



Health Canada Research Ethics Board • Annual Report 2004

Continuing to build a culture of research ethics

C O N T A C T U S

For more information about Health Canada's Research Ethics Board, contact the Senior REB Officer at (613) 941-5199, or visit the REB website at www.hc-sc.gc.ca/ocs-besc/advice-avis/reb-cer/reb_e.html

A blue-tinted photograph of a microscope, showing the objective lenses and eyepiece, positioned in the upper left corner of the page.

C O N T E N T S

Foreword	1
About this report	1
About Health Canada's Research Ethics Board	2
Achievements 2004	3
Key activities	3
REB key indicators at a glance	4
REB training activities, presentations and other meetings	5
Feedback	7
Looking ahead	8
How the REB works	9
Background	9
Discussing research proposals	9
Decision-making process	10
Ongoing communications	10
Assistance from the REB Secretariat	10
Profile of Health Canada's Research Ethics Board	11
Members of the Board	11
Appendix A	16
Appendix B	18



A message from the Chairperson of the Research Ethics Board,

I am pleased to introduce the Health Canada Research Ethics Board report for 2004. This second annual report reflects a year of steady progress and consolidation, as the culture of ethical reflection on research involving human participants and population groups progressively permeates the activities in which Health Canada personnel engage. We have gained experience through the feedback provided by several stakeholders in activities, which the Board encourages. The Board looks forward to enriching its membership by adding to its core several colleagues as alternates. The Board welcomes the opportunity to express its appreciation of the excellent, attentive support it has continued to receive through the Office of the Chief Scientist.

Dr. Bernard Dickens

A message from the Acting Chief Scientist (Health Canada),

Two years into operations and I am pleased to note that the Research Ethics Board (REB) is changing the way departmental researchers approach research involving human subjects. The ethics review has become an accepted—even welcome—part of the way we do research at Health Canada.

The 2004 researchers' survey results indicate that researchers appreciate the ethics advice of the REB as well as the timeliness of decisions. As Chief Scientist, I am grateful for the verification of ethics in our research. But the ultimate beneficiaries of their hard work and dedication are the people implicated in the research projects whose human rights and interests are protected by the process. That is our best marker of success.

Dr. Pierre-Gerlier Forest

About this report

This report is published annually to inform the public, Health Canada research staff and other interested stakeholders about the achievements, forward-looking plans and roles of the Health Canada Research Ethics Board (REB). Far more than a recap of the Board's activities, this report documents how Health Canada scientists—from biomedical sciences to the social sciences—are working together to strengthen the vibrant research-ethics culture within the department. This year's report documents how all major goals for 2004 were met—and in some cases exceeded—and provides a glimpse of the REB's proposed activities for 2005. Also featured in this report is a summary of the REB's role and profiles of members of the Board—distinguished professionals who are making a difference in the pursuit and promotion of research ethics at Health Canada.



Achievements 2004

For the REB, 2004 was a year of accomplishments made possible in part by the earlier efforts during the previous years when the Board was first created. Having found its footing in the department (and in a relatively brief span of time), the REB and its ethical standards have quickly become core components of work of researchers in the department. As Health Canada's Chief Scientist points out in the Foreword section of this report, "the ethics review has become an accepted—even welcome—part of the way we do research at Health Canada."

Helping to ensure that Health Canada research meets the highest ethical standards and that the greatest protection is provided to participants who serve as research subjects—that is the mission of the department's REB. The REB has been tireless in fulfilling its responsibilities. Key among them: providing ethics review of diverse research projects carried out by the department; updating REB guidelines to include a new research-ethics appeal process; and advising senior management on REB issues.

Key activities of the Board and the REB Secretariat:

- Revised the REB Operational Guidelines and the REB Policies and Procedures Manual;
- Designed a compliance plan to ensure all human-based research at Health Canada is subject to REB review/ approval—the latter of which is still ongoing;
- Developed and adopted an REB appeal process, which will soon be posted online for use by Health Canada staff and researchers;
- Developed and launched the REB website:
www.hc-sc.gc.ca/ocs-besc/advice-avis/reb-cer/reb_e.html

- Identified a roster of alternate REB members who will be recommended for appointment to the Board by the Deputy Minister of Health Canada;
- Maintained ongoing work with the National Council on Research in Human Ethics (NCEHR) to provide training to Health Canada researchers and managers;
- Continued to provide brief presentations on the REB to groups within Health Canada;
- Ensured ongoing training of REB members so they remain up-to-date on the issues concerning research ethics within Health Canada and in the broader science and research communities;
- Provided opportunities for the REB members and REB Secretariat staff to attend conferences on various ethical/privacy issues;
- Participated in Health Canada committees on topics related to privacy and REB governance;
- Participated in the Alberta Research Ethics Community Consensus Initiative (ARECCI), an initiative of the Alberta Research Foundation for Medical Research, to enhance the ethical oversight of knowledge-generating projects (i.e., research, quality improvement, program evaluation) in health care;
- Contributed to the development of national and international research ethics policies and procedures through participation in conferences sponsored by the NCEHR and the Canadian Association of Research Ethics Boards (CAREB).

About Health Canada's Research Ethics Board

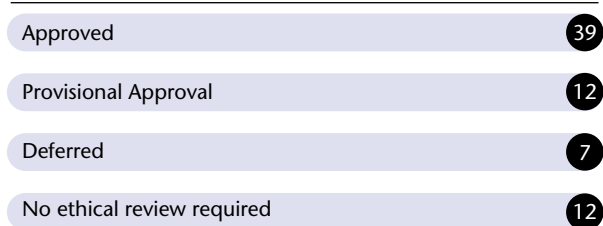
Founded in 2002, Health Canada's REB is an independent advisory body that helps ensure that all human-based research carried out or funded by the department meets the highest scientific and ethical standards. Equally important, the Board helps ensure that safeguards are developed to protect participants who serve as subjects in connection with research of this nature.

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

- in circumstances of intramural study;
- carried out at Health Canada involving technical or consultation support, including equipment, laboratories or other facilities;

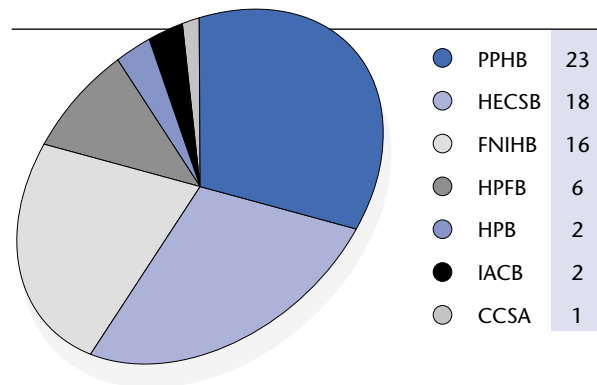
REB key indicators at a glance

All Health Canada research involving humans must be reviewed and approved by the REB. From October 1, 2003–September 30, 2004, the Board received 70 applications for ethical review from various branches of the department. That figure almost matches last year's total (68).



Of those applications: thirty-nine were approved as submitted; twelve required certain conditions to be met or modified; seven were deferred for additional information to be provided to the Board by the Principal Investigator; and twelve were considered by the REB Chair or REB Secretariat as not requiring an ethical review.

In addition, of the total number of applications, 31 were considered as requiring expedited review by the Chairman.



During 2004, a significant majority of all applications for ethical review within Health Canada originated from the Population and Public Health Branch (PPHB), the Healthy Environments and Consumer Safety Branch (HECSB) and the First Nations and Inuit Health Branch (FNIHB)—23%, 18% and 16% respectively. The balance was comprised of requests from the Health Products and Food Branch (HPFB, 6%), the Health Policy Branch (HPB, 2%), the Information Analysis and Connectivity Branch (IACB, 2%), and the Canadian Centre on Substance Abuse (CCSA, 1%).

- undertaken in collaboration or partnership between Health Canada and external researchers;
- funded by grants and contributions; and
- conducted under contract with Health Canada.

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

REB training activities, presentations and other meetings

Among the REB's core activities, the Board meets regularly and its Secretariat undertakes training and presentation for Health Canada staff to raise awareness about research-ethics related issues in the department. During 2004, Board members met monthly and in accordance with the group's workload to examine ethics-review applications. Applicants and investigators were invited to make brief presentations to the Board, followed by question and answer sessions to assist members in their review.

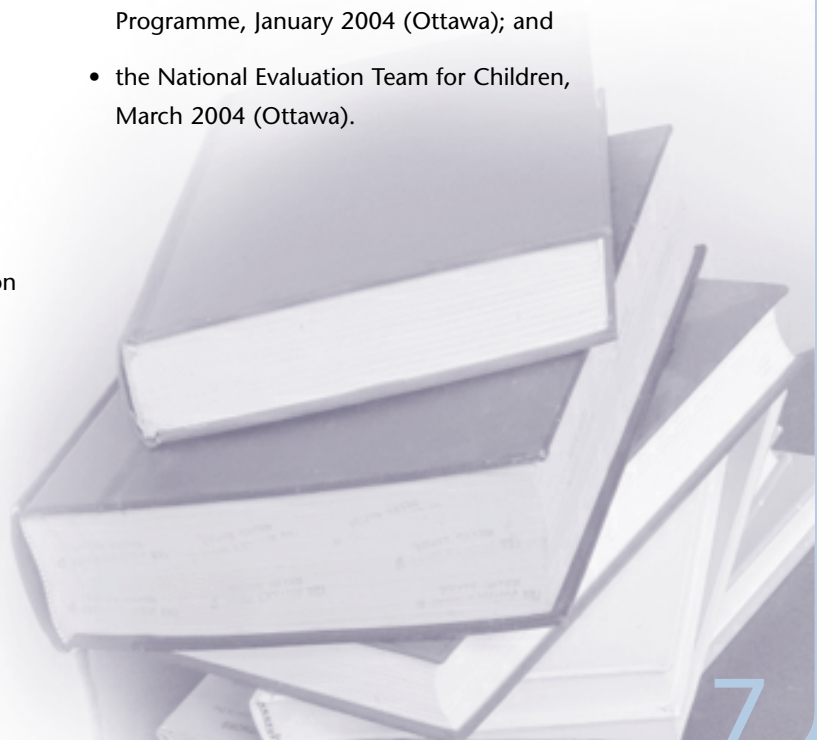
In November 2003 and March 2004, in collaboration with the National Council on Ethics in Human Research, the REB Secretariat provided orientation sessions for Health Canada staff and managers. The session agenda included a broad scope of presentations:


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

A total of 82 participants attended sessions that took place at the following dates and venues: November 13, 2003 (Ottawa), March 12, 2004 (Ottawa); and March 15, 2004 (Toronto).

The REB Secretariat also made several presentations to various groups within the department to raise awareness about the REB:

- First Nations and Inuit Health Branch, November 2003 (Thunder Bay);
- Healthy Environments and Consumer Safety Branch divisional meeting, November 2003;
- Ontario Nunavut Region, Regional Director General's Office, January 2004 (Toronto);
- Drug Strategy and Controlled Substances Programme, January 2004 (Ottawa); and
- the National Evaluation Team for Children, March 2004 (Ottawa).





“The REB Secretariat was extremely helpful and facilitated the processes involved in preparing the project for submission to the HC-REB. The committee was highly professional and asked appropriate questions in regards to many aspects of the project including the protection of confidentiality.”

Dr. Erling Rud
Researcher, Health Canada

Feedback

Survey of researchers

In 2003, Praxis Research was hired by the REB to undertake an independent assessment of the efficiency and effectiveness of the Board and of the research-approval process. The response rate was very impressive (80%) and the feedback received was quite positive.

In 2004, a follow-up survey was undertaken to assess the perspectives of researchers about the REB during its second year of operation. (see Appendix B)

Again, the response rate was impressive: 38 of 49 surveys were completed by researchers, and the report found that “a strong majority of respondents reported that they were ‘satisfied’ or ‘very satisfied’ with most of the steps in the process.” Noting that ten researchers elaborated

on their responses, the report noted that “almost all of the comments were favourable... most people reported that the forms were easy to follow and that they encountered no difficulties completing them.”

Almost all of the comments were favourable... most people reported that the forms were easy to follow and that they encountered no difficulties completing them.

Researchers indicated they were highly satisfied with:

- the clarity of most aspects of the application process (but electronic communications could be improved);
- the timing of the steps in the review process;
- the services provided by the REB Secretariat to researchers; and
- the interaction that most researchers had with the Board.

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

- providing clarification about documents and the ethics review process;
- enhancing perceptions within Health Canada of the overall value of receiving REB approval, especially in cases where such approval has already been obtained from another ethics review body;
- exploring ways to increase attendance figures at training sessions; and
- better ensure that the Board include members with expertise in the applicant’s discipline and proposed methodology.

“ Whenever we were asked by the REB to follow-up on an ethical issue or a question, all I could think of was either: ‘We should have thought of that!’ or ‘I wish I had thought of that!’ It is with great appreciation that I also thank the REB Secretariat for the assistance provided prior to and after each meeting...I look forward to meeting with the REB Secretariat, and learning more from the REB in the coming year.”

Dr. Katherine Dinner
Researcher, Public Health Agency of Canada

Looking ahead

Since its inception in 2002, the REB has worked hard to establish and refine ethics review processes and raise awareness within Health Canada about research ethics issues. The REB has similarly ambitious plans for 2005. As part of its ongoing efforts to promote the highest ethical standards of research at Health Canada, the REB and REB Secretariat will be undertaking the following activities:

- Providing ongoing advice of ethical issues to the Chief Scientist;
- Revising the REB Policies and Procedures Manual to address issues of compliance and process for dealing with collaborative and supplemental services offered by Health Canada;
- Investigating options for allowing researchers to submit electronically their research ethics application;
- Continuing to participate in Health Canada committees on matters including privacy and REB governance and accreditation;
- Sustaining ongoing work with the NCEHR to provide training to Health Canada's researchers and managers;
- Submitting the list of alternate members to the Deputy Minister of Health Canada for appointment to the Board;
- Hiring summer students to continue development of REB policies and of a records-management system.
- Maintaining participation in the ARECCI, to enhance the ethical oversight of knowledge generating projects in health care; and
- Sustaining efforts to update the skills of all REB members and REB Secretariat staff by arranging for them to attend conferences hosted by NCEHR and CAREB.

A blue-tinted background image of a microscope, showing the objective lens and eyepiece, with a blurred view of a specimen on a slide.

How the REB works

Background

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

Discussing research proposals

Face-to-face meetings are essential for adequate discussion of research proposals and for the collective education of the REB. A schedule of upcoming REB meetings is posted on the website for researchers so that their research can be planned properly. Quorum for an REB 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 are asked to attend meetings to ensure that the required range of background and expertise is met.

The REB meetings are planned in accordance with the workload. Board members are given two-weeks in advance of the meeting to review the application documents. Minutes of meetings are recorded and approved by the REB according to its approval procedure. Discussions and the record of recommendations taken at REB meetings are kept confidential.

Researchers are asked to attend REB meeting to participate in discussions about their proposals, but are not present when the Board is making its final recommendation. When the REB is considering a recommendation to terminate research or not to approve it, it provides the researcher with written reasons for doing so and gives the researcher an opportunity to reply before rendering its final recommendation.

For a researcher to obtain an ethical review by the members, the REB Secretariat produced and webposted a list of documentation required to be submitted to the Board.

Decision-making process

All research projects involving humans will be subject to a full review by the REB in which every Board member reviews the proposal. In some circumstances, the REB may review applications either as expedited reviews or as time-sensitive reviews. The REB may recommend approval, rejection, proposed modifications to, or termination of, any proposed or ongoing research involving humans that is conducted by or on behalf of Health Canada.

Ongoing communications

REB resources, forms, policies and procedures, as well as annual reports are available online at the REB website at http://www.hc-sc.gc.ca/ocs-besc/advice-avis/reb-cer/reb_e.html

Assistance from the REB Secretariat

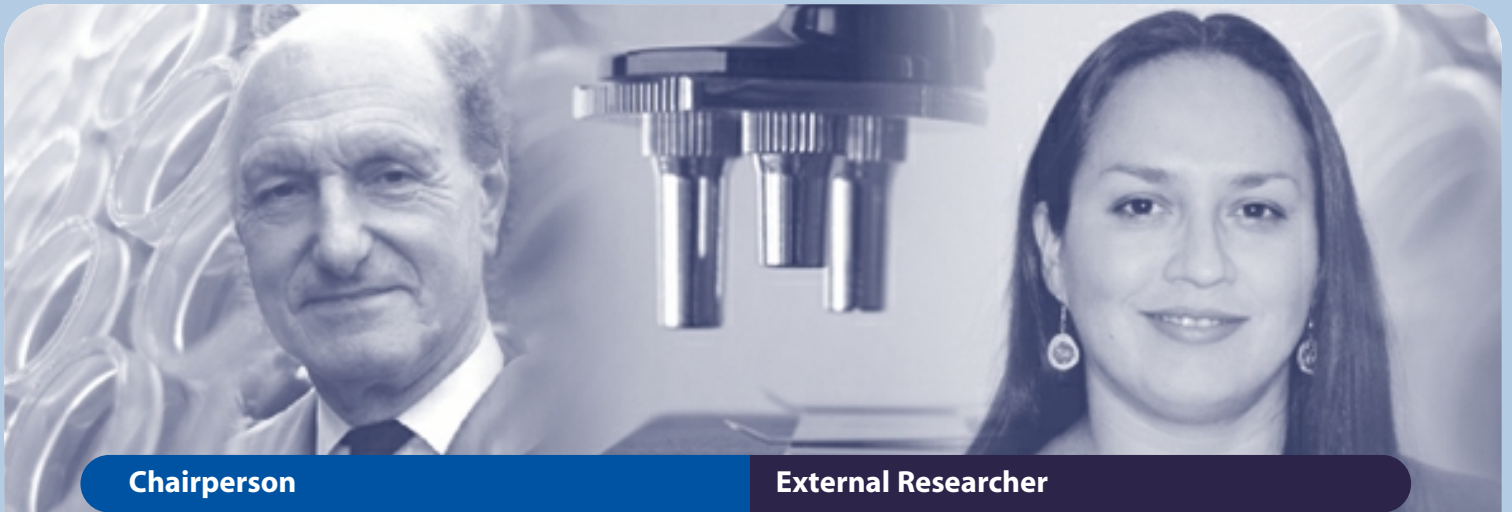
The REB Secretariat is responsible for managing all administrative affairs of the group. Specifically, the key activities include: organizing REB meetings and agendas; managing all applications; developing and delivering departmental training programs for the REB; developing REB policies and procedures, and operational guidelines; maintaining the REB website; receiving written confirmation from managers and researchers that their research will be carried out in accordance with what was approved by the REB; and addressing all communications regarding individual applications to the REB.

Profile of Health Canada's Research Ethics Board

Members of the Board

Health Canada's Research Ethics Board membership consists of eight expert representatives: one member has expertise in law, two members are experts in bioethics, one member is a researcher from outside of the department, two members are researchers from

within Health Canada and two members represent the community at large. Together, these members ensure that Health Canada applies a consistent approach to ethical reviews of research involving human subjects. Each member holds tenure with the REB for three years, up to a maximum of six years.



Chairperson

Dr. Bernard Dickens (LL.B, LL.M., Ph.D., LL.D., F.R.S.C.)

In addition to serving as Chairperson of the Research Ethics Board, Dr. Dickens is the University of Toronto's Dr. William M. Scholl 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 350 publications, including books, book chapters, articles and encyclopedia 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.

External Researcher

Dr. Cornelia Wieman (MD, FRCPC)

Dr. Wieman was Canada's first female Aboriginal psychiatrist. Since 1997, she has worked as a Consultant Psychiatrist with Six Nations Mental Health Services, a community mental health clinic based on the Six Nations of the Grand River Territory. She is both Co-Director of the Indigenous Health Research Development Program and Assistant Professor in the Department of Public Health Sciences, Faculty of Medicine at the University of Toronto. During 2000–2004, she worked part-time as the Director of the Native Students Health Sciences Program for the Faculty of Health Sciences at McMaster University and continues to hold an academic appointment there as an Assistant Clinical Professor in the Department of Psychiatry & Behavioural Neurosciences.

Dr. Wieman is a co-investigator on several initiatives funded through the Canadian Institutes of Health Research – Institute of Aboriginal Peoples Health including the National Network of Aboriginal Mental Health Research. She was a member of the Advisory Group on Suicide Prevention that developed a framework document for the Assembly of First Nations and First Nations & Inuit Health Branch to address the issue of First Nations youth suicide. She serves on the Drug Utilization Evaluation Advisory Committee, Non-Insured Health Benefits, First Nations & Inuit Health Branch, Health Canada. She has also worked with the National Aboriginal Achievement Foundation and Creative Wellness Solutions Act Now Role Model Program on creating and delivering programs for Aboriginal youth. She was a 1998 recipient of a National Aboriginal Achievement Award, recognizing career achievement in the category of medicine and was the inaugural recipient of the University of Waterloo, Faculty of Applied Health Sciences Alumni Achievement Award (2002).



Ethicist

Dr. George Webster

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

Expertise in human research ethics

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

Dr. Enzle served as a faculty member in the Department of Psychology at the University of Alberta for 30 years. In 2003, he was appointed as full-time Director of the University's newly created Human Research Protection Office. Dr. Enzle has long been involved in the development and implementation of research ethics policies at the University of Alberta, and has chaired several research ethics boards as well as the University's ethics policy board. He is a member of the National Council on Ethics in Human Research and chairs its Education Committee. He has chaired the Council's last four national meetings. In 2003, Dr. Enzle was appointed as Chair of the Canadian Institutes of Health Research Stem Cell Oversight Committee. His academic research focuses on voluntary consent, privacy issues and power relationships.

Community representative

Ms. Monique Martineau

Ms. Martineau was nominated to Health Canada's REB by Lupus Canada—an organization that she has been a member of for over 20 years, including roles as Vice President and a national board member. She has also worked for a legal firm in Montreal in an administrative capacity and is familiar with precedents and changing laws. Ms. Martineau has served as editor of the French version of "Lupus—Disease of 1000 Faces," and served on the Strategic Planning Task Force for Lupus Canada. She is familiar with the grants process as well as the communications and public relations areas.



Community representative

Health Canada researcher

Health Canada researcher

Me Susy Landreville (B.Sc. LL.B)

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

Dr. Agnes Klein (MD, DPH)

Dr. Klein is currently Senior Medical Advisor, 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 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.

Dr. Klein has been with the Biologics and Genetic Therapies Directorate since April 2000. 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 Acting Director for a newly created evaluation centre within BGTD. She is an active member of several medical and scientific organizations nationally and internationally.

Dr. Tom Wong, MD, MPH, FRCPC

Dr. Wong is the Director of Community Acquired Infections Division within 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 the Emerging Infectious Disease Research Network and the Canadian Sexually Transmitted Infections Expert Working Group.

Appendix A

Research Ethics Board guiding principles

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

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

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

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons—to those whose diminished competence and or decision-making capacity make them vulnerable. Children, institutionalized persons or others are entitled—on grounds of dignity, caring, solidarity and fairness—to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable

individuals in the research enterprise will often translate into special procedures to protect their interests.

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

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process has fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. Yet

distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

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

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without the

participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

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

Appendix B

Survey of researchers