Health Canada's Research Ethics Board

ANNUAL REPORT

2008–2009

July 2009

Canada

ABOUT THIS REPORT

This Annual Report of Health Canada's Research Ethics Board (REB) covers the fiscal year 2008–2009 and includes plans for 2009–2010. It is published as part of the Science Policy Directorate'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 Board, key results achieved and also the activities of the REB Secretariat in the Science Policy Directorate, Strategic 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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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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MESSAGE FROM THE CHAIR

The Research Ethics Board (REB) experienced several transitions during the 2008-2009 fiscal year.

First, there was a change in the reporting structure. In place of reporting to the former Office of the Chief Scientist, the REB now reports to the Deputy Minister of Health. In addition, changes were made to membership categories, several new REB members were appointed, and a new REB Chair was appointed. We owe a debt of gratitude to Professor Bernard Dickens who helped create, develop and steer our Board through its first six years of operation, leaving it in a strong position to undertake its work this year.

Amid these transitions, there was an important *unchanging* factor—the hard work and dedication of Yvette Parent, a valued member of the REB Secretariat. She continues to serve as a valued resource to the Board and is an enthusiastic champion of research ethics. We are grateful for her attention to detail and for her support.

During this fiscal year, we reviewed an increasing variety of research ethics applications from within Health Canada, an increasing number of applications from the Public Health Agency of Canada (PHAC), and new applications from First Nations communities. In doing so, we continued to refine the criteria for research proposals.

This included requiring a research-ethics review, and to ensure that we all learn from the research endeavours that are undertaken.

With this point in mind, we continue to greatly appreciate the presence and strength of PHAC representatives on our Board. Further, the REB benefits from good representation from across Canada. This helps keep us informed and updated about concerns and changes in research ethics structures and reviews across Canada. While we miss the Board members who recently completed their terms, we have welcomed new members and alternates and the fresh insights they bring to the Board.

As the fiscal year came to a close, we were involved in an orientation to the revisions to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* and we were preparing our own submission in response to those revisions. The Board awaits with interest the final outcomes of these intensive efforts.

It has been a great honour to Chair this REB this past year. I look forward to the increasing challenges and the opportunities we have to enhance research ethics review in the coming year.

Janet L. Storch,
RN, BScN, MHSA, PhD,
DSc (Hon)
Chair, Health Canada
Research Ethics Board

MESSAGE FROM THE REPORTING AUTHORITY AT HEALTH CANADA

Since its inception, the Research Ethics Board has been supported by a secretariat within Health Canada. Previously via the Office of the Chief Scientist, the REB Secretariat is now located in the Science Policy Directorate of the Strategic Policy Branch.

It's a logical fit. Both Health Canada and the REB members are devoted to the pursuit of excellence in science.

Addressing the ethical conduct of research involving humans means that our scientists today must contend with issues that generate debate that extend well beyond their research activities.

Members of the REB play a pivotal role in balancing potential opportunities for improving health with ethical challenges and potential risks posed by scientific research involving humans.

I commend the work of Health Canada's REB, and thank them for their dedication and hard work. Having developed the tools needed, the Board contributes to fostering and continuously improving a culture of research ethics within Health Canada—and that's something that can benefit Canadians everywhere.

Pierre J. Charest, Ph.D.

MESSAGE FROM THE REPORTING AUTHORITY AT THE PUBLIC HEALTH AGENCY OF CANADA

The Public Health Agency of Canada (PHAC) is committed to the highest standards of excellence in scientific research and public health innovation.

Reaching these standards is made possible thanks to the assistance of the Health Canada's REB, which reviews all Agency research involving humans to ensure it is carried out in an ethically sound manner.

This report highlights another successful year for the REB. It also notes the steps taken by PHAC in 2008–2009 to strengthen its commitment to ethics reviews of research projects.

As Senior Assistant Deputy Minister, I was appointed by the Chief Public Health Officer, Dr. David Butler Jones, as the Agency's reporting authority responsible for approving research. In that capacity, I wish to express my appreciation to the members of the Health Canada's REB for their dedication in reviewing the ethics of Agency research projects.

REB members contribute numerous volunteer hours reviewing research protocols. Their work in support of protecting human subjects is to be commended.

Ms. Jane Billings

1. OPERATIONS

LEADERSHIP & AUTHORITY

Health Canada's Research Ethics Board (REB) was founded in 2002 by the Deputy Minister of Health Canada as an independent advisory body. Its role is to help ensure that all research involving human subjects carried out or funded by Health Canada and/or 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.

Authority of the REB

Currently, the REB reports to the Deputy Minister of Health Canada. It makes recommendations to the reporting authorities on whether to approve, reject, modify or terminate any proposed or ongoing research involving humans, conducted by or on behalf of Health Canada and/or PHAC. The Board reviews applications of proposed research projects in accordance with the minimum standards set forth in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (*TCPS*).

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.

Independence of the REB

To help ensure the independence of the REB, the Deputy Minister of Health Canada is not directly responsible for setting the Board's research priorities, for developing research protocols, or for funding decisions linked to research. The REB's independence is further strengthened by ensuring that the Board's terms of reference, membership and operating procedures are publicly available.

A new reporting structure

Prior to the 2008–2009 fiscal year, the REB was reporting to the Office of the Chief Scientist (OCS). In February 2008, as a result of a departmental review, the OCS was integrated fully into Health Canada to become part of the department's Strategic Policy Branch. This move gave science a more visible role in the department and served to support evidence-based decision making.

As a result, the Science Policy Directorate (SPD) was created within the Strategic Policy Branch, comprising the former OCS (including the Research Ethics Board's Secretariat), the department's Biotechnology Office, and the Health Services Policy Division. On the recommendation of the SPB, responsibilities over REB matters were retained by the Deputy Minister of Health Canada.

The new Science Policy Directorate (SPD) provides leadership to integrate a strong science foundation and evidence into departmental decision-making. In carrying out its mandate, the SPD promotes a strategic approach to science policy issues as well as tasks that involve a range of organizations. The outcome is a strengthened departmental science culture in which the SPD acts as a champion, facilitator and coordinator. It works closely with the science and policy communities within Health Canada, as well as with partners and stakeholders.

Staffing and delegated authority

Following the August 2008 appointment of Dr. Pierre Charest as Director General for the SPD, the Deputy Minister of Health Canada acted on a recommendation by the SPB, and delegated to that position the reporting authority for the REB.

As a result, the Director General of SPD is now responsible (in a delegated capacity) for:

- the approval, rejection, modification or termination of research projects reviewed by the Health Canada's REB;
- the research ethics functions within Health Canada;
- applying the Health Canada research ethics policy and the standards contained in the TCPS within Health Canada.

As for the Public Health Agency of Canada (PHAC), in January 2009, the Chief Public Health Officer appointed Ms. Jane Billings, Senior Assistant Deputy Minister of Planning and Public Health Integration as the Reporting Authority for all REB matters pertaining to 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.

SCOPE & MEMBERSHIP

The scope of activities of the REB involves reviewing all research activities 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.

In fiscal year 2008–2009, the REB reported directly to the Deputy Minister of Health Canada and made recommendations to the Reporting Authorities of Health Canada/PHAC on the reviews undertaken by the Board members on all proposed research projects involving humans.

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 REB. 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;

Tenure

REB full-time members, alternate members and the REB Chair are appointed by the Deputy Minister of Health Canada for a three-year term. The terms of the membership for the full members, alternate members and the Chair may be renewed to ensure the continued availability of qualified members on the REB, in light of the highly specialized knowledge and experience required. Alternate members may be appointed by the Deputy Minister to possibly serve out the remaining term of a full member who resigns from the Board.

- One member representing the community-at-large; and
- One member representing Aboriginal communities.

Together, these members ensure that Health Canada/PHAC applies a consistent approach to ethics reviews of research involving human subjects.

Alternate Membership

As provided under the *TCPS*, the REB nominates substitute members so that the Board is not hindered by illness or other unforeseen circumstances. The use of alternate members is not to alter the membership structure of the Board. Furthermore, they help ensure that the REB always has adequate expertise to hold an ethical review and uphold the ethical guidelines elaborated 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;
- One member representing the community-at-large; and
- One member representing Aboriginal communities.

Ethically-sound research

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

- The potential benefits of the research project significantly outweigh 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.

ROLES & RESPONSIBILITIES

The following highlights the roles and responsibilities of all key positions within the REB, specially the Reporting Authority, the Chair, full-time and alternate members, as well as the REB Secretariat.

The Reporting Authority is responsible for implementing Health Canada or the PHAC's research ethics policy, specifically:

- Conveying in writing, the REB ethics decisions to the Principal Investigator;
- Directing (in writing) that researchers must submit their proposals to the REB if they have not already done so;
- Directing (in writing) that the research be suspended if it has not received an ethics review or if there is reason to believe it is proceeding contrary to the decisions of the REB; and
- Advising the Deputy Minister of Health Canada on the REB and its decisions on an annual basis.

The REB Chair is responsible for the overall management of the Board and its ethics review process. The duties include:

- Determining if proposals for research involving humans are suitable for expedited review;
- Reaching a decision on whether to allow the proposed research to proceed on ethical grounds;
- Conveying (in writing) the REB ethics decisions to the Reporting Authority of Health Canada or PHAC;
- Promptly reporting to the Reporting Authority the suspension or termination of approved research project within Health Canada or PHAC;
- Speaking and writing on behalf of the REB;
- Developing guidelines and procedures for implementing the requirements of this policy consistent with the needs of the relevant research disciplines served by the REB;
- Monitoring the REB's decisions for consistency and ensuring that these decisions are recorded properly;

Addressing conflict-of-interest matters and other disclosures

All REB members have been advised of—and comply with—Health Canada's Policy on Conflict of Interest. Members comply with the Treasury Board Secretariat's *Values and Ethics Code for the Public Service.* REB members are also informed of the Health Canada's Policy on the Management of Advisory Committees. This requires that all external advisors to Health Canada make a formal disclosure of real, potential or perceived situations of conflict of interest prior to providing service and during their term of service. The REB also ensures, in accordance with the *TCPS*, that a member who has declared a conflict of interest is not present when the REB is discussing or making its decisions. In such circumstances, the member recuses himself/herself from the review, when deemed necessary by the Chair.

- Ensuring that researchers are given written communication of the REB's decisions (with reasons for negative ethics decisions);
- Conducting the continuing review of ongoing research projects, amendments and any adverse events reported by the principal investigators;
- Promptly reporting any adverse events, suspension or termination of research project to the Reporting Authority of Health Canada and/or PHAC and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken; and
- Providing an Annual Report on REB activities to the Reporting Authority of Health Canada or the PHAC.

The REB full-time and alternate members ensure that all research involving humans carried out by Health Canada/PHAC meets the highest ethical standards, and that safeguards provide the greatest protection to participants who serve as research subjects. Duties include:

- Undertaking timely ethics reviews of proposed research projects;
- Conducting the continuing ethics review of ongoing research projects, amendments and any adverse events reported by the principal investigators;
- Providing their professional opinions to the Reporting Authority of Health Canada and/or PHAC as to whether the research projects should proceed as submitted;
- Requesting that additional information be provided by the researchers in order to conclude the ethics review of the research projects;

- Reviewing and monitoring of additional information requested by the REB to ensure compliance with the *TCPS*;
- Assisting in the development of guidelines and procedures for implementing the requirements of this policy consistent with the needs of the relevant research disciplines served by the REB;
- Assisting in the monitoring of the REB's ethics decisions for consistency and ensuring that these decisions are recorded properly by the REB Secretariat;
- Assisting the REB Secretariat in preparing the Annual Report to be submitted to the Reporting Authority in Health Canada and/or the PHAC.

The REB Secretariat manages all the administrative affairs of the REB and is responsible for:

- Organizing the REB meetings and meeting agendas;
- Managing all applications received from Health Canada and the PHAC;
- Developing REB policies and procedures, and operational guidelines for REB and senior management approval;
- Preparing all certificates of ethics approval for the REB Chair's signature on all approved research protocols;
- Communicating with principal investigators (PIs) on the required revisions to be made to the proposed research project as recommended by the REB;
- Seeking additional information from the PIs as required by the REB to conclude the ethics review of a proposed research project;
- Seeking (in between meetings) the REB's ethics approval on the additional information provided by the PIs in response to the comments raised by the REB members;
- Following-up with members of the REB who were present at a Board meeting to seek feedback and approval on outstanding research protocols;
- Producing the minutes of the REB meetings, summarizing all REB members' comments and documenting this in a final email to the members for their feedback and approval;
- Consulting with REB member(s) not in attendance at a Board meeting and seeking further expertise and comments on specific issues;

- In the absence of an REB member at an upcoming Board meeting, providing that member's comments to the Board on matters related to a specific research project under review by the REB;
- Receiving, in writing, confirmation from researchers that the research will be carried out in accordance with the protocol as approved by the REB and conveying this information back to the Chair and the Reporting Authority;
- Dealing with all communications regarding individual applications submitted to the REB;
- Developing and delivering Health Canada training programs on the REB; and
- Maintaining the REB website.

2. OUTCOMES FOR 2008–2009

The following section highlights the key outcomes achieved by the REB during the 2008–2009 fiscal year.

APPOINTMENT OF REB MEMBERS

During 2008–2009, the Deputy Minister of Health Canada made the following appointments to the membership of the Research Ethics Board, based on recommendations by the SPB:

- Dr. Janet Storch (University of Victoria) as the Chair of the REB, effective June 12, 2008;
- Ms. Jean R. House (Newfoundland and Labrador), reappointed to a second three-year term as a full-time member of the REB; and
- Dr. Agnes Klein (Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products in the Biologics and Genetic Therapies Directorate, Health Products and Food Branch), reappointed to a third three-year term as a full-time member of the REB.

Furthermore, in August 2008, the Chair of the REB nominated Dr. Barbara McGillivray (University of British Columbia) as the Deputy Chair of the Health Canada REB.

See Appendix A of this report for a complete listing of the revised Health Canada REB membership.

APPOINTMENT OF REB ALTERNATE MEMBERS

During 2008–2009, the REB had two vacancies for alternate membership: (1) a researcher from outside the department; and (2) a community representative.

As is customary, the SPD consulted with the Chair of the Board, with other REB members, and with the National Council on Ethics in Human Research (NCEHR) to identify suitable candidates to fill these vacancies. On its recommendation, the Deputy Minister appointed:

- Dr. Kathleen Oberle (University of Calgary); and
- Ms. Wendy McBride (community representative).

REVISED GUIDELINES, POLICIES AND PROCEDURES

In 2008, on the advice of the SPD, revisions were made to the tenure for REB members. This resulted in the elimination of a provision that limited membership to two consecutive three-year terms. This was warranted to ensure the continued availability of qualified members on the REB, particularly in light of the highly specialized knowledge and experience required by the Board.

Furthermore, in early 2009, the REB Secretariat revised the REB policies and procedures manual, including the following new sections:

- Responsibilities of Researchers
- Conflict of Interest Involving Researchers
- Conflict of Interest Involving REB members
- Special Care Required for Certain Populations

See Appendix B for a detailed summary of each of these items.

ETHICS REVIEW PROCESS

During fiscal year 2008–2009, all research projects involving human subjects carried out for or by Health Canada/PHAC were subject to an ethics review by the Health Canada REB.

The REB undertook an ethics 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/PHAC:

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

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.

REB MEETINGS

Face-to-face meetings are essential for adequate discussion of research proposals, and for the collective education of the REB members. The REB Secretariat posted on its website a schedule of its meetings in 2008–2009, so that researchers could plan their schedules accordingly.

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/PHAC 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.

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*.

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 members and are to be maintained in a confidential manner.

The REB had nine face-to-face meetings in 2008-2009, during which the members:

- Undertook a timely ethics 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

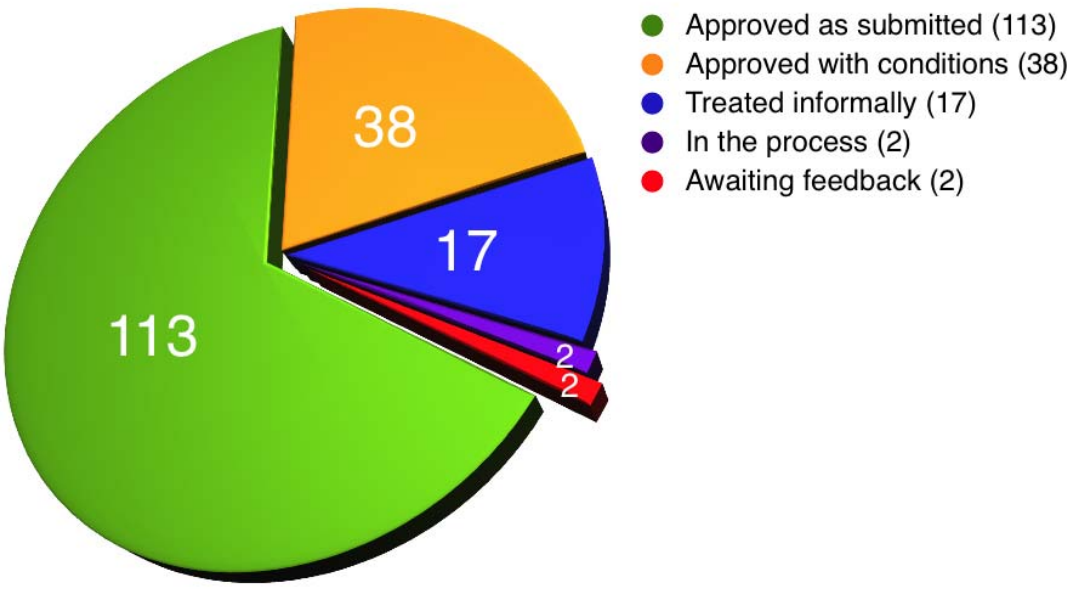
During fiscal year 2008–2009, the REB received 172 applications from researchers from Health Canada and PHAC for an ethics review by the members of the REB. Of these applications, the Board reviewed: 77 new research proposals; 35 amendment reports; 39 annual progress reports; and 21 completion reports.

Of the 77 new research proposals received by the REB, 44 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 172 applications received by the REB in 2008–2009:

- 113 applications were approved as submitted;
- 38 applications were approved once certain REB-mandated conditions or changes had been satisfied;
- 2 applications remained outstanding pending additional information to be provided to the REB by the Principal Investigators;
- 2 applications remained outstanding pending a response from the REB; and
- 17 applications were considered by the REB Chair or REB Secretariat as not requiring an ethics review.

Figure 1: Action taken by REB on applications for ethics review



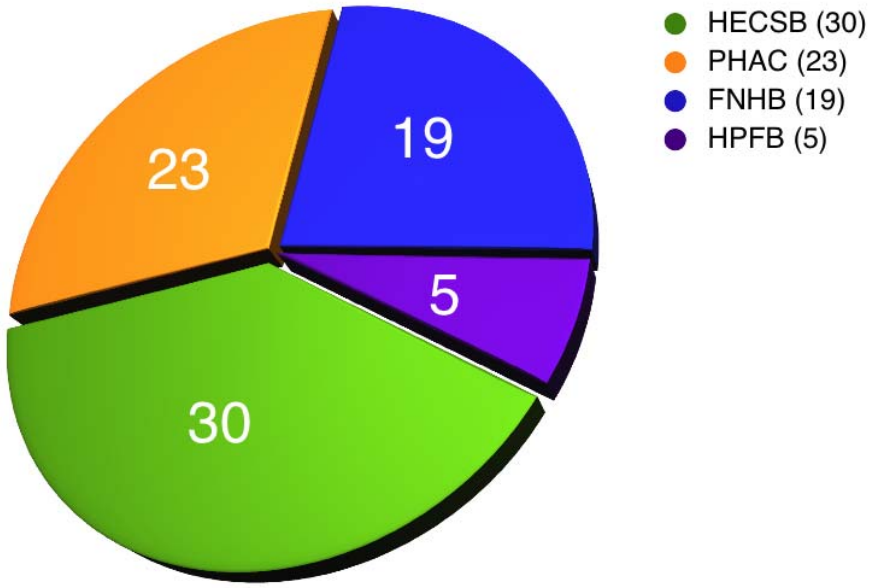
As illustrated in Figure 2, of the 77 new research projects received by the REB Secretariat during fiscal year 2008–2009:

- 23 requests applications were from PHAC; and
- 54 requests were from Health Canada.

Of these 54 new research projects received from Health Canada researchers:

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

Figure 2: Origins of requests for ethics review



FEEDBACK FROM REB MEMBERS

The REB Secretariat contracted Praxis Research in 2008–2009 to undertake an independent survey of all REB members to determine member satisfaction with its services. The information obtained from the survey is intended to help the Secretariat and SPD to maintain or improve performance as needed and make plans for the future.

The survey was designed to seek comments from the REB members on their experiences in the following areas: meetings, support, priorities of the REB and training.

The results of this survey indicated that REB members have an overwhelmingly positive view of the work of the Secretariat. There were also a very small number of negative responses to the questions posed. In addition, there were suggestions on how to improve processes and support for REB members while conducting ethics reviews of research projects involving humans.

Improvements that were suggested by the REB members included the following:

- Participation in the collaboration of ethics review with other agencies (e.g., PHAC and CIHR);
- Continue development of tools used in the ethics review process (i.e., electronic forms that can be submitted online);
- Provide additional support where possible to members who feel overburdened;
- Provide a means for REB members to better understand background, experiences of other members, and their connections to other agencies to make best use of each individual on the Board;
- Although the REB members all felt the presentations to the REB by researchers were satisfactory, they were split on whether the Secretariat should be doing more to help researchers prepare;
- Training initiatives including—but not limited to—additional education in ethical review of public health research, ensuring that newer members without REB experience receive adequate training and discussion of the new TCPS guidelines;
- Members indicated room for policy development and suggested some areas for consideration; and
- Taking steps to reduce the amount of time required for Health Canada to reimburse expenses to REB members.

The Praxis Report can be viewed under *Appendix C – Health Canada Research Ethics Board Members Survey 2008–2009*.

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, three orientation seminars were organized in 2008–2009 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.

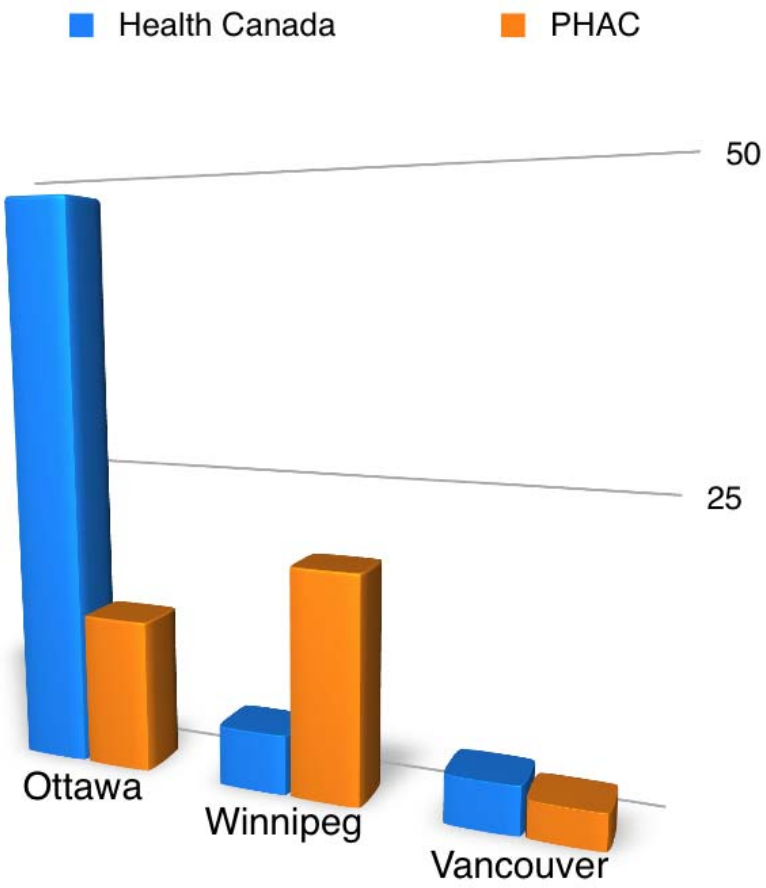
A total of 93 participants attended these sessions, which were held in Winnipeg on September 11, 2008, (24 participants), in Ottawa on January 28, 2009, (62 participants), and in Vancouver on March 13, 2009, (7 participants). In Winnipeg, 19 participants were from PHAC, and five were from Health Canada. In Ottawa, 13 participants were from PHAC and 48 from Health Canada. Of these 48 participants, the following branches were represented:

- 16 were from Healthy Environments and Consumer Safety Branch (HECSB);
- 18 were from Health Products and Food Branch (HPFB);
- six were from Strategic Policy Branch;
- two were from Chief Financial Officer Branch (CFOB);
- two were from Public Affairs, Consultation and Communications Branch (PACCB);
- four were from First Nations and Inuit Health Branch (FNIHB).

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.

At the Winnipeg session, the REB Secretariat was accompanied by Mr. Jean Francois Luc (Director, Policy and Partnerships, Public Health Agency of Canada's Office of Public Health Practice in Ottawa). Also from PHAC was Ms. Mireille Lacroix (Senior Policy Analyst, Public Health Law and Ethics Program). Also present was Ms. Lina Al-Karkhi (Manager of the Public Health Law and Ethics Program).

Figure 4: Breakdown by branch of attendance at REB information sessions (2008–2009)



REB SECRETARIAT ACTIVITIES

Site visit by the National Council on Ethics in Human Research

In 2008, the National Council on Ethics in Human Research (NCEHR) was contracted to perform a site visit of the Research Ethics Board at Health Canada.

The objectives of the NCEHR site visit were to:

- Discuss the process of ethics review with the responsible people, 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, as well as other international guidelines; and
- Identify means by which the quality of ethics review and participant protection may be enhanced.

In August 2008, the final report on the NCHER site visit of the Health Canada REB was presented by Dr. Padraig Darby (President of the NCHER), at a meeting with REB Secretariat officials. The report highlighted the perceived strengths of the Board's ethical review process, specifically:

- The Board's commitment to—and familiarity with—human research ethics within Health Canada remains very strong;
- The current accountability arrangement (i.e., REB is an external advisory body accountable directly to the Deputy Minister) minimizes the perception of conflict-of-interest;
- The membership of the REB is exceptionally strong and includes recognized expertise on research ethics from across Canada. In addition, the membership includes strong scientific expertise in a number of disciplines relevant to the nature of the research reviewed by the REB.

- The Chair is skilled at guiding the REB to reaching a decision while encouraging input from all members.
- The support from the ethics office (REB Secretariat) to the both the REB and researchers is strong and knowledgeable.
- The resources allocated to the REB and the general ethics operation is impressive.
- There is a comprehensive website available to researchers and the public.
- Responsibility for policy development, as contained in the Operational Guidelines document, is located in the ethics office.

The Evaluation Team also addressed some concerns regarding aspects of the REB's ethical review process, particularly: conflicts-of-interest, the U.S. Federal-Wide Assurance, and criteria for expedited reviews. In response to the final report on the NCEHR site visit, REB members indicated that this document would be very helpful in assisting the Board as well as the REB Secretariat in making modifications to the existing REB policies and procedures.

Proposed revisions to *Tri-Council Policy Statement* (TCPS)

In February 2009, Ms. Susan Zimmerman (Executive Director, Interagency Secretariat on Research Ethics) made a presentation to the REB, recapping the proposed revisions to the TCPS. Topics included: definition of the TCPS; why revisions are being proposed; an outline of consultation received to date; policy premise; ethics framework; and an update of core principles.

Ms. Zimmerman concluded by providing a summary of next steps:

- Completion of consultations and submission of written comments by March 31, 2009; and
- Revision of the proposed draft to integrate consultation feedback between April and June 2009.

The targeted date for the release of the revised draft is autumn 2009. Next, in February 2010, the Panel will submit a final revision to three agencies: Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) for their consideration.

The REB members had several discussions in regards to these proposed changes to the TCPS and provided their comments in a response to the Secretariat by the established deadline.

Canadian Institutes of Health Research's guidelines for health research involving Aboriginal peoples

Guidelines have been produced by the Ethics Office of the Canadian Institutes of Health Research (CIHR), in conjunction with its Institute of Aboriginal Peoples' Health. Their purpose is to assist researchers and institutions in carrying out ethical and culturally competent research involving Aboriginal peoples. They are also intended to promote health through research that is in keeping with Aboriginal values and traditions. These guidelines will assist in developing research partnerships that will encourage mutually beneficial and culturally competent research. Moreover, they will promote ethics reviews that enable and facilitate rather than suppress or obstruct research.

The guidelines are applicable to researchers carrying out research to which CIHR has made a financial contribution. The CIHR has indicated that these guidelines are not regulations. Nor are they meant to be of general application. They should be followed by anyone who carries out research involving Aboriginal peoples in Canada. The REB Secretariat has made reference to these guidelines in the REB Policy and Procedures Manual (to be posted on the REB website by Summer 2009).

U.S. Federal-Wide Assurance

The U.S. Department of Health and Human Services (DHHS) is the principal federal agency responsible for protecting the health of Americans. Under U.S. law, foreign institutions engaged in research projects involving human subjects that are funded, supported or conducted by the DHHS must have a Research Ethics Board in place to review research proposals in a manner that is equivalent what is required by federal laws. Further, any such foreign institution may not collaborate with DHHS-supported agencies unless a formal agreement is signed, attesting that

the foreign institution's REB is following procedures equivalent to those followed in the United States.

When a Federal-Wide Assurance (FWA) is reached, it provides assurance that the research involving humans will be carried out in accordance with the specified ethical principles, and that in the case of a Canadian REB, the latter will be guided by the Canada's Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans (TCPS).

Since Health Canada already meets and exceeds the U.S. requirements, in September 2008, the SPD recommended that the Deputy Minister of Health Canada sign an FWA. In doing so, it now allows Health Canada's researchers to continue collaborating with their U.S. counterparts.

Michael Enzle Annual Memorial Prize

Dr. Michael Enzle was a member of the Research Ethics Board at Health Canada from 2002 until his death in 2007 after a lengthy illness. In his memory, the Michael Enzle Award was established at the NCEHR's 2008 National Conference. It celebrates his life and helps ensure that his work continues to be carried on in fostering excellence in human research ethics. In particular, this award focuses on Dr. Enzle's commitment to educating and mentoring excellence in the education and training of graduate students doing research in ethics and the protection of human participants in research.

MEETING ANNUAL GOALS

As illustrated in the table below, the REB Secretariat was diligent in setting and meeting goals for itself during the 2008–2009 fiscal year.

Results and actions by the REB Secretariat to meet 2008–2009 goals

Goals	Results
Refine REB procedure and guidelines.	Since research ethics is a continually evolving subject, the REB's policies and procedures may be revised periodically. During 2008–2009, the REB Secretariat was responsible for maintaining an up-to-date manual of REB policies and procedures, and for posting these on the REB website.
Organize the REB's meetings and manage all applications submitted for an ethical review.	The REB Secretariat managed nine meetings during the fiscal year—each in an efficient, effective manner to the satisfaction of REB members. It also reviewed all applications requiring an ethical review by REB members.
Deal with all communications regarding individual applications.	Communicated the results of the ethics review to all investigators in an efficient and timely manner to the satisfaction of the researchers.
Investigate options for allowing researchers to submit electronically their research ethics applications	REB Secretariat continues to work with departmental officials to develop an electronic submission form for research applications.
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.
Elaborate a policy on research with vulnerable persons.	The revised REB Policy and Procedures Manual contains a section on vulnerable persons.

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 2008–2009.
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 2009–2010, including in regions outside of the National Capital Region.	REB Secretariat, in consultation with NCEHR, provided three orientation seminars: one in Winnipeg, in Ottawa and in Vancouver.
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.	An educational session for the REB members was organized and keynote speakers were invited to brief the members on the new Aboriginal guidelines.
Develop a policy to address and resolve conflicts of interest for researchers in relationship with Health Canada and the REB.	Developed a conflict of interest policy and the processes was incorporated within the REB Policy and Procedures Manual. These are to be posted by the summer of 2009.
Continue to revise the REB Policies and Procedures Manual to address compliance issues with U.S. Federal-Wide Assurance.	The revised REB Policy and Procedures Manual was approved by the REB members. Currently, the REB Secretariat is working with officials to post this material on REB website.
Update of the REB Network for Board members.	The REB Secretariat was responsible for ensuring that the REB Network was kept up-to-date throughout 2008–2009.
Develop a Compliance Officer position within the REB Secretariat for monitoring research protocols approved by the REB.	The REB Secretariat worked with Health Canada to draft a position within the REB Secretariat for an officer to monitor all research projects approved by the REB over the last seven years.

LOOKING AHEAD FOR 2009–2010

During fiscal year 2008–2009, the REB and its 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 2009–2010, 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 REB 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 2009–2010. It will:

- Continue to refine REB procedures and guidelines, while managing and providing Secretariat services to the Board;
- Organize the REB's meetings and manage all applications submitted for an ethics review by the REB, including all communications regarding individual applications;
- Develop a policy to address compensation issues pertaining to research participants;
- Work with PHAC to establish a joint REB between PHAC and Health Canada;
- Continue in working collaboratively with Health Canada to finalize the development of a Monitoring Officer's position within the REB Secretariat for monitoring research protocols approved by the Board;
- 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, including regions outside of the National Capital Region; and
- 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.

3. ACKNOWLEDGEMENTS

The Health Canada Research Ethics Board and its Secretariat wishes to thank and acknowledge a number of individuals that it had the pleasure of working with during the past fiscal year.

DEPARTURES FROM THE REB

The following individuals are to be highly praised for their hard work and dedication during their tenure on the Research Ethics Board. It is hoped that their time on the REB has been as rewarding for them as it has been for Health Canada. The department takes this opportunity to wish them success in their future endeavours.

Full-time Members

Bernard Dickens, O.C., Ph.D., LL.D., F.R.S.C. — Dr. Dickens was appointed to the Health Canada REB as the Chair of the REB from June 2002 to June 2008. He 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.

George C. Webster, B.A., M.A., S.T.B., M.Div., D.Min. — Dr. Webster served the REB as an ethicist from June 2002 to June 2008. He is currently a Clinical Ethicist with the Health Care Ethics Service at St. Boniface General Hospital in Winnipeg, Manitoba. From 1982 to 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. He is currently a member of the Canadian Institutes of Health Research

(CIHR), Governing Council, Standing Committee on Ethics (SCE). In addition, 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.

Thomas Wong, MD, MPH, FRCPC — Dr. Wong was appointed to the Health Canada REB as a researcher within the Public Health Agency of Canada (PHAC). He is the Director of Community Acquired Infections Division within PHAC'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 the Emerging Infectious Disease Research Network and the Canadian Sexually Transmitted Infections Expert Working Group.

Alternate Members

Monique Martineau-Enzle — Nominated to the REB by Lupus Canada as a Community Representative, Mrs. Martineau-Enzle served on the Board from June 2002 to June 2008. Previously, 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 organizations. She served on the Board of Directors of Lupus Canada for several years, as well as two-year term as Vice-President of Lupus Canada. She also 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, and edited the French version of "*Lupus-Disease of 1000 Faces.*"

Rae Mitten, LL.B., LL.M. Ph.D. Student — In November 2005**,** Ms. Mitten was nominated to the Health Canada Research Ethics Board as an external researcher. She 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.

In addition, 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:

Dr. Marlene Brant Castellano, MPH. **—** Dr. Castellano was invited to join the REB members at a special event that was held in Ottawa on June 11, 2008, to say goodbye to those REB members who were departing after completing their full terms, and to welcome new appointees to the Board. Dr. Castellano made an excellent presentation on Aboriginal matters and briefed the REB members on the release of the CIHR Guidelines for Health Research Involving Aboriginal People. Dr. Castellano is a Professor Emeritus of Trent University (Indigenous Studies), a member of the Interagency Advisory Panel on Research Ethics (PRE) and Chair of PRE's Aboriginal Research Ethics Initiative. She has also served on the Institute Advisory Board of the Canadian Institutes of Health Research on Aboriginal Peoples' Health from its inception in 2001 until 2006.

Dr. Padraig Darby, President of NCEHR, assisted the REB Secretariat by providing two orientation seminars in fiscal year 2008–2009 (one in Winnipeg and the other in Ottawa) to all researchers and managers of both Health Canada and the PHAC. Dr. Darby presented his point of view on the *Tri-Council Policy Statement*. It was a valuable exchange of information between the presenter and the participants that attended these orientation seminars.

APPENDIX A: MEMBERSHIP OF HEALTH CANADA'S RESEARCH ETHICS BOARD

FULL-TIME MEMBERS

Chair

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-1970s. 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 1994–2002. 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 a 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. Prior to 1990, she was Professor and Director of the Masters in Health Administration Program at the University of Alberta. Her academic training includes a BScN, an MHSA and a PhD in Sociology, as well as a certificate from her studies at the Kennedy Institute of Ethics in Washington, D.C. Dr. Storch remains active 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 within Health Canada. A scholar in residence at the Canadian Nurses Association in 2001–2002, she continues to work with CNA in the review and revision of their code of ethics for registered nurses, as well as in developing research ethics guidelines for registered nurses.

Law

Robert P. Kouri, B.A., LL.L., M.C.L., D.C.L. — Dr. Kouri is professor of law at the Faculté de droit at the University of Sherbrooke. He teaches and pursues research in Health Law and Civil Law. He has published *"La responsabilité civile médicale"* [Medical civil liability] (in collaboration with Alain Bernardot), *"L'intégrité de la personne et le consentement aux soins"* 2nd edition [Inviolability of the person and consent to care] (in collaboration with Suzanne Philips-Nootens), *"Éléments de responsabilité civile médicale"*, 3rd edition [Elements of medical civil liability] (in collaboration with Suzanne Philips-Nootens and Pauline Lesage-Jarjoura), *"Le mandat donné en prevision de l'inaptitude"* [Mandate given in anticipation of incapacity](in collaboration with Lucie Laflamme and Suzanne Philips-Nootens), as well as several articles. Dr. 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 lecturer 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 chair of the Groupe de recherche en politiques de la santé at the University of Sherbrooke, and is a member of 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 as well as Associate Dean (Research) at the University of Sherbrooke.

Researcher External to Health Canada

Barbara McGillivray, MD, FRCPC, FCCMG — Dr. McGillivray is a professor and clinical geneticist at the University of British Columbia's Department of Medical Genetics. Her 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. Most recently, she participated 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). She 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 1974, and has occupied many scientific and management positions within the department and its regulatory arms. This includes having acted as the Director of the Bureau of Human Prescription Drugs, and as Director for the Biologics and Genetic Therapies Evaluation Centre. From 2001–2004, 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 Acting 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. Some four years later in 1992, he joined Health Canada's Bureau of Communicable Disease Epidemiology 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. He then became Senior Advisor on Scientific Affairs in the Center 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, Dr. Sutherland returned to Canada to become Executive Director of International Public Health of the Public Health Agency of Canada based in Ottawa.

Ethicist

Glenn G. Griener, Ph.D. — Dr. Griener is an Associate Professor at the University of Alberta and a philosopher specializing in health ethics and research ethics, with a joint appointment to the School of Public Health and the Department of Philosophy. He is also a member of the John Dossetor Health Ethics Centre. He has had regular responsibility for teaching ethics to students in nursing and pharmacy. Dr. Griener also teaches in the occupational medicine, surgery and psychiatry residency programs, and offers an interdisciplinary graduate seminar in research ethics that is open to students from across campus.

Community Member – General population

Jean R. House, B.A., B.Ed., LL.B. — Ms. House is presently retired. She was a lawyer (non-practising status), 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). Ms. House 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. from New York State University at Potsdam College, majoring in biology, and an M.S. in Epidemiology at the University of Ottawa. She 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 developed in the early 1980s 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.

ALTERNATE MEMBERS

Law

Ms. Julie Samuël — Ms. Samuël holds a Bachelor of Law degree from Laval University and has been a member of the Quebec Bar since 2001. She also has a Master's degree in law and biotechnology for the University of Montreal. Her thesis analyzes the obligations and the liability of doctors in sport doping. She also performed an internship at the International Olympic Committee, in Lausanne, Switzerland, and served as a research lawyer at the Quebec Court of Appeal under Justices Jacques Delisle and René Dussault. Since 2005, she has worked as a project manager at the Centre de recherche en droit public (University of Montreal). Her research focuses primarily on studies involving children, gene therapy, genetic testing and biobanks. She works on Canada-wide projects involving organizations such as the Stem Cell Network, the National Council on Ethics in Human Research (NCEHR) and the Réseau de médecine génétique appliquée du Québec (RMGA).

Researcher Outside Health Canada

Kathleen Oberle, RN, BscN, MN, PhD — Dr. Oberle is a Professor with the Faculty of Nursing and Adjunct Associate Professor with the Faculty of Medicine at the University of Calgary. Her scholarly interest focuses on clinical and research ethics. Dr. Oberle has been a past member of the CIHR Standing Committee on Ethics, a member of CIHR's review panel for Ethics, Law and the Humanities, and a member of a working subcommittee mandated to revise the Tri-Council Policy statement to make it more user-friendly for qualitative researchers. She was member of the executive of the Canadian Bioethics Society for a number of years. Dr. Oberle's research interests and methods are varied. Qualitative studies have explored doctors' and nurses' perceptions of ethical problems, the effects of cost constraints on ethical decision making in intensive care, and a recent study on the experiences of nurses caring for patients enrolled in clinical trials. In addition, she has conducted psychometric studies to develop

instruments to measure nurses' moral reasoning, parents' attitudes toward research with newborns, nurses' attitudes toward obesity, and health needs of pregnant women. She and several colleagues recently completed a randomized clinical trial to explore the effectiveness of elk velvet antler in managing symptoms of rheumatoid arthritis. Dr. Oberle has been a member of a variety of Research Ethics Boards for approximately 18 years, and for several years taught a graduate course in research ethics. A recently completed textbook titled *Ethics in Canadian Nursing Practice: Navigating the Journey* (co-authored by Shelley Raffin Bouchal) has just been released by Pearson Education.

Health Canada Researcher

Tye Arbuckle, Ph.D. — Dr. Arbuckle has a Ph.D. 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 an 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 during the ethicist's maternity leave. Dr. Coughlin was involved with the Catholic Health Association of Canada in helping to draft the Health Care Ethics Guide and the current Health Ethics Guide, and is a founding member and a Past President of the Canadian Bioethics Society.

Community Representative – General Population

Wendy McBride, BA (York), **MA** (Toronto) — Ms. McBride was the Executive Director of the Canadian Association of Schools of Nursing (CASN) from 1994 until 2005. She has over 20 years of experience as a manager and director in the Canadian federal and provincial governments in a wide range of departments in the social and economic sectors. Her broad experience has included native land-claim settlements, teaching at York University, international health development in West Africa, and strategic planning and priority setting in Health Canada and at the University of Ottawa Health Sciences Complex (which included faculties of medicine and health sciences, teaching hospitals and the District Health Council). As Executive Director of CASN, Ms. McBride represented Canadian academic nursing and research to government, funding agencies, other health organizations, and foreign governments. She directed the Canadian accreditation program for nursing education, was a founding member and co-chair of

the Association of Accrediting Agencies of Canada. She planned and organized national council meetings of university and college schools of nursing, national symposia and workshops on issues, such as Aboriginal health, human resources education, nurse practitioner education, clinical practice, accreditation of nursing education (both in Canada and in North and South America). Since retiring from CASN, Ms. McBride was asked to develop a national strategy for Aboriginal health human resources for Health Canada, and plan a national symposium on that subject.

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, where he teaches Tort 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: SUMMARY OF REVISED REB POLICIES AND PROCEDURES MANUAL

Responsibilities of Researchers

Researchers have the primary responsibility to ensure that their research is carried out in an ethical manner. Investigators play a crucial role in protecting the rights and welfare of human participants, and are responsible for carrying out sound ethical research consistent with research plans approved by the REB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include:

- Obtaining and documenting informed consent of participants or participants' legally authorized representatives prior to the participants' participation in the research;
- Obtaining prior ethics approval from the REB for any modifications of the previously approved research, including modifications to the informed consent process and document; and
- Ensuring that progress reports and requests for continuing review and approval were submitted to the REB in accordance with the REB policy and procedures. Investigators are also responsible for meeting the following requirements:
    - Providing the REB with prompt reports of any unanticipated problems involving risks to participants or others;
    - Providing the REB with prompt reports of serious or continuing noncompliance with the requirements or determinations of the REB; and
    - Keeping certain records as required by the REB for at least three years after completion of the study or as specified in the research protocol.
- Investigators are also responsible for reporting to the research participants any significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation in the study.
- Investigators are responsible for reporting to the Health Canada REB any real, apparent or potential conflict of interest that they may have with their research. Such conflicts should be reported as soon as they emerge. The REB members assess the conflicts and plan the management.

Researchers have to be familiar with and comply with the REB's policies and procedures and other ethical guidelines relevant to their research discipline. It is the responsibility of the researcher to obtain ethics approval as described in this policy for any project involving human participants before starting the

research. If there is uncertainty as to whether the research needed an ethics review and approval, the researcher is encouraged to consult with the REB Secretariat for advice.

Conflict of Interest Involving Researchers

The burden of avoiding or of managing conflicts-of-interest resides first with the individual. Researchers are to conduct themselves with respect of the highest ethical standards elaborated in the *TCPS*. The importance of managing conflicts of interest is in its proper identification and in the way it is dealt with.

Real or apparent conflicts of interest or appearance of one may not have always be avoidable. When unavoidable, there is a need for transparency with these interests. Investigators were responsible for reporting to the Health Canada REB any real, apparent or potential conflict of interest that they may have had with their research. The REB assessed the situation by looking at the likelihood that the conflict of interest could or appear to influence the researcher's judgment by other interests. The REB then assessed the potential harm resulting from these conflicting interests. The REB dealt with the situation accordingly and took the proportionate approach needed. If the existence or the appearance of a conflict of interest from the researcher was noted, then the REB recommended that such be mentioned in the informed consent forms.

Conflict of Interest Involving REB members

REB members may have a variety of conflicts that may bias the decision-making process. Most obviously, a member may be part of the research team undertaking the study under review. As co-workers or academic colleagues, board members would commonly have personal relationships with those submitting protocols for review. Further, while it is helpful for an REB member to have research or clinical experience in the subject matter of the protocol under review, there may also be an element of conflict. An REB decision may impact a member's own work within the institution or other responsibilities within the institution. For example, a member who also works as legal counsel, or in the research programs, may be faced with conflicting obligations. All conflicts of interests were reported to the REB Chair and were dealt with on a case-by-case basis.

Special Care Required for Certain Populations

Special care is required to be undertaken by researchers when their research projects involve vulnerable populations. Vulnerable populations include women, single mothers, Aboriginals, visible minority populations, the homeless, immigrants with insecure status, and street youth. These populations may also include people with psychiatric, cognitive, or developmental disorders and substance abusers, persons

who are mentally incompetent; persons who have been abused; persons with neuro-motor impairment; persons with low socio-economic status; elderly persons; and persons with similar histories which raise concern. Certain contexts may make individuals vulnerable at points in time; for example those in emergency situations.

Children are considered a vulnerable population because they develop decision making skills and related competencies over time. Other vulnerable populations, including those who are institutionalized and may be not be free to choose without coercion or undue influence (e.g., penitentiary inmates).

APPENDIX C: HEALTH CANADA RESEARCH ETHICS BOARD MEMBERS SURVEY (2008–2009)

Link: Health Canada Research Ethics Board Members survey