the responsible people, and to identify and exchange information on relevant issues with them;
- identify issues of concern in the policy area of research ethics review;
- identify administrative issues related to research review;
- identify and discuss issues related to the implementation of policies and guidelines, including the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, the Good Clinical practice Guidelines, and international guidelines; and
- identify means by which the quality of ethics review and participant protection may be enhanced.

In 2008, a preliminary report from the NCEHR's Evaluation Team was received by the REB Secretariat, which highlighted different perceived strengths of the Board's ethical review process, such as its strong commitment to human research ethics, the recognized expertise of the REB members and the knowledgeable support from the REB Secretariat to the researchers.

The Evaluation Team was, however, concerned with certain aspects of the REB's ethical review process concerning conflicts of interest, U.S. Federal Wide Assurance and criteria for expedited reviews. The preliminary report was provided to the REB members who indicated that this report would be very helpful in assisting the members and the REB Secretariat in making some modifications to the existing REB policies and procedures.

A final report from the NCEHR's Evaluation Team is expected in the summer of 2008.

MEETING ANNUAL GOALS FOR 2007–2008

As illustrated in the table below, the REB Secretariat in Health Canada's Office of the Chief Scientist, Health Policy Branch has been diligent in setting and meeting goals for itself during the fiscal year 2007–2008.

Results and Actions Taken by the REB Secretariat to Obtain Goals Set Out for Fiscal Year 2007–2008

Goals	Results
Continue to refine REB policies and procedures manual.	Since research ethics is a continually evolving subject, this manual may be modified from time to time. The REB Secretariat was responsible for maintaining up-to-date REB policies and procedures.
Manage and provide Secretariat services to the REB.	The REB Secretariat has managed the operational component of the REB and provided an excellent service to the REB members in meeting their goals.
Organize the REB's meetings and manage all applications submitted for an ethical review.	Managed 10 meetings during the fiscal year in an efficient and effective manner to the satisfaction of the REB and reviewed all applications requiring an ethical review by the REB.
Deal with all communications regarding individual applications.	Communicated the results of the ethical review to all investigators in an efficient and timely manner to the satisfaction of the researchers.
Promote the Canadian Institutes of Health Research Aboriginal Guidelines and ensure compliance to these Guidelines on all research involving Aboriginal people.	An educational session for the REB members was organized and key-speakers were invited to brief the members on the new Aboriginal guidelines.

Sustain ongoing work with the National Council on Ethics in Human Research (NCEHR) to provide training to Health Canada/PHAC's researchers and managers in 2007–2008, including in other regions and the National Capital Region.	REB Secretariat in consultation with NCEHR provided two orientation seminars, one in Winnipeg and another in Halifax.
Continue to participate in Health Canada and external committees and events on matters including privacy and REB governance and accreditation.	REB Secretariat continues to participate in Health Canada and external committees and events to obtain and exchange information on privacy, governance and accreditation.
Continue efforts to update the skills of all REB members and the REB Secretariat staff by arranging for them to attend conferences hosted by the National Council on Ethics in Human Research and the Canadian Association of Research Ethics Boards.	Provided opportunities for the REB members to attend the 2008 NCEHR Conference that was held in Ottawa and the CAREB Seminar held in Toronto to maintain a specialized knowledge of the ethics processes.
Develop a policy to address and resolve conflicts of interest with emphasis on the impact on the REB, its operations and the relationship with Health Canada.	Developed a conflict of interest policy and the processes will be incorporated within the REB Policy and Procedures Manual.
Work with PHAC to conclude a formal, multi-year agreement on ethics reviews of selected PHAC research.	The Memorandum of Understanding between PHAC and Health Canada was concluded for the provision of REB services in 2007–2008.

Provide early information on the development of a policy on scientific integrity within Health Canada.	The REB Secretariat provided information to the Health Research Secretariat in the Office of the Chief Scientist. The Health Canada Scientific Integrity Working Group was established to develop a scientific integrity policy framework that should address all scientific activities in the Department. The report from the Working Group is to be submitted to the Senior Management Board for approval in December 2008.
Revise the REB Policies and Procedures Manual to address compliance issues with the United States Federal-wide Assurance Program.	Revised the REB Policy and Procedures Manual and circulated this Manual to the REB members for their review and approval.
Providing First Nations research expertise to the REB.	Research protocols were reviewed and approved by the REB members.

LOOKING AHEAD FOR 2008–2009

During fiscal year 2007-2008, the REB and the REB Secretariat worked hard to establish and refine ethics review processes and raise awareness within Health Canada and PHAC about research ethics issues. Looking ahead to fiscal year 2008-2009, the Board will continue to provide an essential service to Health Canada/PHAC researchers to ensure compliance with the highest level of ethical standards. The Board will provide support to Health Canada and PHAC as a leading science-based department and agency, respectively.

The REB Secretariat also has ambitious plans for fiscal year 2008–2009. It will:

- continue to refine REB procedure and guidelines;
- manage and provide Secretariat services to the REB;
- Organize the REB's meetings and manage all applications submitted for an ethical review;

- deal with all communications regarding individual applications;
- investigate options for allowing researchers to submit electronically their research ethics applications;
- continue to participate in Health Canada and external committees and events on matters including privacy and REB governance and accreditation;
- sustain ongoing work with the National Council on Ethics in Human Research to provide training to Health Canada/PHAC's researchers and managers in 2008–2009, including in other regions and the National Capital Region;
- sustain efforts to update the skills of all REB members and the REB Secretariat staff by arranging for them to attend conferences hosted by the National Council on Ethics in Human Research and the Canadian Association of Research Ethics Boards;
- develop a policy to address and resolve conflicts of interest for researchers in relationship with Health Canada and the REB;
- work with PHAC to conclude a formal, multi-year agreement on ethics reviews of selected PHAC research;
- continue to revise the REB Policies and Procedures Manual to address compliance issue with the Federalwide Assurance;
- elaborate a policy on research with vulnerable persons;
- update of the REB Network for REB members; and
- develop a Compliance Officer position within the REB Secretariat for monitoring research protocols approved by the REB.

RECOGNITION OF REB WORK

The Health Canada Research Ethics Board and its Secretariat would like to make reference to a number of individuals that it had the pleasure of working with during the past few years.

Departures from the REB

Michael B. Coulthart, Ph.D. –Prior to joining Health Canada's Laboratory Centre for Disease Control in 1995 as a research scientist in microbial population genetics, Dr. Coulthart completed doctoral and postdoctoral work in molecular population genetics and evolution at McMaster University, Dalhousie University (Canadian Institute for Advanced Research), and the John P. Roberts Research Institute. In 1998, he was appointed by Health Canada to found and direct Canada's first federal reference laboratory for human prion diseases—providing laboratory reference services and research into Creutzfeldt-Jakob Disease. Dr. Coulthart is currently Director of the Host Genetics and Prion Diseases Program at the Public Health Agency of Canada, and is the Senior Advisor for Public Health in a Canadian Network of Centres of Excellence for research on prion diseases (PrioNet Canada). He is the author of more than 30 publications on molecular genetics, population genetics and evolution. His technical expertise lies in analytical biochemistry, molecular genetics and bioinformatics. Due to other career opportunities, Dr. Coulthart resigned from the REB during fiscal year 2007–2008.

Don Willison, M.Sc., Sc.D. –Dr. Willison combines training in pharmacy, (University of Toronto, 1977), clinical Epidemiology and Biostatistics (M.Sc., McMaster University, 1984), and health policy and health services research (Sc.D., Harvard School of Public Health, 1996). His current research interests include: pharmaceutical policy, and data privacy issues in health services research. In the area of pharmaceutical policy, Dr. Willison's research has focussed on how Western industrial countries are balancing the pharmaceutical cost-containment with access to needed medications and their interest in attracting or maintaining pharmaceutical R&D in their countries. His research also examines challenges associated with the patenting of genetic material, and the impact of policies that restrict reimbursement for coxib non-steroidal anti-inflammatory drugs. Regarding data privacy, Dr. Willison's research has focussed on variation in

how research ethics boards address privacy, confidentiality and security issues when reviewing research involving secondary use of personal information. His research also looks at public opinion about consent to the secondary use of personal information for health research, as well as the development and evaluation of a consent-based patient registry. Due to new career opportunities, Dr. Willison left the REB in September 2007.

Tom Wong, MD, MPH, FRCPC –Dr. Wong is the Director of Community Acquired Infections Division within the Public Health Agency of 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 clinical medicine and public health, including authorship of various journal publications. He has dual academic appointments at the University of Ottawa's Department of Medicine (Division of Infectious Diseases), and 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, Co-chair of both the Emerging Infectious Disease Research Network, and the Canadian Sexually-Transmitted Infections Expert Working Group. After finishing his second term as a researcher from PHAC, Dr. Wong left the REB in January 2008.

Departure from the REB Secretariat

Glennis Lewis, Ph.D., LL.M. –Dr. Lewis has both a Masters degree in Law and a Ph.D. in biological sciences and has worked at Health Canada since 1999 on diverse projects, including revisions to the *Quarantine Act*. Dr. Lewis also represented Health Canada in the international negotiation of the Cartagena Protocol on Biosafety. In 2002, she was awarded a Queen's Jubilee medal for her contributions to the federal public service. On May 9, 2007, Dr. Lewis left the Office of the Chief Scientist on an assignment to join the Public Health Agency of Canada. In March 2008, Dr. Lewis accepted a position with the Public Health Law and Ethics within the Public Health Agency of Canada's Office of Public Health Practice.

Memorial Dedication

Michael Enzle, B.A., Ph.D. –Dr. Enzle was a member of the Health Canada Research Ethics Board from 2002 to 2007. Dr. Enzle passed away September 26, 2007 at the Edmonton General Hospital from a brain tumour diagnosed in October 2006. Dr. Enzle, a dedicated teacher and mentor, served as a faculty member in the Department of Psychology at the University of Alberta for 30 years, where his academic research focused on voluntary consent, privacy issues and power relationships. In 2004, he was appointed full-time Director of the University's newly created Human Research Protections Office. Dr. Enzle contributed to the development and implementation of research ethics boards on campus as well as the University Committee on Human Research Ethics. He chaired the Education Committee of the National Council on Ethics in Human Research and the Society for Experimental Social Psychology.

Arthur Kroeger, BA –Mr. Kroeger passed away on May 9, 2008, at the Élisabeth Bruyère Health Centre in Ottawa with his family by his side. In June 2007, Mr. Kroeger was invited as a guess speaker to an REB event to discuss the report from the Experts Committee for Human Research Participant Protection in Canada. Mr. Kroeger was the Chair of this Committee and a Chancellor Emeritus at Carleton University. In 1989, he has been made an Officer of the Order of Canada and in 2000, a Companion of the Order of Canada. Mr. Kroeger has also written a non-fiction book, *Hard Passage*, describing the history of his Mennonite family for three generations.

Acknowledgements

The Health Canada Research Ethics Board and its Secretariat would like to thank the following individuals who provided their expertise to the REB members during the past fiscal year:

Burleigh Trevor-Deutsch, Ph.D., LL.B., M.Phil. –On June 21, 2007, Dr. Trevor-Deutsch attended a meeting of the REB and provided a presentation entitled *CIHR Guidelines for Health Research Involving Aboriginal People*. The REB would like to thank him for his help and participation on the subject. Dr. Trevor-Deutsch is a bioethicist in private practice in Ottawa and

an advisor to the World Health Organization. He also chairs the Bayer Advisory Council on Bioethics and is an Adjunct Professor in the Faculty of Medicine of the University of Ottawa.

Ms. Jane Gray of the Assembly of First Nations (AFN) –Ms. Gray made a presentation to the REB at an REB meeting on March 13, 2008. She provided an overview of the responsibilities of the AFN as the national organization representing First Nations citizens in Canada. The AFN represents all citizens regardless of age, gender or place of residence.

APPENDIX A

MEMBERSHIP OF HEALTH CANADA'S RESEARCH ETHICS BOARD

1. Full-Time Members:

Chair

Bernard Dickens, O.C., Ph.D., LL.D., F.R.S.C.—Dr. Dickens, in addition to serving as Chairperson of the Research Ethics Board, is the University of Toronto's Professor Emeritus 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 400 publications, including books, book chapters, articles and encyclopaedia contributions, primarily in the field of medical and health law. 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, and Officer of the Order of Canada in 2006.

Researcher External to Health Canada

Barbara McGillivray, MD, FRCPC, FCCMG—Dr. McGillivray is a professor and clinical geneticist in the Department of Medical Genetics at the University of British Columbia. Dr. McGillivray's research interests include inherited cancers (breast, ovarian and colon cancer), clinical genetics, and prenatal diagnosis. She has been involved for many years in the field of ethics of research involving humans. She was a member of the Tri-Council Working Group for the Code of Ethical Conduct for Research Involving Humans, a member of the Standing Committee on Ethics of Medical Research Council and the Canadian Institutes of Health Research (CIHR). She is also an experienced REB Chair, and has been on both biomedical and social science REBs. Dr. McGillivray was a council member of National Council on Ethics in Human Research for several years, and continues as a member of the Evaluation Committee. She

has participated in many site visits to evaluate research ethics boards and most recently, in a series of visits to evaluate the CIHR Guidelines for Health Research involving Aboriginal Peoples.

Health Canada Researcher

Agnes Klein, MD, DPH—Dr. Klein is the Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products in Health Canada's Biologics and Genetic Therapies Directorate (BGTD). Dr. Klein received her medical degree from the University of Toronto, and trained in Endocrinology, Medical Biochemistry and Public and Community Health. She joined Health Canada and the Drugs Directorate in late 1974 and has occupied many and varied scientific and management positions within the department and its regulatory arms, including having acted as the Director of the Bureau of Human Prescription Drugs and as Director for the Biologics and Genetic Therapies Evaluation Centre. From 2001 to 2004, she was the Manager (Clinical Evaluation Division) of a newly created division responsible for Clinical Trial Application as well as the pre-market review and decisions regarding post-market events relating to biological/biotechnology agents. Since September 2004, Dr. Klein has served as Senior Medical Advisor and Director for a newly created evaluation centre within BGTD. She is an active member of several medical and scientific organizations nationally and internationally.

Public Health Agency of Canada Researcher

Don Sutherland, MD, M.Comm H., MSc. —Dr. Sutherland is the Executive Director, International Public Health Division, Public Health Agency of Canada. He studied medicine at the University of British Columbia and practiced clinical medicine in Canada for several years before becoming a district medical officer in rural Malawi. He subsequently completed postgraduate studies in community medicine at the Liverpool School of Tropical Medicine and in epidemiology at the London School of Hygiene and Tropical Medicine. After practicing community medicine in Canada, Dr. Sutherland served as senior technical advisor on refugee health for the United Nations High Commissioner for Refugees in Somalia and as senior

technical advisor to the International Red Cross Child Health Program, which was implementing projects in Latin America, Africa, and Asia. In 1988, he joined the World Health Organization (WHO) Global Program on AIDS as a team leader/epidemiologist in Uganda. He joined Health Canada's Bureau of Communicable Disease Epidemiology in 1992 as head of the HIV/AIDS Division. In 1995, Dr. Sutherland became Director of the Bureau of HIV/AIDS, STD and TB for Health Canada. In that role, he was responsible for planning, directing and managing epidemiology, laboratory research and surveillance programs as part of the National AIDS, STD and TB Strategies throughout Canada and the world. Dr. Sutherland then became Senior Advisor on Scientific Affairs in the Centre for Infectious Disease Prevention and Control. In 2003 Dr. Sutherland was seconded to WHO to coordinate the HIV Department's Strategic Information including HIV/AIDS Surveillance, Monitoring and Evaluation, Operational Research and the WHO HIV Drug Resistance Global Strategy. In 2007, he returned to Canada to become Executive Director of International Public Health of the Public Health Agency of Canada, based in Ottawa.

Ethicist

George C. Webster , B.A., M.A., S.T.B., M.Div., D.Min.—Dr. Webster is currently a Clinical Ethicist with the Health Care Ethics Service at St. Boniface General Hospital in Winnipeg, Manitoba, Canada. From 1982–1996 he was Director of the first full-time hospital-based Ethics Service in Canada at St. Michael's Hospital, St. Joseph's Health Centre and Providence Centre in Toronto, Ontario. Dr. Webster completed his Doctoral studies at the Toronto School of Theology, University of Toronto. He has served on various regional, provincial and national ethics committees and research ethics boards including St. Michael's Hospital in Toronto, and the University of Manitoba, Faculty of Medicine, Research Ethics Board. He previously chaired the National Research Council of Canada, Winnipeg Research Ethics Board and has served on the Board of the Society for Bioethics Consultation (U.S.), the Ethics Committee at Casey House Hospice in Toronto, the Canadian HIV Trials Network, National Ethics Review Committee and the Canadian Anesthetists' Society, Committee on Ethics. He is currently a member of Health Canada's Research Ethics Board and the Canadian Institutes of Health Research (CIHR), Governing Council, Standing Committee on Ethics (SCE). Dr. Webster is an Assistant Professor

in the Faculty of Medicine at the University of Manitoba and is cross-appointed in the Department of Philosophy. He is a member of the Canadian Bioethics Society and the American Society for Bioethics and Humanities.

Janet Storch, RN, BScN., MHSA, PhD., DSc. (Hon), CHE—Dr. Storch has been involved in bioethics, health ethics, administrative, organizational and research ethics since the mid-seventies. She served as President of the Canadian Bioethics Society in 1991–1992, and as member and President of the National Council on Ethics in Human Research from 1994 to 2002. She is a Professor Emeritus at the University of Victoria, where she served as Director of the School of Nursing and where she continues an active research program in nursing and health care ethics. She was Chair of the University of Victoria Human Research Ethics Committee from 2002–2005, as well as member of the Vancouver Island Health Authority REB during those same years. Prior to her appointment at the University of Victoria in 1996, she was Dean of Nursing at the University of Calgary, and prior to 1990, was Professor and Director of the Masters in Health Administration Program at the University of Alberta. Dr. Storch's academic training includes a BScN, an MHSA and a PhD. in Sociology, as well as a certificate from her studies at Washington, D.C.'s Kennedy Institute of Ethics. She continues active service on several local clinical ethics committees, serves on the B.C. Ministry of Health committee to develop clinical ethics resources, and serves on other provincial and national committees, including two committees of Health Canada. In 2001–2002, she was scholar in residence at the Canadian Nurses Association and continues to work with that organization in helping to review and revise their code of ethics for registered nurses, as well as in developing research ethics guidelines for registered nurses.

Community Member –General Population

Jean R. House, B.A., B.Ed., LL.B.—Ms. House is a lawyer (non-practising status), currently employed at the Newfoundland and Labrador Health Boards Association. Previously, she served as a legal representative on the Human Investigation Committee (Memorial University of Newfoundland Research Ethics Board) for a seven-year term. She serves on committees at Memorial University dealing with the development of policies and guidelines in research ethics

and privacy, and sits on the Human Investigation Committee Appeal Board. Ms. House also worked on legal policy with the Newfoundland and Labrador Department of Health and Community Services, drafting provincial standards for genetics research and consulting on legislation, most relevantly on legislation to establish a single province-wide health research ethics authority and health research ethics board (HREB). As part of the Transition Team composed of representatives of public and private research stakeholders, she is working on the implementation of the legislation and a smooth transition to the HREB. She has been a member of the Board of the Newfoundland and Labrador Centre for Applied Health Research and serves on the Advisory Committee for the Canadian Institutes of Health Research Regional Partnership Program (Newfoundland and Labrador). She is currently a clinical assistant professor at the Memorial University Medical School. Her particular interest is in health legislation, privacy and confidentiality, and ethics.

Community Representative –Aboriginal Population

Maxine Cole, B.A., M.S.—Ms. Cole received a B.A. at the State University of New York at Potsdam College, majoring in biology and a M.S. in Epidemiology at the University of Ottawa. Ms. Cole is currently at the Akwesasne Freedom School (Mohawk immersion program) as a teacher for Mohawk language and English-based subjects. Ms. Cole's past and current experience includes clinical and research and educational outreach in health and environment issues. For the past nine years, she has been a member of the Akwesasne Task Force on the Environment (ATFE) and the co-chair for the Research Advisory Committee (RAC) for the ATFE. The ATFE is a community-based non-profit organization that was developed in the early 1980’s to oversee all research within the Mohawk Nation at Akwesasne. The RAC/ATFE established research ethic guidelines that are strongly recommended for all proposed research within the Mohawk Nation. The RAC reviews all research proposals, and recommends amendments and monitors the research work.

2. Alternate Members

Law

Robert P. Kouri, B.A., LL.L., M.C.L., D.C.L.—Dr. Kouri is a professor of law at the Faculté de droit at the Université de Sherbrooke. He teaches and pursues research in the Law of Obligations, Civil Responsibility and Medical Law. He has published *"La responsabilité civile médicale"* [Medical civil liability] (in collaboration with Alain Bernardot) and *"L'intégrité de la personne et le consentement aux soins"* [The human body, inviolability of the person and consent to care] (in collaboration with Suzanne Philips-Nootens), as well as several articles. Professor Kouri was president of the Editorial Committee for the first and second editions of the *Private Law Dictionary and Bilingual Lexicons* at the Quebec Research Centre of Private and Comparative Law. He was a visiting professor at the Faculty of Law of McGill University. Dr. Kouri acted as consultant to the Office de révision du Code civil as well as to Justice Canada, the Québec Ministère de la Justice, the Law Reform Commission of Canada and the Medical Research Council of Canada. He is a member of the Groupe de recherche en droit de la santé de l'Université de Sherbrooke and the Board of Professional Advisors of the American *Journal of Contemporary Health Law and Policy.* He also served as director of the graduate programmes in Health Law and Policy and Associate Dean (Research) at the Université de Sherbrooke.

Researcher Outside Health Canada

Rae Mitten, LL.B., LL.M. Ph.D. Student—Ms. Mitten is currently a Ph.D. student and lecturer/law teacher at the University of Saskatchewan. Her Ph.D. dissertation is an interdisciplinary study in the fields of law, medicine, education, psychology and justice. Ms. Mitten's professional associations include memberships in the Law Society of Saskatchewan, the Indigenous Bar Association of Canada, the Canadian Bar Association, and the Saskatchewan Teachers' Federation. She is a member of the Métis Nation of Saskatchewan, and serves as a board member of the Saskatchewan Fetal Alcohol Syndrome Support Network.

Health Canada Researcher

Tye Arbuckle, Ph.D.—Dr. Arbuckle has a PhD. in Epidemiology and her areas of expertise are in environmental and reproductive epidemiology and exposure assessment to environmental chemicals. Dr. Arbuckle's current science and research interests are in pesticides, disinfection by-products in municipal water supplies, influences of environmental chemicals on pregnancy, child health and development and male reproductive health. She has academic appointments with: the University of Ottawa, Department of Epidemiology and Community Medicine, Institute of Population Health and Department of Obstetrics and Gynecology; and with Queen's University, Department of Community Health and Epidemiology.

Public Health Agency of Canada Researcher

Katherine Dinner, B.Sc., M.Sc.—Ms. Dinner is the Health and Social Services Advisor in the Community Acquired Infections Division at the Public Health Agency of Canada. She has over 20 years of primary and public health experience in research, clinical practice, community and street outreach, and in the development, coordination and evaluation of health programs, in a variety of urban, rural and remote settings in Canada. She has worked with First Nations and Inuit Health both as a community health nurse and as a communicable disease epidemiologist. Her commitment and hands-on work with First Nations Communities in Manitoba were recognized when she was the 2002 recipient of the Queen Elizabeth II Golden Jubilee Medal. Her formal academic background includes a B.Sc. (Life Sciences) from Queen’s University and a M.Sc. (Nursing) from McGill University.

Ethics

Michael D. Coughlin, Ph.D.
Dr. Coughlin has worked as a clinical ethicist for over 20 years and is an Associate Professor at McMaster University in the Department of Psychiatry and Behavioural Neurosciences. His

background includes degrees in philosophy, theology and developmental biology and he has held Faculty appointments at New York Hospital/Cornell University Medical College and at McMaster University and still does some basic research in neurobiology. Dr. Coughlin recently retired from the position of Ethics Consultant at St. Joseph's Healthcare Hamilton, a position he initiated in 1986. During that time he served both as clinical ethicist and as secretary and ethicist for their Research Ethics Board. He continues to be involved in clinical and research ethics in the Faculty of Health Sciences at McMaster and in a number of health facilities. He serves as Chair of the Tri-Hospital Research Ethics Board in Kitchener-Cambridge, and during the past year acted as interim Clinical and Organizational Ethicist at Hamilton Health Sciences.

Community Representative –General Population

Monique Martineau-Enzle—Mrs. Martineau-Enzle was nominated to the Health Canada Research Ethics Board 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, Mrs. Martineau-Enzle served in different capacities at the provincial and national level of lupus organisations. She was on the Board of directors of Lupus Canada for several years, served a two-year term as Vice-President of Lupus Canada and served on the Strategic Planning Task Force for Lupus Canada. Mrs. Martineau-Enzle served as a member of the Board of Directors of Lupus Quebec as well and several terms as President. She also edited the French version of "*Lupus-Disease of 1000 Faces*." Mrs. Martineau-Enzle 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.

Community Representative –Aboriginal Population

Larry N. Chartrand, B.Ed, LL.B, LL.M—Mr. Chartrand is a professor of Law at the University of Ottawa. He teaches Tort law and Aboriginal law. His main research efforts are in the field of Aboriginal rights including self-government, treaty rights, Métis rights, Aboriginal health issues and international human rights as they pertain to indigenous peoples. He is the past

president of the Indigenous Bar Association and an arbitrator for the Sahtu Dened and Métis Land Claim Agreement. Professor Chartrand continues to be affiliated as a scientist with the Institute of Population Health and is a member of the school of Graduate and Post-Graduate studies at the University of Ottawa. He is currently Co-chair of the Institute of Aboriginal Peoples Health Ethics Committee.

APPENDIX B

TRI-COUNCIL POLICY STATEMENT 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*, authored by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. 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 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 C

HEALTH CANADA RESEARCH ETHICS BOARD RESEARCHERS SURVEY 2007–2008 CONDUCTED BY PRAXIS RESEARCH INC.

Health Canada Research Ethics Board Researcher Survey 2007-08

Prepared by

Praxis Research
242, 2451 Dieppe Avenue SW
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April 2008

1.0 PURPOSE

In 2002, the Deputy Minister of Health Canada established an independent Research Ethics Board (REB) to be responsible for reviewing all Health Canada research involving human subjects.

Since 2003, the REB Secretariat has contracted Praxis Research, an independent research and consulting firm, to conduct an independent assessment of the efficiency and effectiveness of the Research Ethics Board and the ethics approval process. Initially both researchers and Board members were surveyed to provide feedback for this assessment. In 2004/05 Praxis Research replicated the survey to assess researchers' perspectives about the REB process during its second year of operation. This report presents the findings of this same survey conducted with researchers for review of the sixth year of operation of the REB and ethics approval process.

2.0 RESEARCH APPROACH

2.1 Survey Design

A survey was designed which asked researchers to report about their experiences in the following areas:

- background information,
- preparing the application – documentation and process,
- preparing the application – the REB Secretariat,
- review by the Research Ethics Board,
- orientation sessions,
- perceived value of ethics review, and
- overall satisfaction with the review process.

The survey included a combination of closed and open-ended questions. French and English versions of the survey were prepared (Appendix D).

2.2 Sample and Response Rate

In February 2008, Health Canada REB Secretariat provided Praxis Research with an email contact list of 88 researchers who had undergone ethical review through the REB Secretariat the previous year. Five researchers were removed from the sample because their correct email and/or telephone contact information was not current and could not be reached by email. The final sample size was 83 researchers who had submitted applications for ethics approval in the past two years. Forty two researchers

completed the survey, resulting in a response rate of 50.6 %. This response rate is slightly better than the 2006 survey year (47.7%).

2.3 Survey Implementation

The survey was administered online. Initially, an introductory email was sent to all researchers by the Secretariat. This email explained that the researchers were being recruited to assess the ethical review process of the REB and that Praxis Research would be sending an email, which provided a link to the survey and an individual password. The purpose of the password was to ensure the confidentiality of responses and to secure access to the responses. Participants who were not able to complete the survey in one session were able to re-enter the survey using their password and complete it later. The survey was administered online during the month of March 2008.

3.0 RESULTS

Data were analyzed using SPSS (Statistical Package for the Social Sciences) v12.0. Frequencies are provided for the quantitative questions. Responses to open-ended questions are summarized or presented verbatim. The results are presented according to the main sections of the survey.

3.1 Background Information about Participants' Research Application

Participants were asked to provide the current review status of their project. The results indicated that for 55% of the respondents, approval had been granted, 27.5% had completed their research and submitted a termination form, 12.5% had their research re-approved for an additional year, and 5% had approval pending or were awaiting re-approval.

Concerning whether their initial application status – 40.5% percent of the respondents indicated that their initial application was approved as submitted, 57.5% were approved with conditions.

Research was classified into five categories based on where it was carried out and how it was funded. The categories consisted of: intra-mural research, research carried out on Health Canada premises, research undertaken in collaboration or partnership with Health Canada, research funded by Health Canada grants or contributions, contract research or 'other' category of research (see Figure 1). Note: Research projects

included under the “Other” classification include; Public Health Agency of Canada projects, “Manitoba Health” project, corporate research in partnership with Maroc Labs and multi-center research.

In comparison with previous years, a similar distribution of research categories was reviewed. However, the proportions changed this year. The top three categories of research reviewed included research carried out in collaboration or partnership with Health Canada (29.3%), research funded by Health Canada Grants and Contributions (22.0%) and research classified as Other (22.0%). There was substantially more contract research reviewed in 2007/2008 (14.6% from 4.8% in 2006) and less intramural (2.4% from 4.8%) and research carried out on HC premises 9.8% from 14.3%).

As in previous years, the majority of the respondents (70.7%) became aware of the REB through communication from senior management or other colleagues. Conversely, in 2008, 9.8% became aware of the REB through Health Canada Broadcast News – up from 0% in 2006. See Figure 2.

Figure 1. Research Classification

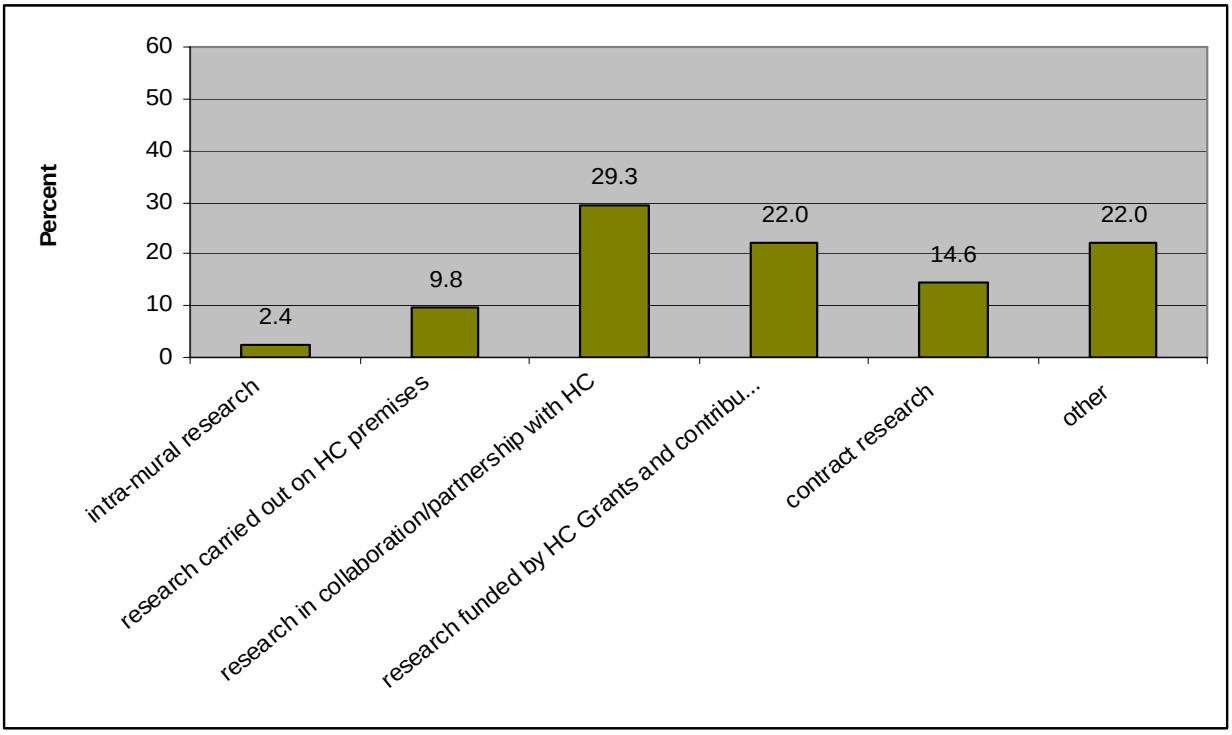
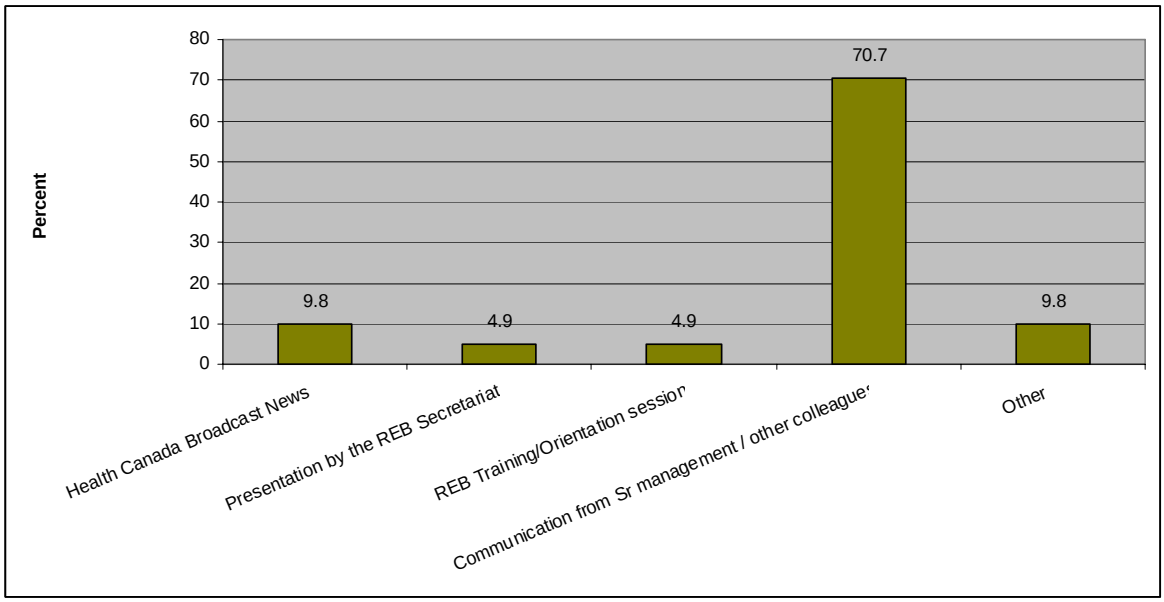


Figure 2. Awareness of the REB



Note: 'Other' sources include; Hepatitis C Program, "followed its evolution from inception", Health Canada Project Manager for the research contract, and by contact with REB secretariat.

3.2 Preparing the Application – Documentation and Process

Respondents were asked to rate their satisfaction with the clarity of six aspects of preparing the application. The results for 2008 are presented in Table 1. Figure 3 shows the means values on these attributes for 3 survey years (2004, 2006, and 2008).

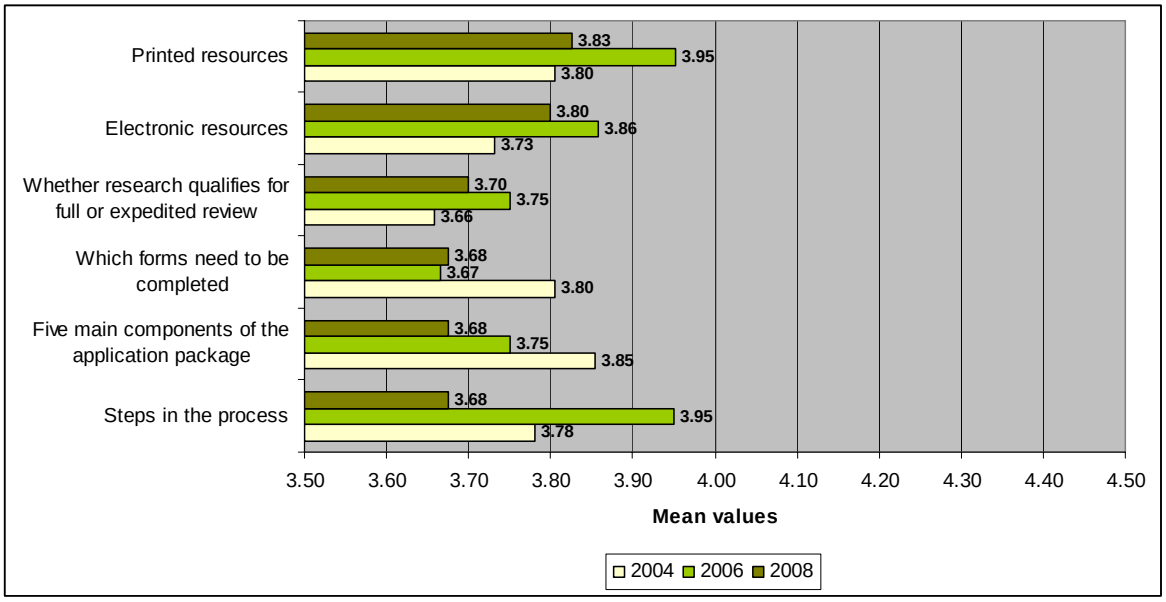
Table 1. 2008 Satisfaction with the thoroughness and clarity of …

	very dissatisfied	dissatisfied	neutral	satisfied	very satisfied
Whether research qualifies for full or expedited review	7.5%	2.5%	22.5%	47.5%	20.0%
Steps in the process	5%	7.5%	20.0%	50.0%	17.5%
Five main components of the application package	5%	2.5%	25.0%	55.0%	12.5%
Which forms need to be completed	5%	5%	25.0%	47.5%	17.5%
Printed resources	5%	5%	17.5%	47.5%	25.0%
Electronic resources	5%	7.5%	12.5%	55.5%	22.5%

There has been a slight decrease in satisfaction levels regarding clarity and various aspects of the application preparation from previous survey results. In addition, three to five respondents were either

dissatisfied or very dissatisfied with the clarity in the application process in all areas, representing up to 12.5% of the respondents. However, one must keep in mind that the mean values are still all close to 4.00 (satisfied) for all areas and the survey sample size was small in 2006 (20 respondents). The only areas that may need to be looked at are 'steps in the process' and 'five main components of the application package'. Mean values decrease over three consecutive in these areas.

Figure 3. 2004 – 2008 Satisfaction with the clarity of . . .



There were a few comments left by respondents, which provided feedback to consider for action or reflection on this aspect of the REB process. These were:

> *"Difficult to complete due to the medium chosen for distribution and completion."*
>
> *"form of the questionnaire was not flexible enough . . . The forms to fill (like your question 1 of the survey) did not have an option which translate 'request for agreement non renewed by health canada' since ethical request was done with another organisation"*
>
> *this is symptomatic of the problems I met with . . . The whole REB was oriented to a drug trial format -- they kept trying to fit this research project into that "box" and all questions and requirements were along those lines. Often the REB did not seem to realize the difference in the project and thus I was often asked to clarify or repeat of change methodologies that were not relevant to the project which was called for and for which I was contracted. It eventually was sorted out, with great effort on the part of the HC Project*

Authority, but clearly the process is very narrowly conceived and executed. It also took much longer than it need have, due to these problems."

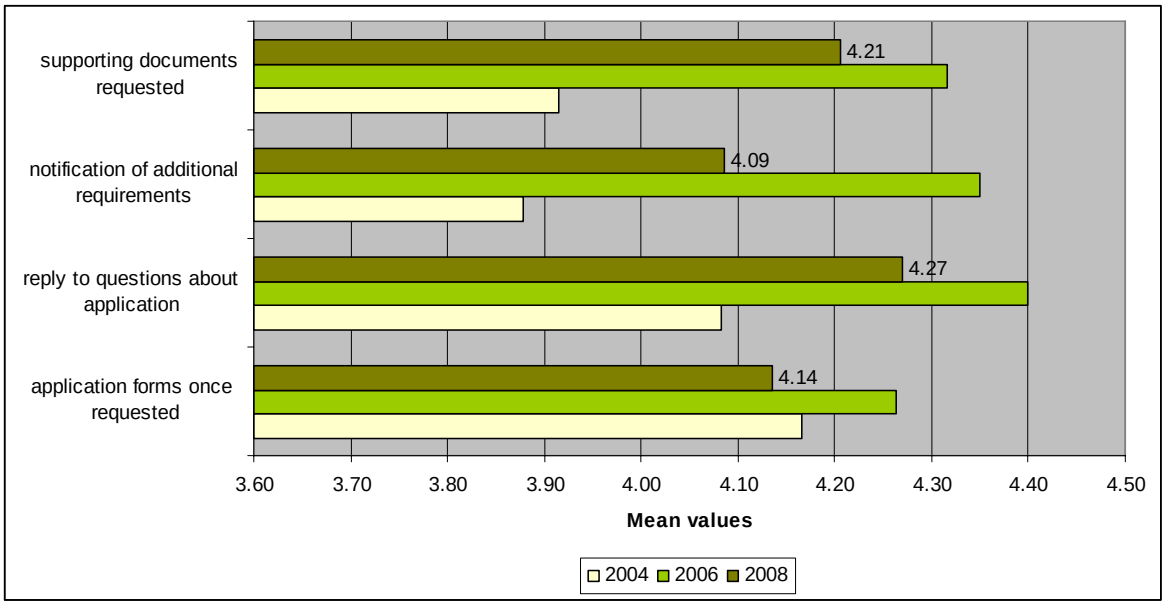
"no info regarding expedited process or meeting dates, deadlines for submission, turn around time, members of the board/background (got at first submission but not subsequent)"

A series of questions were also asked about the time it took to obtain information and documents from the Secretariat. The results for 2008 are presented in Table 2. Mean values on these attributes for 3 survey years are shown in Figure 4.

Table 2. Satisfaction with the time it took to obtain…

	very dissatisfied	dissatisfied	neutral	satisfied	very satisfied
application forms once requested	8.1%	2.7%	10.8%	24.3%	54.1%
reply to questions about application	5.4%	5.4%	8.1%	18.9%	62.2%
notification of additional requirements	2.9%	8.6%	17.1%	20.0%	51.4%
supporting documents requested	0.0%	5.9%	17.6%	26.5%	50.0%

Figure 4. 2004 – 2008 Satisfaction with the time it took to obtain…



These results indicate a high level of satisfaction with the expediency with which researchers received forms or communications from the REB.

3.3 Preparing the Application – The REB Secretariat

In previous years, the 2008 results indicated that the REB Secretariat contact person was helpful with answering questions and providing clarification, that the contact person was accessible and that the Secretariat accommodated requests for time sensitive reviews. See Table 3.

Table 3 REB accessibility, helpfulness and accommodating

	YES*	**NO***
a. The REB Secretariat contact person was accessible.	97.6% (41)	2.4% (1)
b. The REB Secretariat contact person was helpful with answering questions and providing clarification.	97.6% (41)	2.4% (1)
c. The REB Secretariat accommodated requests for time sensitive reviews.	89.5% (34)	10.5% (4)

* percentage (frequency)

Researchers were asked to provide additional written feedback about their experiences with the REB Secretariat in this respect. These are the comments provided:

"very helpful and accommodating"

"excellent; accessible"

"The lady is very kind and made herself very available."

"Very helpful in preparing my application in time for the REB meeting."

"Very friendly and informative."

'again, this was a process that was not adapted to the nature of this kind of research. I also often felt that the review committee itself did not read the material submitted thoroughly and did not understand the nature of what was a simple and rather small project. They would ask things that were irrelevant and/or did not reflect the content or methodology of the project."

"Very prompt processing of the ethics approval given that I was needing the certificate for the NIH (USA)fund release."

"Yvette Parent has always been very servable, accommodating and on time.

"Excellent representation and service of top quality."

"REB Secretariat was most helpful at directing our request and clarified timelines for submission"

"Great experience with Ms. Parent!"

"This was also excellent. Yvette Parent was very helpful & always responded in a timely fashion."

"A system is required for when the REB secretariat is away. There also needs to be a system for an expedited process, especially once initial approval has been obtained."

"Very helpful and supportive of researchers. Provide timely advice."

3.4 The Research Ethics Board Review

Several questions were asked about presenting in front of the REB. The results were similar to previous years with the exception of REB accommodation of time sensitive reviews. In the 2006 survey results, (94.7%) reported that the REB had accommodated time-sensitive reviews. This year's result on this question was 80.6%. See all questions and results in Table 4.

Table 4 REB presentation

Did the Research Ethics Board…	**YES**	**NO**
a. gives you adequate time to discuss your application at the meeting?	97.3% (36)	2.4% (1)
b. communicates its decision to you in a timely manner?	90.2% (37)	9.8% (4)
c. communicates its decision to you in a clear manner?	95.1% (39)	4.9% (2)
d. accommodates time sensitive reviews?	80.6% (29)	19.4% (7)

The percent of respondents reporting that they found the opportunity to appear in front of the REB in person or via teleconference helpful was down from the last survey. In 2006, 94.7% of the respondents reported that they found the opportunity helpful. In 2008, this number was 86.5%. Several respondents

provided feedback on the opportunity to appear in front of the REB in person or via teleconference. Comments for consideration include:

"the teleconference approach worked well and was time efficient, saving considerable expense for travel".

"excellent comments, very friendly and helpful"

"Members of the ethics committee are highly qualified. Their questions helped us to narrow down our request."

"Timing of the meeting was inconvenient . . .. The questions and comments during the meeting were useful, however."

"Useful, but I'm not sure this is necessary for all project"

"My staff felt it was very useful to meet in person and understand where the questions and concerns were coming from."

"My only difficulty was that my interview was bumped up - and I was actually working in the field at the time of the interview. Accordingly, I did not have my documents . . . only work in an office 10% of the time - the rest of the time is in some pretty remote places."

"The time was delayed. Clarity around the expectations of the meeting of the REB would have been helpful in my preparation for the meeting."

" in-person presentation to be quite helpful in communicating additional information that may not be included in the formal application."

"We had to defend the research not if it was ethically sound."

"A useful discussion of issues evolved"

"Was very helpful to meet the board, and have the opportunity to answer questions and engage in some dialogue"

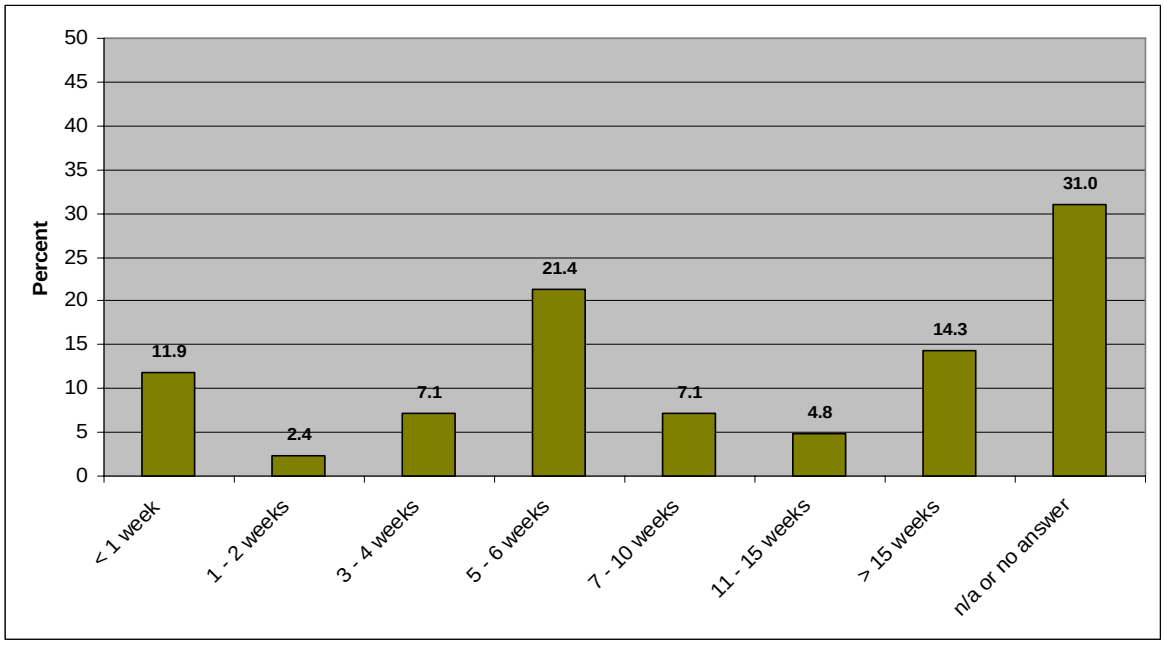
"No or very little expertise to evaluate research based on qualitative methods. Ottawa University at least for request requiring a fast evaluation"

"Communication in person helps clarify any ethical issues for both the researcher and the board members."

The majority of the respondents indicated that they had adequate time to discuss their application at the meeting (97.3%). Also, 90.2% of the respondents indicated that the decision was communicated to them in a timely manner and 95.1% indicated the decision was communicated to them in a clear manner.

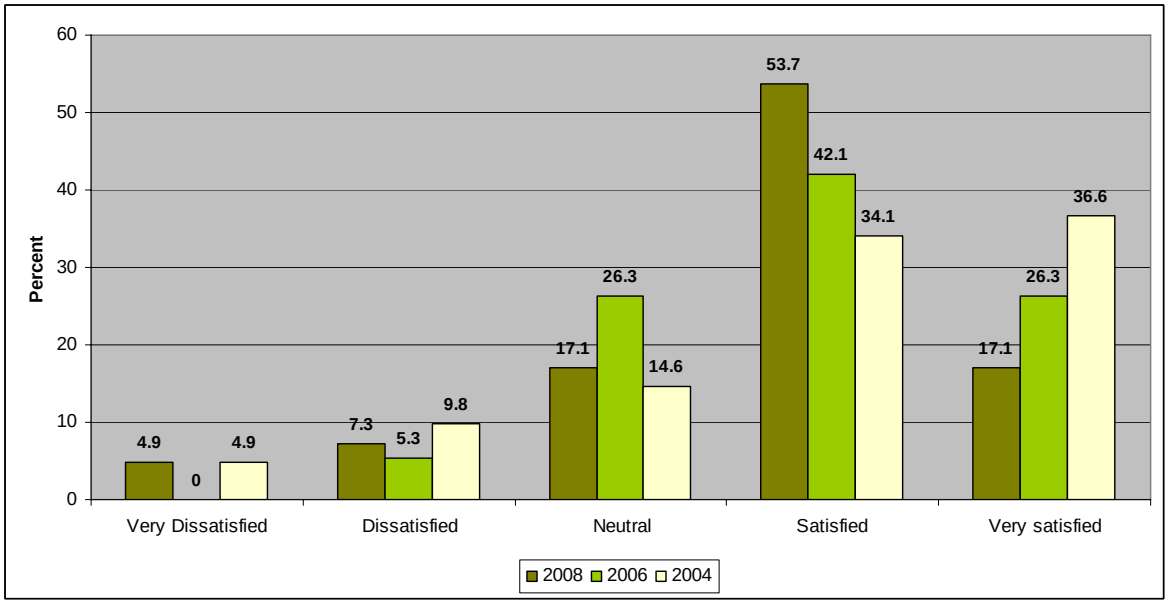
Respondents were asked to identify how long it took to obtain ethics approval from the REB from the time of the application to the time the decision was communicated by the Board. Approximately two thirds of the respondents answered this question. The results shown in Figure 5 indicate that the response time varied across respondents with some clarification for reasons regarding longer time periods (for example, the application was put in right before summer or multi-funded projects held up by other review boards or multiple reviews). Approximately one third of the respondents reported the time for approval taking less than or up to 4 weeks, one third reported approval taking 5-6 weeks and approximately one third reported the time for approval taking greater than or equal to 7-15 weeks.

Figure 5. Length of time it took to obtain ethics approval



Respondents were asked to rate their satisfaction with the overall timing/length of the review process. The results are presented in Figure 6.

Figure 6. 2004 - 2008 Satisfaction with overall timing/length of review process



The findings suggest that most (70.8%) of the respondents were "satisfied" or "very satisfied" with the timing/length of the review process. The respondents were satisfied with both the timing of specific stages of the process and the time entailed by the overall process (i.e., from start to finish). In addition 86.5% of the respondents indicated that the opportunity to appear in front of the REB in person or via teleconference was helpful.

Respondents that offered comments about these areas reported the following:

> *"the board was attentive, encouraging, asked very pertinent questions - I have presented to ethics boards in the past and was impressed with the objectivity of the REB"*
>
> *"REB members extremely helpful"*
>
> *"There was confusion about whether I needed to appear in person . . ."*
>
> *"The REB had requested to review the consent form and they proposed a format to us. This format did contain a recap section where the participant had to answer yes or no if certain elements had been covered during the reading of the consent. The changes that were proposed greatly increased the length of the consent form. In fact, the added section was adding more confusion than anything else; people were a little shocked of how repetitive it was. At the ethics renewal (with the REB of our university), we are likely going to cut this section out."*
>
> *"Feedback over the summer was very slow. "*

“It was appreciated that my application was reviewed by conference call as I live and work outside of province of Ontario.”

“Often an expedited review takes as long a time as a full review, although the proposal has been reviewed and approved by other REBs.”

“ they were fast enough, but not to the point at a number of places in terms of content and requests for clarification”

“We were not informed of the formation of the board and what the process consisted of. The review focused on more on the "science" of the research, not if it was ethically sound or not. I felt the Board completely overstepped its boundaries.”

“Our project was evaluated and deemed a program evaluation. The board was not addressed in person by the team.”

“Was a very positive experience “

“This was excellent last year. I gave a brief PowePoint presentation and questions were all relevant/clear.”

“Certain commentaries were related to elements of methods which did not relate with the ethical dimension of the proposal.”

“We generally were requested to present to the board with little notice time or accommodation for not being in Ottawa. In addition, having to give a formal presentation every time as if for the first time is redundant and inefficient, especially once approval has been given and we have modified requests.”

“As the review board did not meet during the summer of the year i was applying for, it caused a 3 month delay in the project field work. This meant a late fall field research period which may have negatively impacted results. It certainly made travel more difficult due to weather issues.”

“this was the fastest process I have ever encountered with the federal government - there were 2 other ethics reviews for the research that took 8 weeks, Health Canada expedited in <4 wks.”

“time is adequate.”

“Requests for changes were very picky and time consuming. The project had already undergone thorough REB review at my host institution, and additional changes took a lot of time to fix with all other REB boards reviewing this application.”

"Please have another board, or paid board available to meet during the summer as need be."

" . . . It is the time required to complete the forms and get input/approval from colleagues and supervisors that took time."

"Some times different REBs give conflicting instructions for amendments of the documents, which is extremely frustrating. They don't always hold the same norm/rules. One amendment approved by one REB will have to be resubmitted to another REB for approval. When it is a multi-centre study, there will be many REBs involved."

"Very rapid response"

"All was A. OK"

"A very poorly organized inefficient process that does not accommodate requests from outside Ottawa. Also found that the sensitivity and awareness to aboriginal projects and realities of working FN communities was very poor."

"It can be problemative that the board does not sit during the summer months; however, I understand that as a volunteer board, the members need and deserve a break."

3.5 Activities carried out by the Secretariat - Orientation

A small number (9.8%, 4 respondents) attended an REB orientation session and 11.9% (5) indicated they had attended a REB Secretariat short presentation.

The comments left about orientation and in answer to the question – " . . . did you find the session of value? " were:

"Yes. This helped to clarify the process for submitting an application and to whom inquiries should be directed."

"Unfortunately, the scheduled Orientation was cancelled during the funding freeze during the change of government and another session has not been offered in my region."

"no and do not believe there was one for this project"

"Yes. It was some time ago though."

The comments left about REB short presentation and the question – " . . . did you find the presentation to be of value? " were:

"yes"

"yes, otherwise I would not of even known that they existed."

"Info on the process."

"see above" – "Yes. It was some time ago though."

The following comments were provided regarding activities the Secretariat could undertake to assist Health Canada researchers with research ethics issues and:

"Improved information on how to deal/coordinate multiple REBs, especially in multi-centre projects, where each centre has its own REB. Also, there is some confusion of roles of REB vs Privacy Impact Assessments which may need to be clarified."

"Need to streamline the HC REB application process for studies which have already undergone rigorous REB review at another institution. Having to go through this process multiple times takes a lot of time and energy, and does not significantly improve the project. This time could be better spent conducting the research!"

"adapt processes and content to projects that are not drug trials, but social policy research, in effect."

"Site visits to other Canadian jurisdictions"

"My experience with the HCREB has been excellent but I wonder if something could be done to decrease the paper work, meetings etc we PIs need to do to maintain approval annually. We also need to maintain approval through the Ottawa Hospital Research Ethics board & so more paper work for that. One thing of importance to our specific research project is that our patient consent letter is quite long, several pages and we have not had the large number of patients responding that we expected. Hence if these consent letters could be standardized in some way (we need these in both official languages) this might be of benefit to both patients and health researchers."

"sensitivity and awareness education regarding First Nations and community realities and issues. could learn on how to set up efficient REB process from other academic REB institutions"

3.6 Perceived Value of the Ethics Review Process

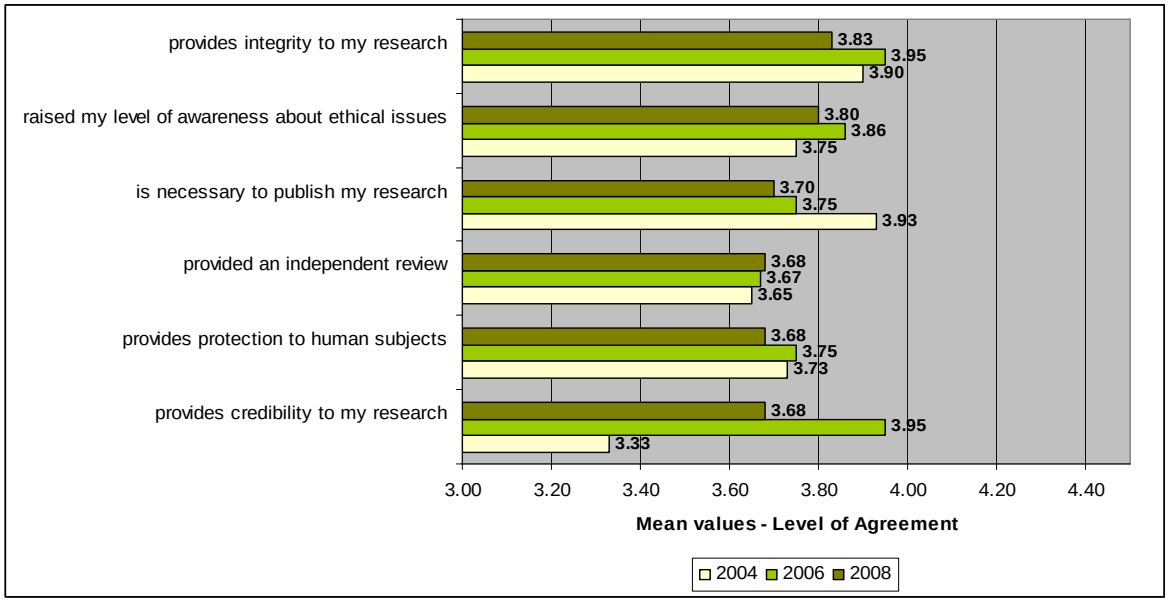
Table 5 shows the frequencies for six statements pertaining to the value of the Health Canada research ethics review process. The 2008 results indicate that over two thirds of the respondents 'agree' or 'strongly agree' with the statements highlighted in green. The statement with the least amount of agreement of value in the REB ethics review process was that the review "provides credibility to my research".

Table 5. The REB approval process

	strongly disagree	disagree	neutral	agree	strongly agree
is necessary to publish my research	0%	4.8%	2.4%	57.1%	35.7%
provides credibility to my research	4.9%	4.9%	43.9%	29.3%	17.1%
provides protection to human subjects	2.4%	7.1%	26.3%	35.7%	28.6%
provided an independent review	4.8%	9.5%	26.2%	33.3%	26.2%
provides integrity to my research	5.0%	0%	27.5%	40.0%	27.5%
raised my level of awareness about ethical issues	2.4%	2.4%	22.0%	39.0%	34.1%

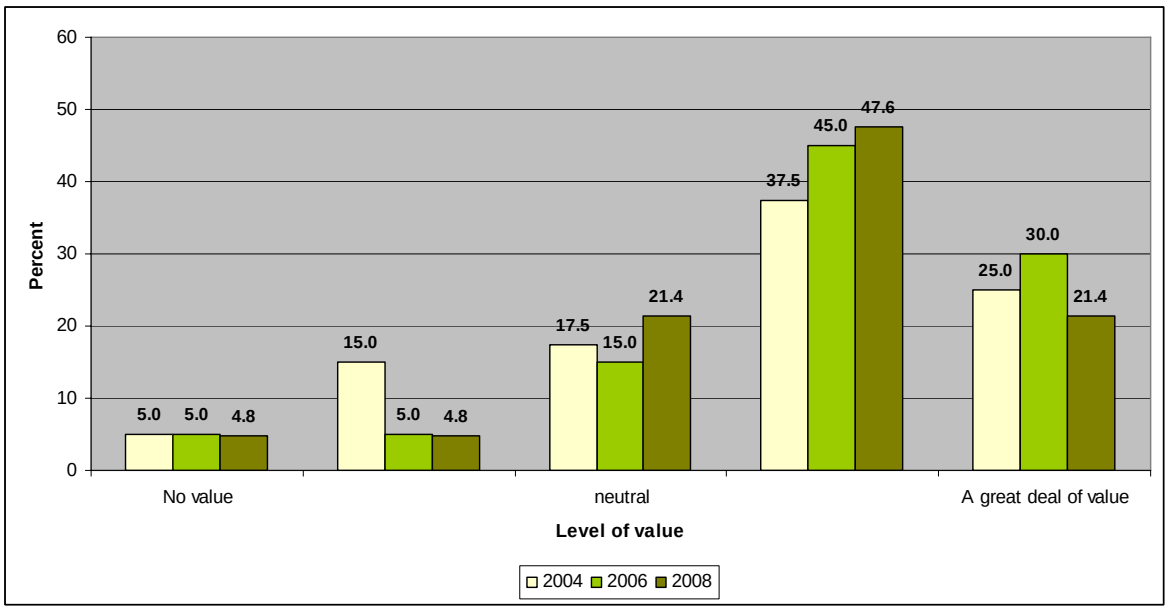
Compared to previous years, the perceived value on various aspects of the review process has decreased. This is likely a function of some researchers repeating the process over the years for different projects. The only dimension where there was an increase in agreement was that the review process "provided an independent review of the ethics of my research".

Figure 7. 2004- 2008 Level of Agreement with REB review process value



Researchers were also asked to rate the overall value of the research ethics review process on their research. The results compared with previous years are presented in Figure 8.

Figure 8. 2004 - 2008 Perceived overall value of ethics review process



Researchers who rated the perceived overall value of the ethics review process as '3' or less were asked to provide their thoughts about how the value of the review process could be improved. The comments left by these respondents are:

". . . I found this particular review very smooth, timely and appreciated the time and attention the REB provided."

"My work needs to undergo ethics review at my university, so the effort is largely duplicated."

"The REB review process is beneficial in many ways, but it is not useful to go through the same process multiple times with different REBs for the same project. The process is so cumbersome that it seriously detracts from the timely conduct of the research under review. This wastes tax payers money in having researchers jump through similar hoops again and again."

"Reduce delays in process"

"The study was an anonymous survey so I'm not sure if the REB process added much value."

"In most cases, our studies are of multi-collaborators in nature, and they are reviewed and approved by other REBs. After we have received approval from external REBs, often the request for an expedited revew by Health Canada's REB does not seem to take shorter time."

"because it was largely irrelevant to the vast majority of the work, it was of little methodological or ethical value. I also object very strongly to what I see as the very "light touch" of attention that the REB seemed to pay to the project and its difference from others. . . . The committee simply did not have, or did not take the time, to absorb the nature of the research project, its' goals, methods, etc."

"While I agree that the HCREB adds much value to the research process, the mandate of the REB is not clear. I found that at times, the comments are scientific in nature, quite outside of "ethics" questions. This needs to be clarified. Should the REB opt to perform scientific reviews of proposals, this needs to be properly indicated in the mandate. Once a month meeting can impose significant delays since at Health Canada, funding operates on a fiscal cycle. If the research project is delayed, then funding is lost not to be recovered in subsequent fiscal years. I am not sure how this can be resolved other than perhaps lobbying to exclude research funding from fiscal year spending limitations. HCREB together with OCS could play a role in supporting this request to upper management. Another area of improvement is in the case of multicenter research projects, when all centers require ethics approval. We have found that independent submissions to multiple centers is burdensome and extremely time consuming, especially if one of the centers is in disagreement with HCREB. A process to streamline ethics requests from multiple centers seems necessary to avoid serious delays that could compromise large scale projects."

"Program evaluation is not traditional research and as such should not be subject to ethics reviews."

"The focus needs to be on ethical conduct, not the validity of the research, i.e. as statistical power. Completely inappropriate."

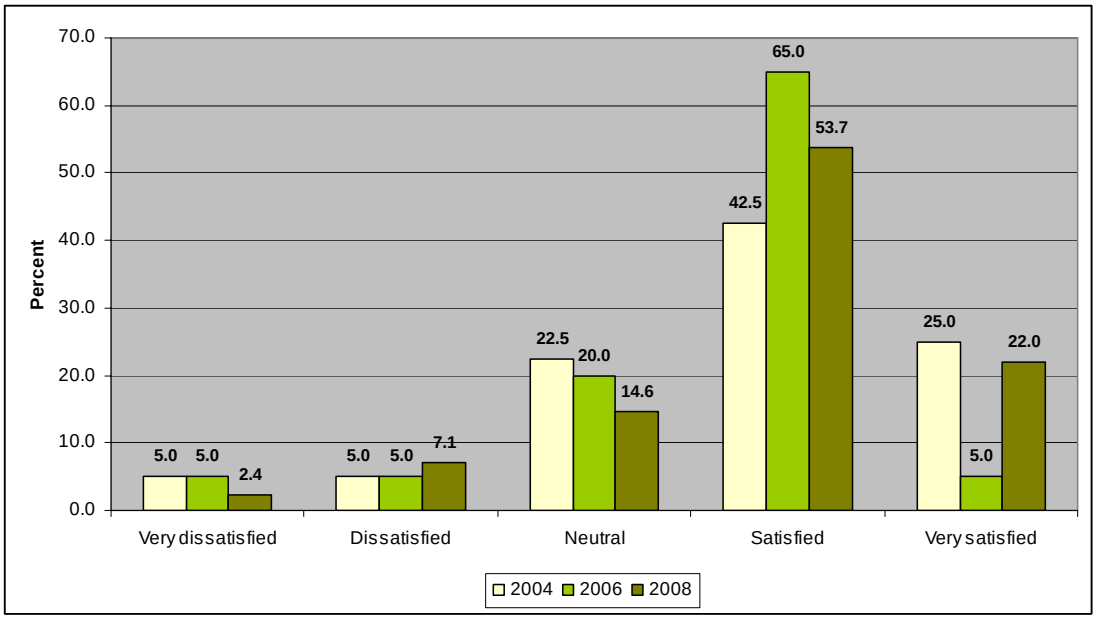
"The role of the ethics review is not to improve one research proposal"

"Duplicate of Academic institutional review. Need to have strategy for out of town applicants. An expidited review is needed, especially for post approval changes and when approval form another credible REB is in place. Much quicker review and turn around is necessary."

3.7 Final Thoughts about the HC Research Ethics Review Process

At the end of the survey, researchers were asked to indicate their overall satisfaction with the review process and to comment about opportunities for improvements.

Figure 9. Overall satisfaction with the review process



As indicated in Figure 6, the proportion of respondents that were 'satisfied' or 'very satisfied' has increased over three consecutive survey years. This year 75.7% of the researchers were "satisfied" or "very satisfied" with the review process compared to 70.0% in 2006 and 67.5% in 2004.

Researchers identified the following opportunities for improvements to the research ethics review process:

"clarity re: process. Some community-based research projects may not require REB approval."

"Maybe some modifications reported to the REB secretariat could have been amended by only the director of the institute if having to wait for the convening of all the members of the ethics committee."

"Need to have more frequent REB meetings. Feedback needs to be provided in a more timely fashion. Timing over the summer was especially slow."

"There needs to be some dialogue, I think, around the process involved in consent, which literature shows hinders some important public health research. Perhaps the Health Canada REB should be a leader in re-defining and stream-lining the process, and perhaps explore the merits and pitfalls of blanket consents in various contexts, making recommendations and providing some guidelines around it."

"The presentation in front of the committee should not be necessary for projects qualifying for a fast evaluation."

4.0 SUMMARY OF RESULTS

In this section, the results of the survey are summarized according to: 1) areas with extremely high satisfaction and agreement ratings, 2) areas with generally high satisfaction and agreement ratings, and 3) areas that may require further discussion or action.

4.1 High Satisfaction and Agreement Ratings (≥ 70%)

Seventy percent or more of the researchers were 'satisfied' or 'very satisfied' or agreed/strongly agreed with the following areas:

- Satisfaction in process of preparing the application with the thoroughness and clarity of **printed resources (72.5%)**
- Satisfaction in process of preparing the application with the thoroughness and clarity of **electronic resources (78%)**
- Satisfaction with the timing of stages involved in the process: time to obtain - **application forms (78.4%)**, **notification of additional requirements (71.4%), supporting documents (76.5%)**, and **reply to questions about the application (81.1%)**
- Agreement with The REB Secretariat contact person was - **accessible (97.6%)**, **helpful answering questions (97.6%)**, **accommodated requests for time-sensitive reviews (89.5%)**.
- Agreement with elements regarding presentation to REB – **opportunity to present to REB board was helpful (86.5%)**, **gave adequate time to discuss application in the meeting (97.3%)**, **communicated the decisions in a timely and clear manner (90.2%)**, **communicated decision in a clear manner (95.1%)** and **accommodated time sensitive reviews (80.6%)**.

- Agreement with the perceived value of the approval process in terms of - **necessary to publish research (92.8%)**, **raised level of awareness about ethical issues (73.1%)**.
- **Satisfaction with the overall timing/length of the review process (70.8%)**
- **Overall satisfaction with the review process (75.7%)**

4.2 Generally Satisfied or in Agreement (50 – 69%)

Between 50% and 69% of the researchers were satisfied/very satisfied or agreed/strongly agreed with the following areas:

- Satisfaction in process of preparing the application with the thoroughness and clarity of **whether research qualifies for full or expedited review (67.5%)**
- Satisfaction in process of preparing the application with the thoroughness and clarity of **steps in the process (67.5%)**
- Satisfaction in process of preparing the application with the thoroughness and clarity of **five main components of the application process (67.5%)**
- Satisfaction in process of preparing the application with the thoroughness and clarity of **which forms need to be completed (65%)**
- Agreement with the perceived value of the approval process in terms of - **providing protection to study participants (64.3%)**, **providing an independent review (59.5%)**, **provides integrity to research (67.5%)**.
- Perceived overall value of the ethics review process – **rated 'has value' and 'great deal of value' was 69%**.

4.3 Opportunities for Further Discussion or Action (< 50%)

Comments and dissatisfaction/disagreement ratings revealed the following opportunities for further discussion or action:

- Agreement with the perceived value of the approval process in terms of - **providing credibility to work (46.4%).**
- assess potential ways to deal with situations where projects have undergone and already received approval from a other agency/organization and multi-center projects
- First Nations research expertise mentioned again as a need
- A few respondents mentioned that they felt the mandate of the REB is unclear if the Board comments or questions issues regarding the research methods
- Expansion of epistemological orientation – comments regarding the process being narrowly conceived in terms of drug trials.

5.0 CONCLUSION

The purpose of this research was to assess the performance of Health Canada's research ethics review process for the fourth year. The 2008 results are very similar to other survey years for the levels of

satisfaction, agreement and/or assessed value on the parameters of the review process that were examined. If taken in its entirety by examining responses to overall ratings of the review process, the results demonstrate that the performance of the REB secretariat has consistently improved over the last four years. The questions that indicate this consistent improvement are; satisfaction with the overall timing/length of the review process (2004 – 51.2%, 2006 – 68.4% and 2008 – 70.8%) and overall satisfaction with the review process (2004 – 67.5%, 2006 – 70.0% and 2008 – 75.7%). In addition, over 80% of the respondents agreed with the statements concerning the accessibility, helpfulness and accommodation received from the secretariat, orientation and presentations by the REB secretariat.

The only parameters that demonstrate consecutive decrease in performance include; satisfaction with the clarity of the five main components of the application package, and there seems to be an unsteady agreement from year to year whether the review process adds value to the respondent's research. It might be useful to include an additional question to identify researchers who have never been through the REB process to determine if this is a recurring problem or one of newcomer's non-familiarity with the REB.

The suggestions for consideration that were the same as previous years were: 1) continuing to explore ways of dealing with the issues of duplicate ethics review processes, and 2) exploring the concerns expressed by a few researchers that the Board did not include members with expertise in the applicant's discipline and proposed research methodology. Several respondents commented on the need for the REB to be more transparent with their mandate or disapproved of the REB questioning researchers on their research methods.

As in previous years, over three-quarters of the researchers learned of the REB through communication with senior management / colleagues or interaction with the REB suggesting that knowledge about and awareness of the REB within the research community remains high. However, in contrast to previous surveys, the some respondents in 2008 indicated they learned of the REB from Health Canada Broadcast News.

APPENDIX D

French and English versions of Survey Instrument

a. Comité d'éthique de la recherche de Santé Canada – Sondage destiné aux chercheurs

Ce sondage porte sur votre expérience avec le Comité d'éthique de la recherche (CER) de Santé Canada. Veuillez répondre à toutes les questions portant sur l'approbation la plus récente que le Comité vous a accordée.

Remarque : Si l'approbation de votre projet est en suspens, ne répondez qu'aux

I. Questions relatives au contexte

1. Quel est l'état actuel de l'évaluation de votre projet?
[ ] approbation en suspens

[ ] approbation accordée

[ ] en attente du renouvellement annuel de l'approbation

[ ] l'approbation de la recherche a été renouvelée pour une autre année

[ ] la recherche est achevée et le formulaire d'achèvement a été soumis

2. Si votre demande initiale a été approuvée, a-t-elle été :
[ ] approuvée telle quelle [ ] approuvée sous certaines conditions

3. Comment votre recherche est-elle catégorisée?
[ ] recherche intérieure

[ ] recherche entreprise dans les locaux de Santé Canada

[ ] recherche entreprise en collaboration ou en partenariat avec Santé canada

[ ] recherche financée par les subventions et les contributions de Santé Canada

[ ] contrat de recherche

[ ] autres (veuillez préciser)

4. Comment avez-vous appris l'existence du CER?

[ ] Avis diffusé par Santé Canada

[ ] Présentation effectuée par le Secrétariat du CER

[ ] Séance de formation ou d'orientation organisée par le Secrétariat du CER

[ ] Information communiquée par la haute direction ou des collègues

[ ] Autres (veuillez préciser)

I. Préparation de la demande

A. Documentation et processus

1. Veuillez indiquer votre degré de satisfaction quant aux aspects suivants du processus de préparation de la demande.

	Très insatisfait	Insatisfait	Sans opinion	Satisfait	Très satisfait
a. clarté quant à savoir si la recherche nécessite une évaluation complète ou accélérée	1	2	3	4	5
b. les étapes du processus d'évaluation étaient clairement expliquées	1	2	3	4	5
clarté quant aux principaux éléments à fournir dans le dossier de demande	1	2	3	4	5
d. clarté quant aux formulaires à remplir pour un type d'évaluation en particulier	1	2	3	4	5
e. rigueur et clarté des ressources imprimées	1	2	3	4	5
f. rigueur et clarté des ressources électroniques	1	2	3	4	5

2. Veuillez fournir des renseignements supplémentaires sur les formulaires de demande que vous avez remplis.

3. Veuillez indiquer votre degré de satisfaction quant au temps qu'il vous a fallu pour obtenir les renseignements suivants.

	Très insatisfait	Insatisfait	Sans opinion	Satisfait	Très satisfait	Sans objet
a. formulaires de demande, après les avoir requis;	1	2	3	4	5	6
b. réponse à une question que vous aviez au sujet de la demande;	1	2	3	4	5	6
c. notification des éléments supplémentaires dont vous aviez besoin pour remplir votre demande;	1	2	3	4	5	6
d. pièces justificatives requises.	1	2	3	4	5	6

B. Le Secrétariat du CER

1. Veuillez répondre par oui ou par non aux énoncés suivants relativement au Secrétariat du CER.

a. Il m'a été possible de parler à la personne-ressource du Secrétariat du CER.	[ ] oui	[ ] non
b. La personne-ressource du Secrétariat du CER a répondu à mes questions et m'a fourni les éclaircissements dont j'avais besoin.	[ ] oui	[ ] non
c. Le Secrétariat du CER s'est efforcé d'accepter les demandes exigeant une évaluation rapide.	[ ] oui	[ ] non

2. Veuillez formuler les observations que vous pourriez avoir au sujet de votre expérience avec le Secrétariat du CER.

III. ÉVALUATION DU COMITÉ D'ÉTHIQUE DE LA RECHERCHE

1. Le Comité d'éthique de la recherche…

a. vous a-t-il octroyé le temps nécessaire pour discuter de votre demande (au cours de la réunion)?	[ ] oui	[ ] non
b. vous a-t-il communiqué sa décision en temps opportun?	[ ] oui	[ ] non
c. vous a-t-il clairement communiqué sa décision?	[ ] oui	[ ] non
s'est-il efforcé de traiter les demandes exigeant une évaluation rapide?	[ ] oui	[ ] non

2. Désirez-vous formuler d'autres observations sur la manière dont le Comité d'éthique de la recherche vous a communiqué sa décision?

3. Combien de temps vous a-t-il fallu pour obtenir l'approbation du Comité d'éthique de la recherche de Santé Canada, depuis le moment où vous avez déposé votre demande, jusqu'au moment où la décision vous a été communiquée? Veuillez préciser le nombre de jours ou de semaines.

_ _____ _

4. Veuillez indiquer votre degré de satisfaction quant à l'opportunité et à la durée générales du processus d'évaluation de l'éthique de la recherche de Santé Canada.

Très insatisfait	Insatisfait	Sans opinion	Satisfait	Très satisfait
1	2	3	4	5

5. Veuillez nous fournir des renseignements supplémentaires sur l'opportunité et la durée générales du processus d'évaluation de l'éthique de la recherche.

6a. Trouvez-vous qu'il est utile de se présenter en personne devant le CER ou de communiquer avec le comité par téléconférence?

[ ] oui [ ] non

b. Veuillez formuler des observations quant à votre expérience.

IV. ORIENTATION

1a. Avez-vous assisté à une séance d'orientation organisée par le Secrétariat du CER?

[ ] oui [ ] non

b. Le cas échéant, avez-vous trouvé la séance utile?

2a. Avez-vous assisté à la courte présentation sur le Comité d'éthique de la recherche que le Secrétariat du CER a donnée?

[ ] oui [ ] non

b. Le cas échéant, avez-vous trouvé la séance utile?

3. Avez-vous des suggestions à faire en ce qui concerne les activités que le Secrétariat devrait entreprendre pour aider les chercheurs de Santé Canada à régler les questions relatives à l'éthique de la recherche?

V. Perception de la valeur de l'évaluation de l'éthique

1. Les énoncés suivants ont trait à la valeur du processus d'évaluation de l'éthique de la recherche de Santé Canada. Veuillez indiquer à quel point vous approuvez ces énoncés.

	Pas du tout d'accord	Pas d'accord	Sans opinion	D'accord	Tout à fait d'accord
Le CER a entrepris une évaluation indépendante de l'éthique de mon projet de recherche.	1	2	3	4	5
b. Les observations émises par les membres du Comité ont accru mon niveau de sensibilisation sur les questions d'éthique rattachées à mon projet de recherche.	1	2	3	4	5
c. À la suite du processus d'évaluation, mon projet de recherche est plus crédible.	1	2	3	4	5
d. À la suite du processus d'évaluation, mon projet de recherche est plus objectif.	1	2	3	4	5
e. Le processus d'évaluation protège les sujets humains qui ont participé à mon projet de recherche.	1	2	3	4	5

L'évaluation de l'éthique est une condition préalable à la publication de ma recherche.	1	2	3	4	5

2. Sur une échelle allant de 1 (aucune valeur) à 5 (une valeur de taille), veuillez coter la valeur que le processus d'évaluation de l'éthique de la recherche de Santé Canada procure à votre recherche.

Aucune valeur				Une valeur de taille
1	2	3	4	5

3. Si vous avez indiqué une valeur de trois ou moins, veuillez faire des suggestions visant à accroître la valeur du processus d'évaluation.

VI. Observations finales quant au processus d'évaluation de l'éthique de la recherche de Santé Canada.

1.Veuillez indiquer votre degré de satisfaction général relativement au processus d'évaluation de l'éthique de la recherche de Santé Canada.

Très insatisfait	Insatisfait	Sans opinion	Satisfait	Très satisfait
1	2	3	4	5

2.Veuillez citer des possibilités d'améliorer le processus d'évaluation de l'éthique de la recherche de Santé Canada.

b. Health Canada Research Ethics Board - Researcher Survey

This survey refers to your experience with the Health Canada Research Ethics Board (REB). Please answer all questions in reference to your most recent approval experience with this Board.

Note: If your approval is still pending, only answer those questions that apply to

I. Background questions

1. What is the current review status of your project?
[ ] approval pending

[ ] approval granted

[ ] awaiting annual re-approval

[ ] research re-approved for an additional year

[ ] research completed and termination form submitted

2. If your initial application was approved, was it
[ ] approved as submitted [ ] approved with conditions

3. How is your research classified?
[ ] intra-mural research

[ ] research carried out on Health Canada premises

[ ] research undertaken in collaboration or partnership with Health Canada

[ ] research funded by Health Canada Grants and Contributions

[ ] contract research

[ ] other (please specify) _____

4. How did you become aware of the REB?

[ ] Health Canada Broadcast News

[ ] Presentation by the REB Secretariat

[ ] Training/Orientation Session from the REB Secretariat

[ ] Communication from Senior management or other colleagues

[ ] other (please specify) _____

II. Preparing the Application

A. Documentation and Process

1. Please rate your level of satisfaction with the following aspects about preparing the application.

	very dissatisfied	Dissatisfied	Neutral	Satisfied	very satisfied
a. clarity about whether research qualifies for full or expedited review	1	2	3	4	5
b. clearly outlined steps involved in the review process	1	2	3	4	5
c. clarity about the five main components of the application package to be completed	1	2	3	4	5
d. clarity about which forms need to be completed for a particular type of review	1	2	3	4	5
e. thoroughness and clarity of printed resources	1	2	3	4	5
f. thoroughness and clarity of electronic resources	1	2	3	4	5

2. Please provide additional information about completing application forms.

3. Please rate your level of satisfaction with the amount of time it took to obtain the following information.

	Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied	Not applicable
a. application forms once requested	1	2	3	4	5	6
b. a reply to any of your questions about the application	1	2	3	4	5	6
c. notification of additional requirements you needed to complete the application	1	2	3	4	5	6
d. supporting documents requested	1	2	3	4	5	6

B. The REB Secretariat

Please answer yes or no to the following statements about the REB Secretariat.

a. The REB Secretariat contact person was accessible.	[ ] yes	[ ] no
The REB Secretariat contact person was helpful with answering questions and providing clarification.	[ ] yes	[ ] no
The REB Secretariat accommodated requests for time sensitive reviews.	[ ] yes	[ ] no

2. Please provide any comments about your experience with the REB Secretariat.

III. The Research Ethics Board Review

Did the Research Ethics Board…

a. give you adequate time to discuss your application at the meeting?	[ ] yes	[ ] no
b. communicate its decision to you in a timely manner?	[ ] yes	[ ] no
c. communicate its decision to you in a clear manner?	[ ] yes	[ ] no
d. accommodate time sensitive reviews?	[ ] yes	[ ] no

Do you have any comments to add about the way in which the Research Ethics Board communicated its decision to you?

3. How long did it take you to obtain ethics approval from the Health Canada

REB from the time of application to the time the decision was communicated to you? Please provide the number of days or weeks.

_____

4. Please rate your satisfaction with the overall timing/length of Health Canada's research ethics review process.

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5

5. Please provide us with any additional information about the timing/length of the approval process.

6a. Did you find the opportunity to appear in front of the REB in person or via teleconference helpful?

[ ] yes [ ] no

b. Please comment on your experience.

IV. Orientation

1a. Have you attended a REB Secretariat Orientation Session?

[ ] yes [ ] no

b. If so, did you find the session of value?

2a. Have you attended a REB Secretariat short presentation on the Research Ethics Board?

[ ] yes [ ] no

b. If so, did you find the presentation to be of value?

3. Do you have any suggestions of what activities the Secretariat could undertake to assist Health Canada Researchers with research ethics issues?

V. Perceived value of ethics review

1. Please rate your level of agreement with the following statements about the value of the Health Canada research ethics review process.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The REB provided an independent review of the ethics of my research proposal.	1	2	3	4	5
The Board members' comments raised my level of awareness about the ethical issues associated with my research.	1	2	3	4	5
The review process provides credibility to my research	1	2	3	4	5
The review process provides integrity to my research.	1	2	3	4	5
e. The review process provides protection to human subjects involved in my research.	1	2	3	4	5
f. Ethics review is necessary in order to publish my research.	1	2	3	4	5

2. On a scale of 1 (no value) to 5 (a great deal of value), please rate the overall value of the Health Canada research ethics review process to your research.

No value A great deal of

				value
1	2	3	4	5

3. If you rated the value as a three or less, please provide your thoughts about how the value of the review process could be improved.

VI. Final thoughts about the Health Canada research ethics review process.

1. Please rate your overall satisfaction with the Health Canada research ethics review process.

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5

2. Please identify opportunities for improvements to the Health Canada research ethics review process.
