Health Canada's Research Ethics Board

Annual Report 2005-2006 and 2006-2007

Canada

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Également disponible en français sous le titre: *Comité d'éthique de la recherche de Santé Canada – Rapport annuel 2005-2006 et 2006-2007*

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ISBN:
H1-9/21-2007E-PDF / 978-0-662-46846-2

About this report

This annual report of Health Canada's Research Ethics Board (REB) covers fiscal years 2005–2006 and 2006–2007 and includes plans for 2007–2008. It is published as part of the Office of the Chief Scientist's ongoing efforts to inform senior decision-makers, the science regulatory and policy communities within Health Canada, the Public Health Agency of Canada (PHAC) and other partners and stakeholders about the work of the REB.

This report describes the mandate of the REB, key results achieved and also the activities of the REB Secretariat in the Office of the Chief Scientist of Health Canada.

Find out more

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contents

A message from the Chair of the Research Ethics Board

I am pleased to introduce the Health Canada REB annual report for 2005–2006 and 2006–2007—the third such report since this REB was created in 2002. This report documents how all major goals were met—and in some cases exceeded. Equally important, it shows the growing role that ethics plays in the research culture at Health Canada and the PHAC. Within both organizations, researchers are deeply committed to the highest standards of protection for human-research participants. This commitment was clearly evident in the excellent presentations made by these professionals to our REB at our monthly meetings. In addition, our REB has welcomed opportunities to provide advice as requested on evolving policies and decisions involving complex ethical issues.

With the ongoing, attentive support given to us by Health Canada's Office of the Chief Scientist, we look forward to a fulfilling year ahead in 2007–2008. This will include working with several new colleagues who have been appointed as alternate members to our REB. All members of the REB take great pride in serving Canadians in this important endeavour, and we look forward to working together for the benefit of scientific research conducted by Health Canada and the PHAC.

Dr. Bernard Dickens,
Chair, Health Canada Research Ethics Board

A message from Health Canada's Acting Chief Scientist

Health Canada, as a federal science-based department, depends on sound science to make its regulatory policies and decisions. This requires that the research it sponsors—and which involves human subjects in particular—conforms to the highest standards of ethical conduct. This is what the REB contributes to Health Canada.

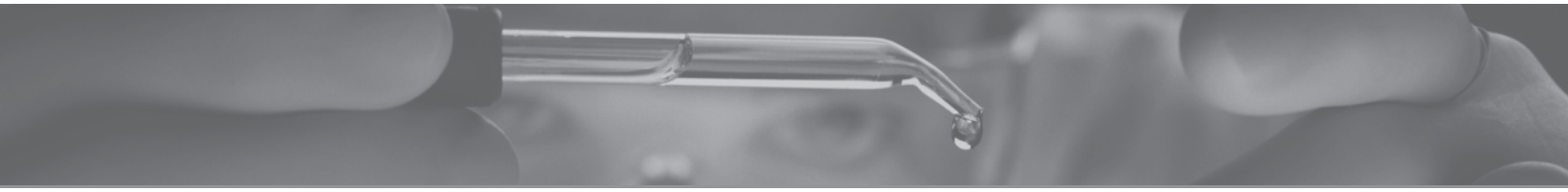
Since its beginning in 2002, Health Canada's REB has grown to become an integral part of the research landscape within both Health Canada and the PHAC. This report reflects how ethics reviews are now an accepted and welcomed part of the research process. This is an important accomplishment—one that is helping foster excellence in scientific research in both organizations.

Results of the REB Secretariat survey of researchers show that the ethics advice of the REB provides and the timeliness of its decisions are highly appreciated by researchers—feedback that underlines how the REB's dedication to quality service is well recognized.

Perhaps the greatest reward for the members of the REB is knowing that the ultimate beneficiaries of their efforts are those research participants whose human rights and interests are better protected by the ethics-review process. And on that note, I wish to pay tribute to the selfless work of the REB Chair, Dr. Bernard Dickens, and all REB members, who each spend countless volunteer hours reviewing research proposals and meeting with researchers. Their efforts make a difference!

Ms. Wendy Sexsmith,
Acting Chief Scientist, Health Canada

vision



About Health Canada's Research Ethics Board

Founded in 2002, Health Canada's REB is an independent advisory body that helps ensure that all research involving human subjects carried out or funded by the department and by the 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.

Scope

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

- intramural study (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.

The REB reports directly and makes recommendations to Health Canada's Chief Scientist, 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.

Health Canada, as a key science-based department, depends on sound science to perform its policy and regulatory functions. The REB's role in ensuring that all Health Canada/PHAC research involving human subjects meets the highest ethical standards is essential to the achievement of this objective.

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

- the potential benefits significantly outweigh the potential for harm or other risks;
- the research is scientifically sound;
- there is adequate process for informed consent and—where applicable—an assent to participate in the research; and
- there is justice and fairness in selection of participants.

Members of Health Canada's Research Ethics Board

Currently, the Health Canada's REB membership (*Appendix A*) consists of eight expert representatives: one member has expertise in law, two members are experts in bioethics, one member is a researcher from outside the department, one member is a researcher from within Health Canada, one member is researcher from PHAC, and two members represent the community at large. Together, these members ensure that Health Canada/PHAC applies a consistent approach to ethics reviews of research involving human subjects. Each member holds tenure with the REB for three years, up to a maximum of six years.

How the Research Ethics Board works

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

Discussing and reviewing research proposals

Face-to-face meetings are essential for adequate discussion of research proposals, and for the collective education of the REB members. A schedule of upcoming meetings is posted on the REB's website, so that researchers can plan their schedules accordingly. Quorum for a 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 *Tri-Council Policy Statement*. Alternate members are asked to attend meetings to ensure that the required range of background and expertise is met.

REB meetings are planned in accordance with the workload of its members and usually take place on a monthly basis with a pause during the summer. REB members are given notice two weeks in advance of a 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.

Decision-making process

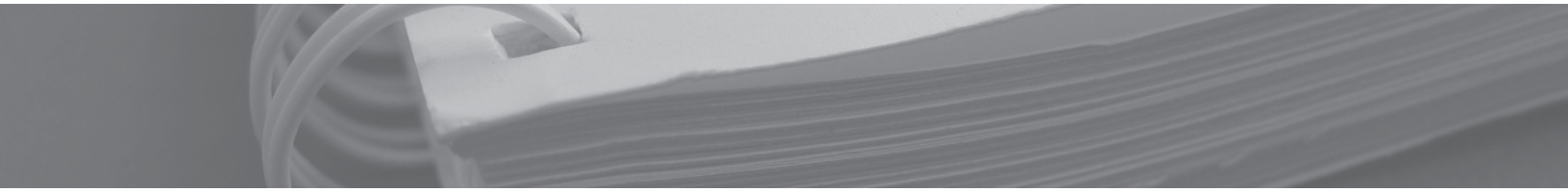
All research projects involving human subjects are subject to a full review by the REB—every REB member reviews each proposal. In some circumstances, the REB may review applications either as expedited reviews or as time-sensitive reviews. The REB may recommend approval, propose modifications to reject, or terminate, any planned or ongoing research involving human subjects that is conducted by or on behalf of Health Canada or PHAC.

Making recommendations

Health Canada/PHAC researchers are asked to attend REB meetings to participate in discussions about their proposals, but are not present when the REB is making its final recommendation. When considering a recommendation to terminate, modify or reject a research project, the REB provides the researcher with written reasons for doing so, and gives the researcher an opportunity to reply before rendering its final recommendation.

The REB's website contains a list of documentation to be submitted by researchers requiring an ethics review of their research protocols.

results



Fulfilling a mission

Since its inception in 2002, the REB has made steady progress in fulfilling its mission. In doing so, it is helping 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.

Meeting annual goals

As illustrated below, the REB Secretariat in Health Canada's Office of the Chief Scientist has been diligent in setting and meeting goals for itself during the fiscal years 2005–2006 and 2006–2007.

GOALS	RESULTS
Receive and process all applications for completeness and submitted them to the REB in a timely manner.	All applications and communications with researchers and managers were managed in an efficient and effective manner to the satisfaction of the REB and concerned researchers.
Develop and implement an information tool for the REB appeal process.	Appeal process approved and posted on the REB website for staff and researchers in September 2006.
Revise the *REB Policies and Procedures Manual* to address compliance issues and implement a process for dealing with collaborative and supplemental services offered by Health Canada and PHAC.	Revised manual was posted on the REB website in September 2006.
Recommend the appointment of alternate members to the REB.	Alternate members were appointed to the REB by the Deputy Minister of Health Canada (2005 and 2006).
Formalize an arrangement with PHAC whereby PHAC researchers may use the services of the REB.	Memorandum of Understanding between PHAC and Health Canada was concluded for the provision of REB services in 2006-07.
Register the Health Canada REB with the U.S. Department of Health and Human Services as an independent REB that reviews collaborative cross-border research projects involving human subjects to ensure they are carried out to specified ethical principles and that they are in compliance with the *Tri-Council Policy Statement.*	Completed. Registered the REB in January 2006. Registration will expire in January 2009.

GOALS	RESULTS
Develop a secure, web-based network that gathers and disseminates information on the day-to-day operations of the REB, which is accessible to all REB members in relation to research projects requiring an ethical review.	Completed. Developed the network and it became operational in September 2006.
Participate in Health Canada committees on matters including privacy and REB governance and accreditation.	Ongoing throughout 2005-2006 and 2006-2007.
Maintain ongoing work with the National Council on Ethics in Human Research to provide training to Health Canada and PHAC researchers and managers.	Five sessions were provided to researchers and managers in 2006 and early 2007.
Provide brief presentations about the REB to groups within Health Canada and PHAC.	Ongoing throughout 2005-2006 and 2006-2007.
Develop a records-management system within the REB Secretariat.	Completed.
Update the skills of all REB members and REB Secretariat staff for the purpose of remaining up-to-date on issues concerning research ethics within Health Canada and PHAC and in the broader science and research communities	Arranged for members and staff to attend several conferences on various ethical and privacy issues.
Participate in the Alberta Research Ethics Community Consensus Initiative to enhance the ethical oversight of knowledge-generating projects (i.e., research, quality improvement and program evaluation) in health care.	Ongoing throughout 2005-2006 and 2006-2007.
Contribute to the development of national and international research ethics policies and procedures.	Participated in conferences sponsored by the National Council on Ethics in Human Research and the Canadian Association of Research Ethics Boards.

Key indicators at a glance

During 2005–2006 and 2006–2007, the REB received 104 applications for ethics review from various branches of the department, and from the PHAC.

As demonstrated in *Figure 1* (in percentages), of those 104 applications: sixty-five (63%) were approved as submitted; fifteen (14%) were approved once certain REB-mandated conditions or changes had been satisfied; two (2%) remained outstanding pending additional information to be provided to the REB by the Principal Investigators; and twenty-two (21%) were considered by the REB Chair or REB Secretariat as not requiring an ethical review.

Of the total number of applications received by the REB Secretariat, forty-four (42%) were considered as requiring an expedited review by the Chair of the REB.

For an application to be considered as requiring an expedited review, the research must meet any of the following criteria:

- The study is non-invasive. Harms cannot include breaking of the skin, noxious procedures, and invasive questionnaires in vulnerable circumstances/context or significant nuisance/inconvenience.
- The study is retrospective, including chart reviews, and subjects are to be contacted for additional information not found in the chart. However, 'cold calling' by the investigator is not permitted and, when a child is involved, at a minimum a caregiver familiar to the patient/parent must be included in the 'request loop'.
- The study involves no direct subject contact, may involve anonymous waste or leftover tissue, and only aggregate data is being reported. However, studies involving foetal waste tissue or genetic material must still be submitted for full REB review.
- The study involves non-invasive product testing or quality assurance activities and publication is planned.

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

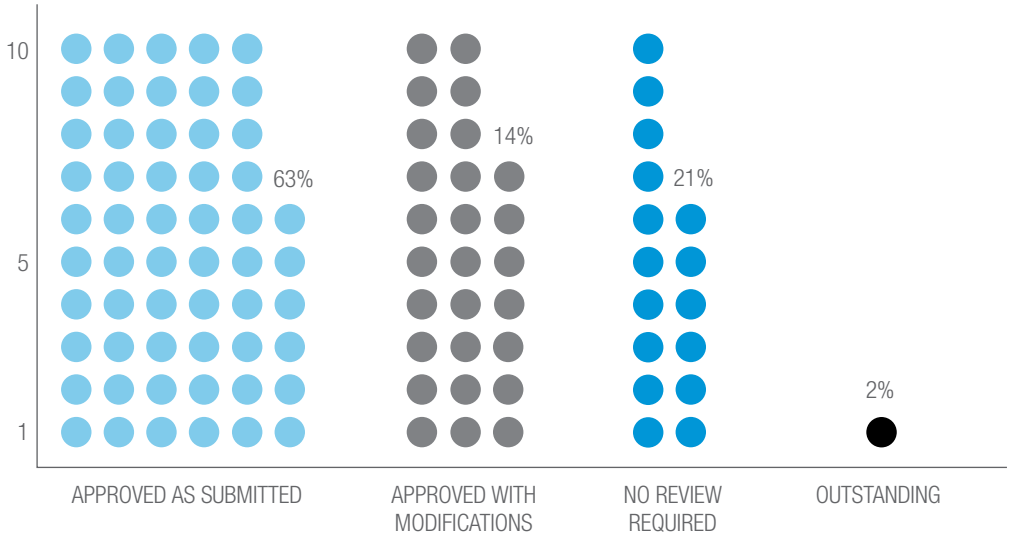
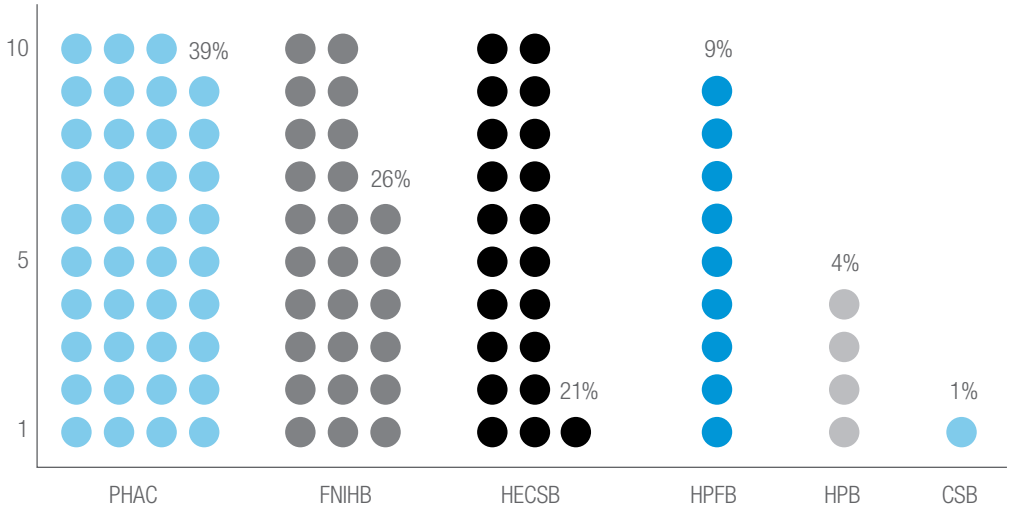


Figure 2 demonstrates that during fiscal years 2005–2006 and 2006–2007, the largest source of the research applications (39%) was PHAC. From Health Canada researchers, 27 applications (26%) were from the First Nations and Inuit Health Branch (FNIHB), and twenty-two (21%) were from Healthy Environments and Consumer Safety Branch (HECSB). The balance consisted of 14 requests (9%) from the Health Products and Food Branch (HPFB) seven (4%) from the Health Policy Branch (HPB) and one (1%) from Corporate Services Branch.

FIGURE 2: Origins of requests for ethics review



Research Ethics Board operations

The REB had 20 face-to-face meetings in 2005–2006 and 2006–2007, during which time the members:

- undertook a timely review of all research protocols (*see Figure 3*) involving human subjects;
- reconsidered decisions 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.

As per the REB Policy and Procedures, the REB recommendations were communicated to the Principal Investigators by the Chief Scientist within 10 days of the meeting at which a decision was reached. When additional information was required from the Principal Investigator in order to conclude the ethics review of their application, a transcript of the decision was communicated to the Principal Investigator by the REB Secretariat within 5 days of the meeting. On occasion, there were delays in the submission of requested additional information by the Principal Investigator, which contributed to some delays in obtaining ethics approval from the REB.

As illustrated in Figure 3, of the 104 applications reviewed by the REB, 64 were approved within 20 days, 30 were approved within 50 days and 10 required more than 50 days to conclude.

FIGURE 3: REB performance

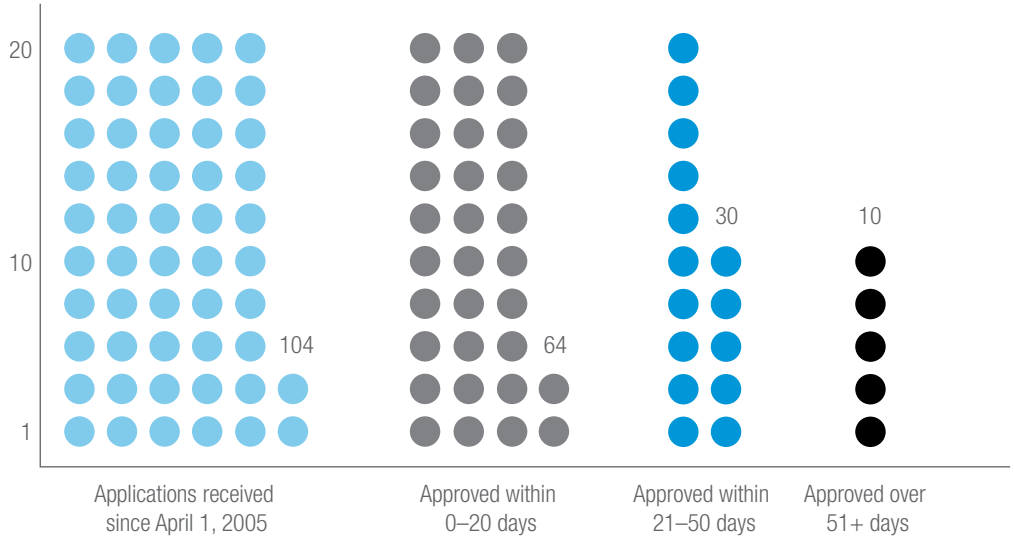
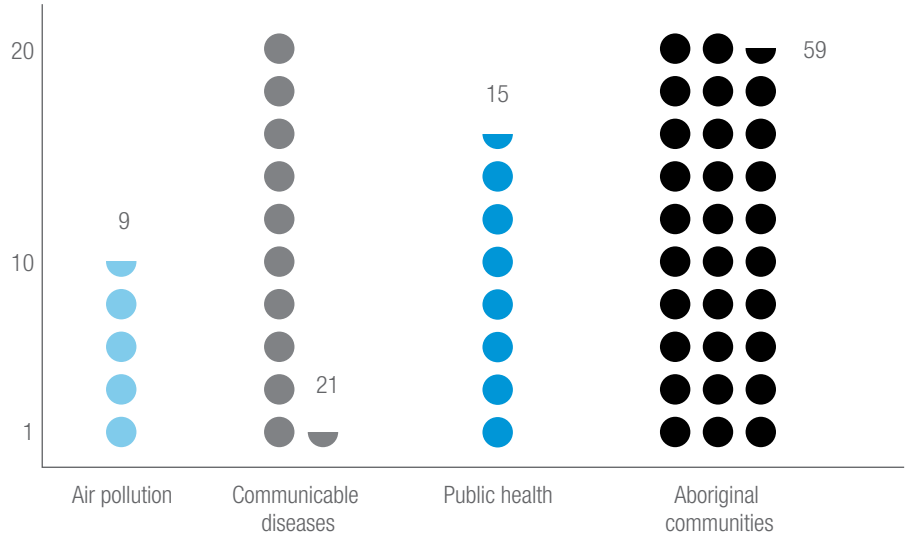


Figure 4 below shows the various thematic categories of Health Canada and the PHAC research projects that were reviewed by the REB during fiscal years 2005–2006 and 2006–2007.

FIGURE 4: Categories of research



The REB Secretariat was responsible for ensuring that:

- all applications were reviewed to ensure completeness to avoid unnecessary delays and were forwarded to the REB in a timely manner;
- all REB recommendations were communicated in writing to the Chief Scientist;
- letters communicating the REB's recommendations—in concurrence with the Chief Scientist—were sent to the Principal Investigator; and
- transcripts requiring additional information from the Principal Investigator were communicated within five days of the REB's meeting, in which they were requested to provide feedback or implement the requested modifications.

All researchers were aware of their obligations to conform with the approved protocol, to report any adverse events and to submit an annual progress report to the REB.

Presentations

During fiscal years 2005–2006 and 2006–2007, investigators were invited to make brief presentations to the REB, followed by question-and-answer sessions to assist members in their review.

Orientation seminars

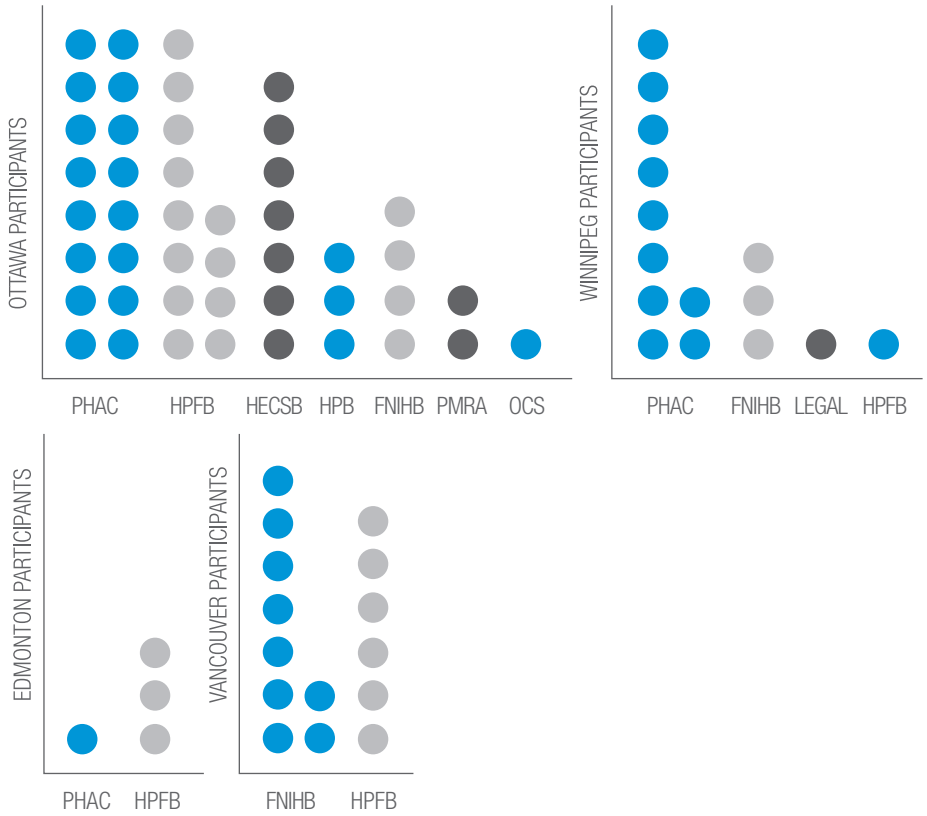
The REB Secretariat undertook training sessions for researchers and managers at Health Canada and PHAC to raise awareness about research-ethics related issues faced by both organizations. In collaboration with the National Council on Ethics in Human Research, two orientation seminars were organized in 2006 and three in early 2007 for Health Canada and PHAC researchers and managers.

The session agendas included presentations on:

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

A total of 79 participants attended these sessions, which were held in Ottawa (45 participants), in Edmonton (4 participants), Vancouver (15 participants) and in Winnipeg (15 participants). *Figure 5* provides a breakdown by branch of employees who attended these sessions. Some participants were responsible for advising other colleagues in their organizations which led to a multiplier effect.

FIGURE 5: Breakdown by branch of attendance at REB information sessions in 2006 and 2007



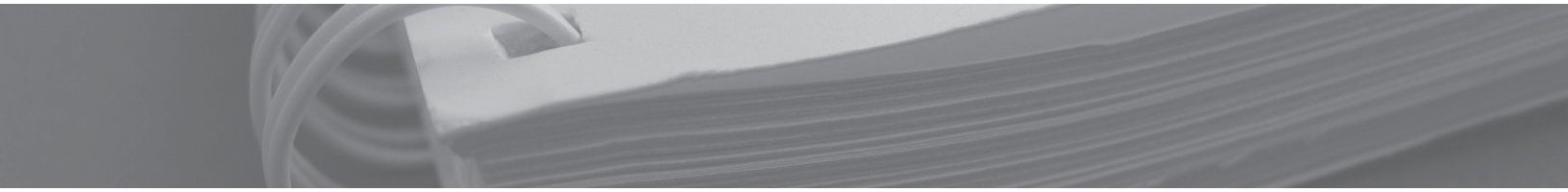
Looking ahead

Since its inception in 2002, Health Canada's REB has worked hard to establish and refine ethics review processes and raise awareness about research ethics issues within Health Canada and PHAC. Its members look forward to continuing their important work in 2007-2008. Health Canada branches make evidence-based decisions. This evidence must be generated by sound and ethical science. The REB provides an essential service to Health Canada/PHAC researchers to ensure compliance with the highest level of ethical standards. The REB is widely seen as a model for other research ethics boards in Canada and, as such, it provides support to Health Canada and PHAC as a leading science-based department and agency, respectively.

The REB Secretariat also has ambitious plans for 2007–2008. It will:

- continue to refine REB procedures and guidelines;
- manage and provide Secretariat services to the REB;
- organize the REB's meetings and manage all applications submitted for an ethical review;
- deal with all communications regarding individual applications;
- promote the Canadian Institutes of Health Research Aboriginal Guidelines and ensure compliance to these Guidelines on all research involving Aboriginal people;
- review options for implementing a Health Canada Policy on Biobanks for Human Biological Material for Research Pruposes; develop inventory system for holdings, review current responsibilities within branches for holdings;
- develop inventory system for holdings, review current responsibilities within branches for holdings;
- investigate options for allowing researchers to submit electronically their research ethics applications;
- continue to participate in Health Canada and external committees and events on matters including privacy and REB governance and accreditation;
- sustain ongoing work with the National Council on Ethics in Human Research to provide training to Health Canada/PHAC's researchers and managers in 2007–2008, including in other regions and the National Capital Region;
- initiate work to develop a quality-assurance policy for the REB;
- sustain efforts to update the skills of all REB members and REB Secretariat staff by arranging for them to attend conferences hosted by the National Council on Ethics in Human Research and the Canadian Association of Research Ethics Boards;
- develop a policy to address and resolve conflicts of interest with emphasis on the impact on the REB, its operations and the relationship with Health Canada;
- work with PHAC to conclude a formal, multi-year agreement on ethics reviews of selected PHAC research; and
- provide early advice on the development of a policy on scientific integrity within Health Canada.

feedback



Survey of researchers

Two surveys of researchers were undertaken by Health Canada's REB in fiscal years 2005–2006 and 2006–2007. In each case, Praxis Research was hired by the REB Secretariat to undertake an independent assessment of the efficiency and effectiveness of the REB, and of the research-approval process.

With a 70% response rate on the first survey, the feedback received was quite positive. A follow-up survey was undertaken in 2006 to assess the perspectives of researchers about the REB during its third and fourth years of operation (*a copy of this survey can be downloaded from the REB website at* www.healthcanada.gc.ca/reb).

Again, the response rate was highly satisfactory (70%), and results indicated high satisfaction levels overall regarding the process of obtaining a research ethics review.

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

- **The process of preparing an REB application**—the clarity of the steps in the process (70%), the five main components of the application package (70%), whether research qualifies for full or expedited review (70%), electronic resources (71.4%) and printed resources (71.5%).
- **The amount of time required to perform steps involved in the REB process**—time required to obtain application forms (94.8%), notification of additional requirements (95%), supporting documents (89.3%), and reply to questions about the application (95%).
- **Support from the REB Secretariat**—being accessible (95.2%), being helpful answering questions (100%), accommodating requests for time-sensitive reviews (95%).

- **Time considerations**—that the REB review gave adequate time to discuss a given application during its meeting (100%) and communicated its decisions in a timely and clear manner (100%).
- **The value of the approval process**—providing an independent review (85%), that this process is necessary to publishing research (80%), providing credibility to work (75%), and providing protection to study participants (85%).
- **The perceived overall value** of the ethics review process (75%).
- **The overall satisfaction** with the review process (70%).

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, as well as forms, policies, consent requirements, procedures, biographies and annual reports.

appendices

Appendix A—Members of Health Canada's Research Ethics Board

Chairperson

Bernard Dickens, O.C., Ph.D., LL.D., F.R.S.C.

In addition to serving as Chair of the Research Ethics Board, Dr. Bernard 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 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 an Officer of the Order of Canada in 2006.

Researcher External to Health Canada

Don Willison, M.Sc., Sc.D.

Dr. Don Willison combines training in pharmacy, (University of Toronto, 1977), clinical Epidemiology and Biostatistics (M.Sc., McMaster University, 1984), and health policy and health services research (Sc.D., Harvard School of Public Health, 1996). His current research interests include: pharmaceutical policy, and data privacy issues in health services research. In the area of pharmaceutical policy, Dr. Willison's research has focussed on how Western industrial countries are balancing the pharmaceutical cost-containment with access to needed medications and their interest in attracting or maintaining pharmaceutical R&D in their countries. His research also examines challenges associated with the patenting of genetic material, and the impact of policies that restrict reimbursement for coxib non-steroidal anti-inflammatory drugs. Regarding data privacy, Dr. Willison's research has focussed on variation in how research ethics boards address privacy, confidentiality and security issues when reviewing research involving secondary use of personal information. His research also looks at public opinion about consent to the secondary use of personal information for health research, as well as the development and evaluation of a consent-based patient registry.

Health Canada Researchers

Agnes Klein, MD, DPH

Dr. Agnes Klein is currently the Director of the Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products (within Health Canada's Biologics and Genetic Therapies Directorate). She received her medical degree from the University of Toronto and is trained in Endocrinology, Medical Biochemistry and Public and Community Health. Since joining Health Canada in 1974, she has held a range of scientific and manage-

ment positions within the department and its regulatory arms, including having acted as the Director of the Bureau of Human Prescription Drugs and as Director for the Biologics and Genetic Therapies Evaluation Centre. From 2001 to 2004, she was the Manager (Clinical Evaluation Division) of a newly created division responsible for clinical-trial application, 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 the Biologics and Genetic Therapies Directorate. She is an active member of several medical and scientific organizations nationally and internationally.

Thomas Wong, MD, MPH, FRCPC

Dr. Thomas Wong is the Director of Community Acquired Infections Division within the Public Health Agency of Canada's Centre for Infectious Diseases Prevention and Control. Trained at McGill, Harvard and Columbia Universities, he is an infectious-disease physician with a Masters Degree in Public Health. Dr. Wong has established an impressive career in clinical medicine and public health, including authorship of various journal publications. He has dual academic appointments at the University of Ottawa's Department of Medicine (Division of Infectious Diseases), and at the University of Toronto's Department of Public Health Sciences. Since 2003, Dr. Wong has been the Chair of the National Clinical SARS Working Group, Co-chair of both the Emerging Infectious Disease Research Network, and the Canadian Sexually-Transmitted Infections Expert Working Group.

Ethicist

George C. Webster, B.A., M.A., S.T.B., M.Div., D.Min.

Dr. George Webster completed his Doctoral studies at the Toronto School of Theology, University of Toronto. From 1982 to 1996, he was Director of the first full-time hospital-based Ethics Service in Canada at Toronto's St. Michael's Hospital (St. Joseph's Health Centre and Providence Centre). Since 1997, Dr. Webster has worked as a Clinical Ethicist with the Health Care Ethics Service at Winnipeg's St. Boniface General Hospital. He is an Assistant Professor in the Faculty of Medicine at the University of Manitoba, and is cross-appointed in the Department of Philosophy. Dr. Webster has extensive experience working with patient-care ethics committees and research ethics boards. He has served on various regional, provincial and national boards including the U.S. Society for Bioethics Consultation, St. Michael's Hospital, Ethics Committee and Research Ethics Board, the Ethics Committee at Casey House Hospice, and the Canadian HIV Trials Network, National Ethics Review Committee. Dr. Webster has served on the University of Manitoba, Faculty of Medicine, Biomedical Research Ethics Board, and the Winnipeg Regional Health Authority, Mental Health Program, Ethics Committee, and chaired the National Research Council of Canada's Winnipeg Research Ethics Board from 1998 to 2003. He is currently a member of, and a consultant to, the Canadian Anesthetists' Society, and the Committee on Ethics. Recently, he was appointed to the Canadian Institutes of Health Research, Governing Council, Standing Committee on Ethics. Dr. Webster is a member of the Canadian Bioethics Society and the American Society for Bioethics and Humanities.

Expertise in human-research ethics

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

Dr. Michael Enzle has 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 that university's Human Research Protection Office. He 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 school's Ethics Policy Board. He is a member of the National Council on Ethics in Human Research, and chairs its Education Committee. Dr. Enzle has also chaired the Council's last four national meetings. In 2003, he 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 representatives

Monique Martineau

Ms. Monique Martineau was nominated to the Health Canada Research Ethics Board by Lupus Canada. 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. During the last 20 years, Ms. Martineau served in different capacities at the provincial and national level of lupus organizations. She was on the Board of Directors of Lupus Canada for several years—including serving a two-year term as Vice-President, as well as serving on the Strategic Planning Task Force for the organization. In her work with Lupus Quebec, she served as a member of the Board of Directors of Lupus Quebec, as well as several terms as President. She previously edited the French version of *"Lupus: Disease of 1000 Faces."* She is familiar with the grants process as well as communications and public relations.

Jean R. House, B.A., B.Ed., LL.B.

Jeannie House is a lawyer (non-practising status), currently employed at the Newfoundland and Labrador Health Boards Association. Previously, she served as a legal representative on the Human Investigation Committee (Memorial University of Newfoundland Research Ethics Board) for a seven-year term. Currently at this university, she serves on committees dealing with the development of policies and guidelines in research ethics, and sits on the Human Investigation Committee Appeal Board. Previously, Ms. House worked with the Newfoundland and Labrador Department of Health and Community Services, drafting provincial standards for genetics research, consulting on legislation to establish a single province-wide health research ethics board, and most recently, new legislation that will govern the management of personal health information. She has been a member of the Board of the Newfoundland and Labrador Centre for Applied Health Research and serves on the Advisory Committee for the Canadian Institutes of Health Research Regional Partnership Program (Newfoundland and Labrador). She is currently a clinical assistant professor at the Memorial University Medical School. Her particular interest is in health legislation, privacy and confidentiality, and ethics.

Alternate members

To ensure that the Research Ethics Board remains functional even in the event of a change in board membership or other unforeseen developments, alternate members are nominated to the Board as substitutes. The nomination of these members does not alter the membership status of the REB members.

Alternate membership to the Board consists of:

- **one** member knowledgeable in the relevant laws;
- **one** member knowledgeable in ethics;
- **three** members with broad expertise in the methods of research conducted by Health Canada—one from outside of Health Canada/PHAC, and one each from within the department and agency; and
- **one** member who has no affiliation with Health Canada/PHAC, but who is recruited from the community served by the department/agency.

These members are invited to REB meetings on a rotational basis. They may engage in the Board's discussions concerning research applications, but they do not participate in preparing final recommendations unless it is a circumstance in which an alternate member is attending in place of an REB member. In such cases, that alternate member may participate fully in the recommendations process of the Board.

Expertise in law

Robert P. Kouri, B.A., LL.L., M.C.L., D.C.L.

Dr. Robert Kouri is a professor of law in the Faculty of Law at the University of Sherbrooke. He teaches and pursues research in the Law of Obligations, Civil Responsibility and Medical Law, and has published *La responsabilité civile medicale* (in collaboration with Alain Bernardot), *Le corps humain, l'inviolabilité de la personne et le consentement aux soins* (in collaboration with Suzanne Philips-Nootens). 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. A member of the Groupe de recherche en droit de la santé at the University of Sherbrooke, and the Board of Professional Advisors of the American *Journal of Contemporary Health Law and Policy*, Dr. Kouri has also served as Director of the graduate programmes in Health Law and Policy and Associate Dean (Research) at the University of Sherbrooke.

Expertise in ethics

Janet L. Storch, RN, BscN, MHSA, Ph.D.

Dr. Janet Storch is Professor and former Director of the School of Nursing at the University of Victoria. Previously, she was Dean of Nursing at the University of Calgary, and Chair of the Health Services Administration Graduate Program at the University of Alberta. A member of the visiting fellow program at the Kennedy Institute of Ethics, Dr. Storch has served as President of the Canadian Bioethics Society, Chair of the Ethics Advisory Committee of the Canadian Nurses Association, President of the National Council on Ethics in Human Research, among several other national offices. In Victoria, she serves on several clinical ethics committees, and recently completed a three-year service as Chair of the Human Research Ethics Committee at the University of Victoria. Dr. Storch was also Ethics Scholar-in-Residence at the Canadian Nurses Association during her sabbatical year in 2002. While there, she facilitated the revisions to the CNA Code of Ethics, and the Ethical Research Guidelines for Registered Nurses.

Health Canada researcher

Tye Arbuckle, Ph.D. (Epidemiology)

Dr. Tye Arbuckle's areas of expertise are in environmental and reproductive epidemiology and exposure assessment to environmental chemicals. Her current science and research interests are in pesticides, disinfection by-products in municipal water supplies, influences of environmental chemicals on child-health and development, and male reproductive health. She has academic appointments with the University of Ottawa's Department of Epidemiology and Community Medicine, and with Queen's University's Department of Community Health and Epidemiology.

Public Health Agency of Canada researcher

Michael B. Coulthart, Ph.D.

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

Researcher outside Health Canada

Rae Mitten, LL.B., LL.M. Ph.D. student

Ms. Rae Mitten is currently a Ph.D. student and lecturer/law teacher at the University of Saskatchewan. Her Ph.D. dissertation is an interdisciplinary study in the fields of law, medicine, education, psychology and justice. Her 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 also a member of the Métis Nation of Saskatchewan, and serves as a board member of the Saskatchewan Fetal Alcohol Spectrum Support Network.

Community representative

Maxine Cole, B.A., M.S.

Ms. Maxine Cole received a B.A. at the State University of New York at Potsdam College, and a M.S. at the University of Ottawa. She is currently at the Akwesasne Freedom School (Mohawk immersion program) as an adult learner of the Mohawk language. Ms. Cole's experience includes clinical and research work in health and environment. In addition, she is currently the Director of Community Outreach for the First Environment Research Project, State University of New York at Albany.

REB Secretariat

Health Canada's Research Ethics Board is supported by a REB Secretariat, located within the Office of the Chief Scientist. The Secretariat is responsible for:

- organizing Board meetings and agendas;
- managing all applications received for an ethics review;
- developing Board policies, procedures and operational guidelines;
- maintaining the REB website, including forms and other information required by researchers when submitting research applications;
- seeking written confirmation that researchers will adhere to approved protocol;
- providing clarification to researchers as to whether a research project involving humans requires an REB review;
- communicating with researchers regarding individual applications reviewed by the Board; and
- developing and delivering training to managers and researchers at Health Canada and the PHAC.

Manager

Glennis Lewis, Ph.D., LL.M.

Dr. Glennis Lewis has both a Masters degree in Law and a Ph.D. in biological sciences and has worked at Health Canada since 1999 on diverse projects, including revisions to the Quarantine Act. Dr. Lewis also represented Health Canada in the international negotiations of the Cartagena Protocol on Biosafety. In 2002, she was awarded a Queen's Jubilee medal for her contributions to the federal public service.

Senior REB Administrator

Yvette Parent

Over the course of Ms. Parent's thirty-plus year career with Health Canada, she has held has held two other positions: Chief of the Briefings and Correspondence Division within the Assistant Deputy Minister's office of the then–Health Protection Branch, and Senior Assistant Coordinator within the Access to Information and Privacy Division.

Appendix B—Research Ethics Board guiding principles

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

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

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

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

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

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

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

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

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