

The Ethics Review Process in British Columbia: An Environmental Scan



Michael Smith Foundation for
Health Research

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1. Executive Summary

During the spring and summer of 2007, at the request of provincial health research stakeholders, and with the endorsement and support of the Ministry of Health and the Ministry of Advanced Education, the Michael Smith Foundation for Health Research (MSFHR) conducted an environmental scan of Research Ethics Boards (REBs) in British Columbia. The scan included REBs that are constituted and operated in compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) published in 1998.

Our scan explored the processes for ethics review of many types of research, from social science to clinical trials, from community-based to data-intensive studies. A consultative process was employed to capture extensive input from a wide range of organizations and institutions with diverse perspectives. Using a combination of a survey (written questions and answers) and informational interviews, we developed this report on B.C.'s REB organizational structures, review processes and policies. We submitted an initial draft of the report to a stakeholders' Task Force¹ and solicited comments which were taken into consideration during the creation of this final document.

We contacted a total of 26 academic, health care and community-based organizations and spoke with 34 persons, most of whom were REB administrators or Chairpersons. We found that, while several B.C. REBS are still in the start-up phase, others are well-established and struggling with heavy workloads. The smallest board we contacted has five members, while the largest has 27. The number of new applications reviewed annually by a given REB ranged from a minimum of one to a maximum of 1200. The number of meetings per year ranged from two per Board to 23.

Our survey identified variations in REB structures, procedures and policies across the province. Some differences are inherent in the make-up of the institution served and the nature of the research typically reviewed by a particular REB. Other variations, such as disparate application forms and informed consent templates, appear to reflect inefficiencies that are acknowledged by administrators, Board members and researchers alike. For all the institutional REBs we surveyed, the majority of members were affiliated with the institution the REB serves. Almost half of the boards reported difficulties in achieving and maintaining the required level of community members on their REBs.

In general, contributors to our scan indicated numerous ways in which REBs foster increased awareness of the social benefits of research, the scientific process, the demand for evidence-based policy and decision-making, the nature of risk as it pertains to individuals in a variety of circumstances and the ethical dilemmas inherent in research involving people as subjects. In addition, there is consensus that ethics review of student research projects enhances the educational experience and prepares students for a research career. It was generally agreed that geographically dispersed boards have opportunities to bring local perspectives to the review

¹ A list of the membership of this Task Force can be found in Appendix C.

process, incorporating knowledge of rural communities, ethnic cultures and other issues of local concern.

Contributors to our scan reported challenges in several key areas, including a lack of funds for administrative assistance; difficulties in recruitment of board members from the community and across disciplines; and lack of access to state of the art information technology that could expedite the application and review process.

This scan found that REBs differ in their approach to multi-site proposals and review of applications previously approved by an academic department, sponsor or another review board. The survey respondents commented that Boards constituted to serve a single institution may not have the expertise or financial resources to accommodate specialized, multi-disciplinary, international and collaborative research, yet the perception that quality of reviews is variable impedes the development of reciprocal relationships which would alleviate the burden of multiple reviews.

Overall, we found a common desire amongst respondents for a more consistent and efficient province-wide approach to the review of research involving human participation. However, their views on how to achieve these goals varied considerably, as did their opinions as to whether such enhancements were likely achievable.

MSFHR gratefully acknowledges the time and effort contributed by the staff and leaders of the REBs who participated in the scan processes which made this report possible. We were overwhelmed by their enthusiasm to participate and their dedication to ensuring the highest possible standards of ethics review in order to provide human research subjects with the protection and respect they deserve.

2. Introduction

Since its founding in 2001 MSFHR has actively fostered provincial excellence in health research. MSFHR consults regularly with stakeholders including the Ministry of Advanced Education, the Ministry of Health and across the academic and health care communities. Among other concerns, this consultation has revealed that the process for ethics review of applications for research requiring human participation has been identified by researchers and institutions alike as an area that presents significant barriers to effective and timely conduct of research across the province.

The Tri-Council² Policy Statement for Research Involving Human Subjects (TCPS), introduced in 1998, establishes ethical principles along with requirements and prohibitions for Research Ethics Boards (REBs) in Canada. The standards set by the TCPS are stringent and implementation by institutions means allocation of considerable resources of time, money and continuing education. Because each of the Tri-Council agencies exclude candidates for new or ongoing funding of human subjects research who have not certified compliance, the TCPS has had an enormous impact on the Canadian scientific community.

Since adoption of the TCPS the Tri-Council and REBs across Canada have witnessed many changes in the research environment. Technological advances, the demands of evidence-based medicine, medical subspecialties and interdisciplinary collaboration; heightened awareness of individual rights to privacy and confidentiality; ethnic and linguistic heterogeneity; community or group advocacy; and the potential for litigation and liability have all increased the complexity of ethics review processes. In response, governments, academic and private institutions have each sought in their own ways to meet these challenges. In Canada the TCPS is widely accepted as the gold standard to which review boards aspire but efforts continue towards achieving the policy statement's goals with efficiency and fairness to both human subjects and researchers. In British Columbia there is general agreement that a comparable or even higher level of protection is achievable within a more coordinated provincial system. A thorough understanding of the current system is prerequisite to a meaningful evaluation of possibilities for improvement. Thus, this report focuses on understanding the current system, as a basis for moving forward collaboratively.

Section two of this report briefly describes recent developments in the Canadian and Provincial research environment that have contributed to the current operating context for REBs. It also describes our methodology for gathering information to contribute to this report, along with a listing of those institutions who responded to our request for participation.

Section three of this report presents the data collected in our environmental scan and compares organizational structures, submission processes and review and decision-making policies. Without identifying individual speakers, we present representative opinions and observations relating to both

² The Tri-Council refers to Canada's three major national research funding agencies: The Canadian Institutes of Health Research (CIHR); the Social Sciences and Humanities Research Council (SSHRC); and the Natural Sciences and Engineering Research Council (NSERC). For definitions of other acronyms and abbreviations used throughout this report, please see Appendix E.

the current situation and respondents' perceptions of opportunities for enhancing processes for ethics review in B.C. through interaction, sharing of expertise, technological networking and/or cooperative agreements.

2.1 Research Involving Human Subjects

Research involving human subject participation spans many fields, including but not limited to anthropology, psychology, sociology, engineering, life sciences, information technology, health care delivery, pharmacology, allied health professions and clinical medicine. Studies range from minimal risk projects to large-scale trials of drugs and medical devices. Typically the greater part of research spending goes to clinical trials designed to evaluate the efficacy and safety of new drugs (or new ways of using existing drugs), therapies and medical devices. A myriad of studies are also conducted to gain essential knowledge about health services, human behaviour and population health. These studies may require access to data collected in the course of prior school, medical or criminal justice activities (secondary data) and take place in a wide variety of settings, ranging from classrooms to city streets. Scientists working in all these areas must seek REB approval to satisfy funding and regulatory requirements, institutional policy requirements, and in some cases, to meet criteria for publication in peer-reviewed journals. Students need ethics approval for coursework involving human subjects studies, but their research is often low-risk. For these future investigators, learning the process for ethics review is highly relevant to their pedagogical experience.

Within British Columbia there are numerous academic institutions, health care facilities (hospitals, outpatient clinics, long-term care facilities, medical offices), data banks (criminal justice and health services), community centres and unstructured communities of interest from which researchers may wish to recruit subjects or access information with the potential for personal identification. REB members responsible for the review of applications for ethics approval of the resulting research projects assume responsibility to protect human subjects through risk/benefit evaluation, assurance of informed consent and monitoring of ongoing studies. However, seemingly straight-forward questions are not always easy to answer. The challenge for ethics reviewers is to carry out their mandate with minimal delays and without imposing unnecessary impediments to the conduct of scientific enquiry.

In 2000 the federal government evaluated oversight of research involving human subjects in Canada through a study of leading provincial research centers. The resulting McDonald report highlighted the need for additional protection.³ Figure 1 on the next page summarizes the changing environment for ethics review nationally as identified by that report. Since publication of the McDonald Report, health policy analysts have expressed continuing concerns about the adequacy of REBs⁴ with respect to scientific expertise, representation of the interests of human subjects, and the Boards' ability to attract community members and financial, technical and human resources to handle the volume of

³ McDonald M. *The Governance of Human Research Involving Human Subjects*. Ottawa, Law Commission of Canada, 2000

⁴ Downie J, McDonald F. *Revisioning the Oversight of Research Involving Humans in Canada*, Health Law Journal, 2004. 12:159-181

new and ongoing studies in medicine, allied health professions, health services delivery and the social sciences.

The Changing Health Research Environment (2000) ⁵		
CHANGE	EXPLANATION	KEY IMPLICATIONS FOR REBS
Emphasis on Cost Control Debate about Privatization	Scrutiny of costs for research support at academic health centers.	<ul style="list-style-type: none"> • Pressures to accommodate research sponsors who can provide research-related revenues for the parent institution. • Increased difficulty in obtaining staff and other resources. • More pressure on staff physicians to generate income with less time available for voluntary commitments to REBs.
Increased Commercialization of Research	Heightened industry role in sponsoring research and emphasis on rapid product development.	<ul style="list-style-type: none"> • Institutional and sponsor pressures for quick reviews. • Sponsor shopping for customer-focused REBs. • Added complexity on issues involving liability, academic freedom and, patient disclosure.
Proliferation of Multi-Center Trials	Proliferation of trials spread across hundreds of sites, even across the world.	<ul style="list-style-type: none"> • Diminished influence of "local" review. • Flood of adverse-event reports to review. • Lack of access to significant information concerning the status of ongoing research.
New Types of Research	Advances in biomedical research in the areas of gene testing and related research. Mental health research issues.	<ul style="list-style-type: none"> • Need for new, highly specialized areas of expertise. • Emergence of thorny ethical issues involving informed consent. • Increased importance of having non-institutional board members.

Figure 1 The Changing Health Environment

⁵ Adapted from McDonald, Michael, *The Governance of Health Research Involving Human Subjects (HRIHS): Report to the Law Commission of Canada*, § B-3 "The Current Context of HRIHS" 2000

2.2 The Canadian and B.C. Context

The ethics review process in British Columbia is governed by federal and provincial laws, regulations and guidelines. Historically the Nuremberg Code, drafted in 1948 by Nazi war crimes prosecutors and the Helsinki Declaration, developed in 1964 at a meeting of the World Medical Association, along with the guidelines of the 1979 Belmont Report from The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, have provided principles for judging the morality of research involving human subjects. In 1990 trends towards commercialization and globalization of pharmaceutical research caused representatives of the regulatory agencies and industry associations of the European Union, Japan and the United States to form the *International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH). Good Clinical Practices (GCP), developed by the ICH, has been adopted by Canada.

2.2.1 Canada

A number of changes at the national level have increased the complexity, volume and nature of ethics review of research in human subjects in Canada. This section briefly addresses some of the major influences.

In 1998, changes in the national and international research environment caused Canada's three federal granting agencies — the Medical Research Council of Canada (MRC), Natural Sciences and Engineering Research Council (NSERC) and Social Sciences and Humanities Research Council (SSHRC) — to draft the *Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans*. Both health care and academic institutions responded to the TCPS with changes in their processes for ethics review. Some institutions already had committees that met the Tri-Council criteria, while others needed to establish compliant boards or face the prospect of exclusion from grant competitions. In 2000 the Canadian Institutes of Health Research (CIHR) replaced MRC. The Tri-Council created the Panel on Research Ethics (PRE) to advise the three federal granting agencies on the interpretation, implementation and educational needs of the TCPS. PRE's advice is intended to promote high standards of ethical conduct, advance the protection of human research participants, and enhance accountability in research ethics.

This year CIHR published *Guidelines for Health Research Involving Aboriginal People*.⁶ The product of lengthy consultation between the CIHR Aboriginal Ethics Working Group and the ACADRE⁷ network, the guidelines promote compatibility between protocols and Aboriginal values and traditions.

⁶ Available online from http://www.cihr-irsc.gc.ca/e/documents/ethics_aboriginal_guidelines_e.pdf

⁷ Aboriginal Capacity and Developmental Research Environments (ACADRE) is a university-based network with links to academic research communities and partnerships.

In November 2003, the National Council on Ethics in Human Research (NCEHR) mandated a task force to make recommendations for the development of an accreditation system for human research protection programs based on previous NCEHR research on models of accreditation and a PRE report on Governance models. The Task Force consulted widely, including three rounds of formal consultation with those involved in the protection of human participants in research as well as less formal consultations with researchers, members of research ethics boards, administrators, research subjects and those responsible for accreditation programs in ethics and other fields. The Task Force's report⁸, published in 2006, described a national accreditation function, and recommended that NCEHR work with appropriate stakeholders to add such a function to its services. As part of the consultation leading up to the Task Force's final report, NCHER also published draft Standards for the Accreditation of Human Research Protection Programs.⁹

Feedback on this report identified the need for an accreditation process implemented by NCHER to be recommended and supported by key organizations. The Canadian General Standards Board proposed that the NCHER recommendations move forward for reviews of clinical trials under Division 5 of the FDA regulations and to natural products and devices and similar trials. Another development in the national research ethics context was the creation of the Sponsor's Table for Human Research Participant Protection in Canada that considered the NCHER report as background to their work. The Sponsors' Table describes itself as:

“a group of organizations that shares a common interest in promoting research involving humans that meets the highest standards in excellence and ethics. This interest includes exploring new ways to encourage ethical practice. One such approach, often suggested in this context, is a system of accreditation or alternative system for human research participant protection.”¹⁰

The Sponsor's Table acknowledges that, for the most part, Canadian research organizations “operate to high ethical standards and involve the dedication of many people.” They note also that:

“the current system of human research participant protection faces increasing pressures related to issues such as governance, transparency and public accountability. To address these pressures, the research community needs a shared vision that will define and build a process that further develops a system to protect research participants while facilitating research that is important to society. Given the national and international implications, it is time for all players to work together toward common solutions based on an open and transparent process.

⁸ NCEHR, “*Promoting Ethical Research with Humans: Report of the Task Force for the Development of an Accreditation System for Human Research Protection Programs*”

http://www.ncehr-cnerh.org/english/Task%20Force%20Report_FINAL_18%20July%202006.pdf

⁹ NCHER, “Proposed Draft Standards for the Accreditation of Human Research Protection Programs”, April 2005; http://www.ncehr-cnerh.org/pdf/task_force/Report_of_Standard_Subcommittee_Appendix_A.pdf

¹⁰ From <http://www.hrppc-pphrc.ca/english/sponsors.html>; a list of Table participants is also available at this website.

“In response, the Sponsors' Table has come together to facilitate a process to develop and assess an accreditation or alternative system for human research participant protection taking into consideration all relevant sectors and players in Canada. The Sponsors' Table aims to support a thoughtful consideration of accreditation or alternative system without prejudice to the final outcome of such a discussion. It will focus on accreditation or alternative systems in such a way that questions and issues are raised in an open and transparent context.”¹¹

To achieve this goal, the Sponsor's Table struck an Experts Committee with a mandate to provide expert advice on the development of a system for human research participant protection in Canada, considering accreditation and alternative models, and taking into account different levels and types of risk in research. This process will include an assessment of existing means of ensuring human research participant protection for various types of research and the gaps that such a system would address.¹²

In August 2007 the Sponsor's Table published the draft report of Experts Committee entitled “Moving Ahead”, and invited comments from the Canadian research community. The report proposes the creation of a new Canadian oversight system for research involving human subjects, including a national accreditation system. Stakeholder consultation on the report is ongoing at the present time; if adopted, the recommended changes could profoundly influence the future of research ethics review in Canada and in B.C.

2.2.2 British Columbia

At the provincial level there have also been numerous changes in the past decade affecting health and social sciences research. This section briefly summarizes some of the major events.

2.2.2.1 Legislative Change

The Health Care Act¹³ and the Freedom of Information and Protection of Privacy Act,¹⁴ [RSBC 1996] Chapter 165, both enacted in 1996, apply to health care professionals.¹⁵ Although the statutes do not delegate responsibility for oversight to REBs, they establish boundaries for human subjects research in tandem with the TCPS and REB members are mindful of their significance within the Province.

¹¹ From <http://www.hrppc-pphrc.ca/english/sponsors.html>

¹² From <http://www.hrppc-pphrc.ca/english/experts.html>

¹³ Health Care (Consent) and Care Facility (Admission) Act, [RSBC, 1996] Chapter 181

¹⁴ Freedom of Information and Protection of Privacy Act, [RSBC 1996] Chapter 165

¹⁵ Specifically, persons “licensed, certified or registered to provide health care”

2.2.2.2 Increasing Research Activity

In 2002, citing the need to address professional labour shortages and better serve rural health needs, the Government of British Columbia doubled the province's future capacity for medical school admissions by increasing the number of spaces in the UBC Faculty of Medicine and establishing satellite medical schools at the University of Victoria and the University of Northern British Columbia.

The resulting increase in the number of medical students undertaking research projects occurred at the same time as a steady and significant increase in overall research funding (and associated activity) in British Columbia. Data from federal sources analyzed by MSFHR shows that, over the past decade, British Columbia has vastly improved its national standing as competitor for the limited supply of health research dollars.¹⁶ With thirteen percent of Canada's population¹⁷ in FY 2005-06 researchers in B.C. successfully competed for a per-capita proportion of CIHR health research funding (\$82 million), compared to just eight percent of national funding (\$25 million) awarded in 2000.

For the years 1999/00 through 2005/06 the rate of increase in federal health research funding was higher in B.C. (228%)¹⁸ than in any other province. During the same time period, B.C. investigators have also increased their success in competing for funding from not-for-profit foundations and corporate sources.¹⁹ All these gains translate into increased numbers of research projects and, in turn, increased workloads for research ethics boards in B.C.

These trends are expected to continue. In 2007 the economy of British Columbia is prosperous; the Province's population is multicultural and growing, largely by immigration, with universities and colleges educating students for careers in the knowledge economy. Research and technological innovation to improve health outcomes are an important part of this economy.

In a report entitled *Strategic Considerations for B.C.'s Future: Issues and Trends 2007* the B.C. Progress Board reflected on the future of research in B.C.: "Promoting commercialization of ideas and new discoveries within business is fundamental to realizing lasting benefits from advanced research and development and to ensuring British Columbia's place as a national and global economic leader in the coming decade."²⁰

¹⁶ The Michael Smith Foundation for Health Research (2007). *Evaluating British Columbia's Performance in Health Research: Technical Report 1999-2006*. Vancouver, B.C.: MSFHR, 2007

¹⁷ As of April 2007 the populations of British Columbia and Canada were estimated at 4,352,800 and 32,852,800, respectively. Source: www.bcstats.gov.bc.ca

¹⁸ The Michael Smith Foundation for Health Research (2007). *Evaluating British Columbia's Performance in Health Research: Technical Report 1999-2006*. Vancouver, B.C.: MSFHR, 2007

¹⁹ The Leaders' Forum Steering Committee, *Strengthening the Foundation of Canada's Health Research Enterprise: A Background*. September 8, 2004.

²⁰ BC Progress Board. *Strategic Considerations for B.C.'s Future: Issue and Trends 2007 Report*. July 10, 2007. Source: www.bcprogressboard.com/2007report/

They also stated that “because of the wide variation in R&D expenditures and its empirically demonstrated positive relationship to productivity growth, increasing comparative levels of R&D and ensuring commercialization of R&D generated ideas is viewed as a primary method of stimulating sustained economic growth in developed economies like British Columbia...”.

2.2.2.3 Health System Restructuring

In December 2001, the B.C. Ministry of Health regionalized administration of the provincial health services system, consolidating 52 administrative bodies into six health authorities responsible for health services delivery. One central body, the Provincial Health Services Authority²¹ (PHSA) was assigned responsibility for provincial services, and five regional Authorities — Vancouver Coastal Health, Vancouver Island Health Authority, Fraser Health, Interior Health and Northern Health — were created to deliver services in their respective geographic areas.

Each Health Authority is now responsible for ensuring ethics review of all research protocols to be carried out at or by an investigator affiliated with a health care facility within its jurisdiction, and four of the six have established REBs accordingly. The other two Health Authorities have reached agreement with the University of British Columbia to carry out ethics reviews on their behalf: clinical studies to be carried out within the Vancouver Coastal Health facilities are reviewed by the UBC Clinical REB (CREB), while behavioural studies are reviewed by the UBC Behavioural REB (BREB). With respect to provincial cancer service agencies administered by the PHSA, adult oncology protocols are reviewed by the BC Cancer Agency REB, and all pediatric oncology research is reviewed by UBC’s CREB. Much cancer-related research is multi-centred and collaborative, hence, in the absence of reciprocal agreements, subject to review by as many REBs as there are relevant institutions.

2.2.2.4 Research Involving B.C.’s Aboriginal People

The Inter Tribal Health Authority (ITHA) was created in 1998 as a society under the B.C. Societies Act. ITHA functions as a representative body, and exercises limited authority with respect to services provided for 28 member First Nations on Vancouver Island and the B.C. coast. Sponsored by Health Canada, ITH has an interim research review committee and is working towards creating an REB that considers both Aboriginal traditional values and the TCPS. ITH facilitates research by referring proposals to individual tribal chiefs or elders for consideration. With respect to data, ITH promotes the application of governing principles relating to Ownership, Control, Access, and Possession (OCAP)²² or Self-Determination Applied to Research to research involving Aboriginal people.

²¹ PHSA governs a wide range of provincial services and institutions, including the BC Centre for Disease Control, BC Children’s Hospital, BC Women’s Hospital and Health Centre, the BC Cancer Agency, the BC Transplant Society and BC Mental Health and Addiction Services.

²² For further background, please see http://www.naho.ca/firstnations/english/ocap_principles.php

2.3 *Creating this Report*

Health research stakeholders across B.C. have identified the need for an effective, coordinated, value-add provincial approach to ethics approval – one that improves quality, access, consistency, efficiency and capacity for ethics review of research involving human subjects. While many agree that there is a clear need for such a provincial approach to ethics, it is not clear what potential approaches or solutions might be acceptable to stakeholders. Options vary widely from adoption of harmonized core guidelines and institutional review reciprocity to a coordinated, shared, provincial ethics review mechanism.

At the request of provincial health research stakeholders, and with the endorsement and support of the Ministry of Health and the Ministry of Advanced Education, in early 2007 the Michael Smith Foundation for Health Research agreed to facilitate a process to explore options in greater depth.

This report is the result of the first of three environmental scanning processes undertaken to inform this exploration initiative. The other two processes are:

- Harmonization Scan: information gathering regarding harmonized ethics review processes and structures adopted in other jurisdictions, particularly across Canada but also including selected other countries such as England and Australia.
- BC Investigator Survey: an online survey of B.C. researchers with recent experience in the application process for ethics review to identify and prioritize the key barriers/areas of concern with respect to quality, access, consistency, efficiency and capacity for ethics review.

Reports arising from all three scans will be presented to a gathering of stakeholder representatives from key B.C. health research institutions and organizations on November 19, 2007. The purpose of this workshop will be to receive the results of the environmental scans and survey; to hear from expert speakers; and to discuss options for a co-ordinated response in meeting the need for a provincial approach to ethics approval.

Following the workshop, in early 2008, MSFHR will publish a report on the conference proceedings that describes the outcomes of stakeholder discussions regarding the issues, barriers and options for coordinating a provincial approach to improving the quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects in British Columbia.

2.3.1 **A Survey of Research Ethics Boards**

This report is the result of a scan that consisted of two main parts: a written request for data in survey form²³ and subsequent follow up interviews (in person or by phone). The written data request focussed on quantitative information, while interviews sought to probe more qualitative questions and garner opinions of respondents with respect to both the current processes for ethics review and

²³ A copy of the data questionnaire is attached in Appendix A.

opportunities to enhance and/or harmonize the B.C. system. In all, a total of 26 academic, health care and community-based organizations were contacted, and we spoke with 34 persons, most of whom were REB administrators or Chairpersons.

There were 23 Research Ethics Boards identified that review research involving human subjects, representing 21 institutions. Of these, 22 REBs responded to the survey (Appendix A Stakeholder Questionnaire), and 23 participated in face to face or telephone interviews of 90 minutes to two hours duration each. Participating institutions are listed in Figure 2 on the next page. Not all REBs responded to every survey question; in the sections that follow, actual numbers of responses for each question are indicated when this number was less than 22.

We also interviewed representatives of the Canadian Western Institutional Review Board (WIRB) located in Vancouver, B.C. WIRB is a for-profit organization based in the United States that provides independent IRB services, often to national multi-centre and international clinical trials.²⁴ Since it is not a B.C. based corporation, data on its process is not included in this report, however it is important to note that the WIRB Canada, along with similar private U.S. and Canadian organizations is a primary service provider to industry-sponsored research in British Columbia.

There is a great variation in age of the REBs that responded to the survey, as seen in Figure 2. Fifteen of the REBs we contacted were created after the introduction of the TCPS in August 1998. Of these 15 Boards, four have been established within the last two years.²⁵

Our survey explored the processes for ethics review of many types of research, from social science to clinical trials, from community-based to data-intensive studies. Following a lengthy analysis of the written data, some clarification of answers was provided by respondents. This information was then combined with the results of the informational interviews, to develop this report on B.C.'s REB organizational structures, review processes and policies. An initial draft of the report was reviewed by the B.C. Research Ethics Harmonization Initiative stakeholders' task force²⁶ and resulting comments contributed to this final document.

²⁴ More information is available at <http://www.wirb.com>

²⁵ Please note that some "new" REBs (i.e. those established since 2004) may have been created to replace predecessor bodies established under earlier administrative structures. For example, some Health Authority REBs have taken on the role previously fulfilled by individual hospital REBs within their respective geographic areas.

²⁶ A list of the membership of this Task Force can be found in Appendix C.

Contributors to the Environmental Scan		
Organization	Type	REB established
BC Cancer Agency*	Health Services Academic	2003
BC Institute of Technology*	Academic	1999
Camosun College*	Academic	2006
Canadian Blood Services (B.C.)*	Health Services (national NGO)	2001
Community-Based REB*	Community	1999
Fraser Health*	Health Services	2004
Interior Health*	Health Services	2005
Inter Tribal Health Authority	Aboriginal	(in progress 2007)
Kwantlen University College	Academic	2002
Malaspina University-College*	Academic	2002
Ministry of Advanced Education	Government	n/a
Ministry of Health	Government	n/a
Northern Health*	Health Services	2007
Provincial Health Services Authority	Health Services	n/a
Providence Health Care*	Health Services	1996
Royal Roads University*	Academic	2000
Simon Fraser University*	Academic	1996
Thompson Rivers University*	Academic	2001
Trinity Western University*	Academic	1995
University College of the Fraser Valley*	Academic	2002
University of British Columbia*	Academic	Clinical: 1983 Behavioural: 1976
University of Northern BC*	Academic-Medical Faculty	1994
University of Victoria*	Academic-Medical Faculty	1999
Vancouver Coastal Health	Health Services-Academic	n/a
The Vancouver Foundation*	Community	2004
Vancouver Island Health Authority*	Health Services	Clinical: 1987 Health: 2006

Figure 2 Contributors to the Environmental Scan

*Completed Stakeholder Questionnaire

3. Survey Data: What We Learned

Our environmental scan sought to understand the way each REB, as an independent entity, undertakes to fulfill the responsibilities delegated by its institution, carry out the duties mandated by the Tri-Council and honouring commonly-accepted principles of ethical conduct.²⁷ We sought to gather information regarding processes for ethics review of research involving the full spectrum of behavioural, clinical, biomedical, social and multi-disciplinary research. Although our survey did not address every duty/principle encompassed in the TCPS statements, we did seek to explore those which are most relevant to potential harmonization or reciprocity arrangements.

3.1 Structure

3.1.1 A Snapshot of B.C. REB Activity

Figure 3 below reports on selected data items drawn from our responses to the questionnaire of 22 B.C. Research Ethics Boards. Taken together they present a quantitative snapshot of the variety and scope of activity undertaken by these boards.

A Snapshot of B.C. REB Activity	
Members	Number of members serving on an REB in B.C.: 285 Average number of members per REB: 13 Range in number of members: 5 to 27
Meetings	Average number of meetings an REB holds each year: 10 Range in number of meetings held each year: 2 to 23 Average length of an REB meeting (in hours): 2.3 Range in meeting length (in hours): 1.5 to 4.5
Applications (As reported by REBs for the year 2006)	Number of new ethics review applications received per year in B.C.: 4465 Average number of new applications received by an REB per year: 203 Range in number of new applications received by REBs per year: 3 to 1200 Total number of protocols that receive review each year in B.C.: 13593
Reviews	Proportion of all new applications in B.C. that receive full Board review: 30% Average number of reviewers assigned to each full review: 5 Range in number of reviewers assigned to each full review: 1 to 16

Figure 3 A Snapshot of B.C. REB Activity

²⁷ A copy of the data questionnaire is attached in Appendix A.

3.1.2 Authority and Governance

TCPS: Requires REBs to be established by the highest levels of the institution.²⁸

Most commonly, the REB managers or directors (terminology for this position varies among institutions) report directly to the Vice President/Provost of Research at their governing institutions (45%), 27% report directly to the Board of Directors/Governors/Senate, 18% to the President, and 9% to other (e.g. Director of Research). In several cases the REB had secondary reporting requirements to special committees (e.g. Medical Advisory Committee) or to the Board of Directors/Governors/Senate. Our survey found that the person(s) responsible for selecting the REB Chair varies among institutions, however, in five cases initial selections must be approved at a higher level (e.g. Vice President, President or Senate). The status of persons eligible to be appointed as Chair differs widely. In most instances the person appointed is either a current or past Board member.

3.1.3 Independence

TCPS: Requires institutions to ensure that REBs have the appropriate financial and administrative independence to fulfil their primary duties.²⁹

To address independence we asked about methods for selection and appointment of REB Chairs, the source of budgets and authority for allocation. Responses indicated a fair degree of variability. The process of selecting or appointing and approving REB chairs varies among REBs but our survey found that up to five levels of the institution may be involved in the process, which are not mutually exclusive and seen in Figure 4.

Authority for Selection of REB Chairs	
Authority involved in selection:	Number of REBs
REB Members	8
Vice President/Provost Research	6
President or other Executive	5
Board of Directors/Governors/Senate	4
Director/Dean	4

Figure 4 Authority for Selection of REB Chairs

²⁸ TCPS Sec.1, B3, Art. 1.4

²⁹ TCPS Sec.1, B1, Art. 1.2

REB managers and chairs did not report any attempts to compromise their independence and indicated that there are mechanisms for reporting any concerns that may arise.

Contributors reported a wide range of sources for REB funding and authority to allocate those resources, as described in Figure 5. For additional comments relating to financial resources, please see section 3.1.4 regarding data collected with respect to REB budgets. The REBs surveyed only charged fees only for industry-sponsored research, with the exception of one small community REB, which charged fees to all applicants as the primary source of funds.

Source of REB Budgets and Authority to Allocate Funds*	
Source of Funds	13 respondents indicated funds came from institutional sources, including research office budgets and research-funding “indirect costs”
	5 respondents reported receiving fees from commercial sponsors
	1 respondents reported receiving fees from all applicants
	2 respondents reported ‘other’ sources
	4 respondents did not answer
Authority to Allocate Budget	6 Director/Manager
	4 Vice President
	2 Board of Directors/Governors/Senate
	2 Research Office
	2 “Other Executive”
	3 respondents did not answer

*Responses were not mutually exclusive

Figure 5 Sources and Allocation of Funds

3.1.4 Efficient Management

TCPS: *Exhorts REBs to husband their resources and expertise prudently.*³⁰

It is difficult to estimate the true cost of administering an REB and processing applications. Where administrative assistants are not dedicated to REBs, it was reported that, in order to accomplish required tasks, they spend more time on REB work than is allocated in their job descriptions. In other cases administrative and management roles are assigned to the same person. For example, two

³⁰ TCPS Sec.1, B2, Art. 1.3

REB Chairs also perform the duties of Senior Administrators, five Senior Administrators provide administrative support and one Chair is also the administrative contact person for their REB.

Managers of REBs reported experiencing periods in which heavy workloads of high-risk studies required them to limit the number of items to be reviewed in order to provide sufficient time for meeting preparation and discussion. For such REBs capacity is an issue and leads to increases in the length of time between submission and decision. In light of this frequently-expressed concern, a significant effort was made to analyze the nature of and variations between REBs in member workload. Further data on this topic are presented in section 3.1.6 below; a more detailed description of the process used to develop quantitative estimates of member and REB workload is presented in Appendix D.

Although the survey specifically asked institutions to provide information regarding their budget allocations for administration and conduct of ethics review, our environmental scan was unable to obtain complete information about budgets (Figure 6). Of particular note is the apparent correspondence between declining to answer the question and REB size: in general, the largest REBs considered budget information to be confidential.

Responses to Budget Information Requests from 22 REBs		
Budget figure reported	36%	8
Respondents reported “budget unknown” or unable to report separate budget amount for REB activity	23%	5
Declined to report budget	41%	9

Figure 6 Responses to Requests for REB Budget Information

Interview respondents reported a lack of funds for administrative assistance, compensation of Board members, continuing education and information technology. Reports of resource shortfalls characterize each segment of the REB process: review of submissions, interface with researchers, planning for meetings, recruiting new members, recordkeeping and distribution of minutes; and compensation of board members from the community and across disciplines and monitoring of approved research. Most respondents reported that funds would not be readily available for items that they believed would enhance the quality and responsiveness of their institutions’ ethics review process, for example, additional administrative personnel, compensation to REB members and purchase and maintenance of state-of-the-art or customized software.

Several REBs reported that they operate under research office budgets as a discretionary account rather than a fixed line item. Limited funding for travel to Board meetings and continuing education is reported to be the norm. With respect to REBs affiliated with academic institutions, a few reported

that Chairs and faculty members are compensated through “course release” time but such compensation was not financially quantified in survey responses. Out of 21 survey responses five REBs reported that they provide course release time to the Chair or Vice-Chair and one REB reported course release time for administrative personnel.

3.1.5 Membership

TCPS: Requires at least five members, men and women, two with “broad expertise” in the REBs area of research, one knowledgeable in ethics, one community representative unaffiliated with the institution.³¹

Indicates “majority” of Board members should have “both the training and the expertise to make sound judgements.”

Suggests a member knowledgeable in the relevant law (see below for biomedical legal expert requirement).

Considers effective community representation to be “essential” and indicates that the number of community representatives should increase in proportion to the size of the Board.

Advises REBs to nominate “substitute” members to avoid “paralysis”.³²

Our survey found that as of July 2007, a total of 285 persons are currently serving as voting REB members across the Province. The majority of REBs have more than 10 members. Figure 7 illustrates the variation in size of Boards who responded to our survey.

Terms of Reference also differ among REBs in the requirement for REB members with certain areas of expertise: a wide variation was reported amongst REBs province-wide. Figure 8 describes the type of expertise among REB members. Several REB members were reported to have more than one main area of expertise, and therefore the total number of members represented in Figure 8 is greater than 285. The majority of REB members have expertise in either Clinical/Biomedical or Social/Behavioural fields of research. ‘Other’ types of expertise were commonly reported as students in academic institutions or members serving as a representative from a particular geographical region.

³¹ TCPS Sec.1, B2, Art. 1.3

³² TCPS Sec.1, B2, Art. 1.3

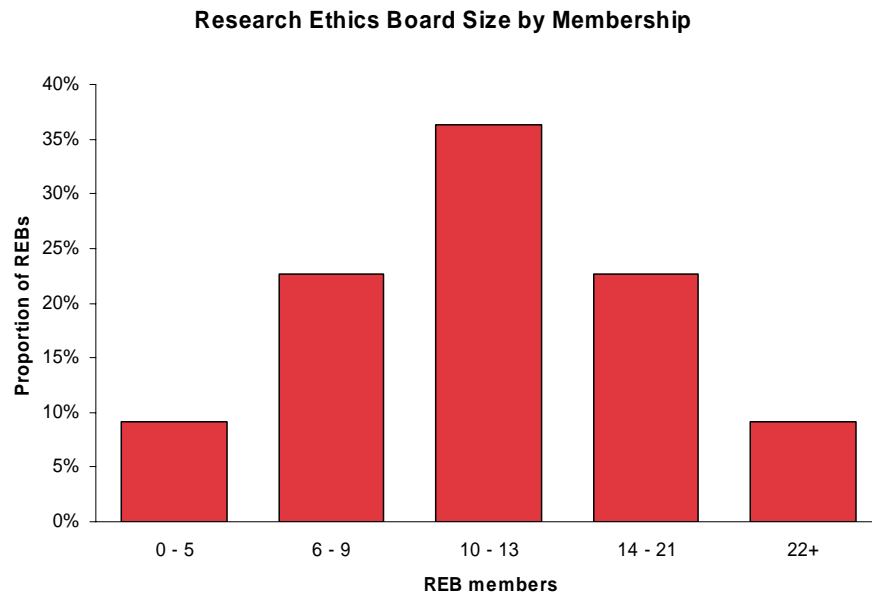
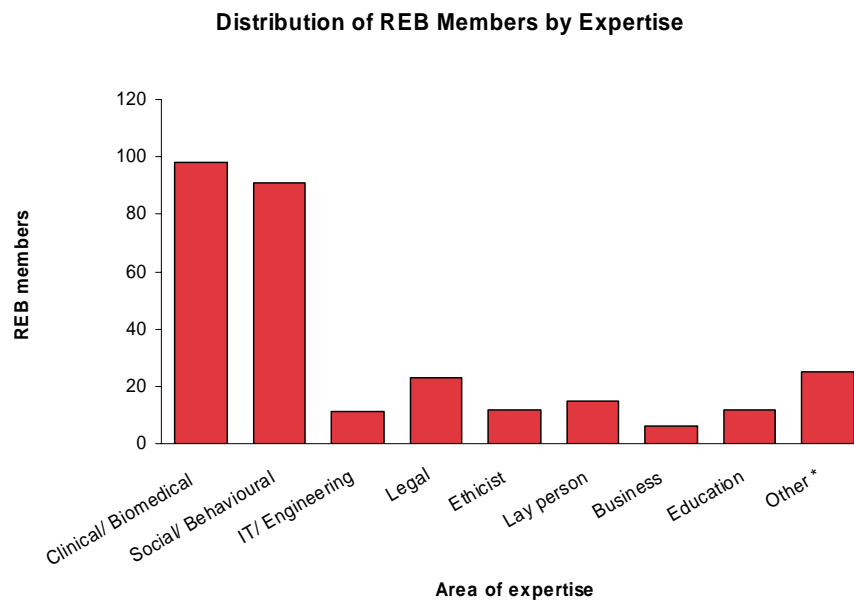


Figure 7 Size of REBs by Membership



**Examples of 'Other' include Statistician, Student, Spiritual, person selected from geographical representation, Admin Support, Natural Health Products*

Figure 8 Expertise of REB Members

Figure 9 below describes how the types of expertise are represented among REBs. The proportion of REBs that have members serving with a particular expertise is shown. Survey results show that 86% of REBs include members with Clinical or Biomedical research expertise, while 68% include members with Social/Behavioural backgrounds.

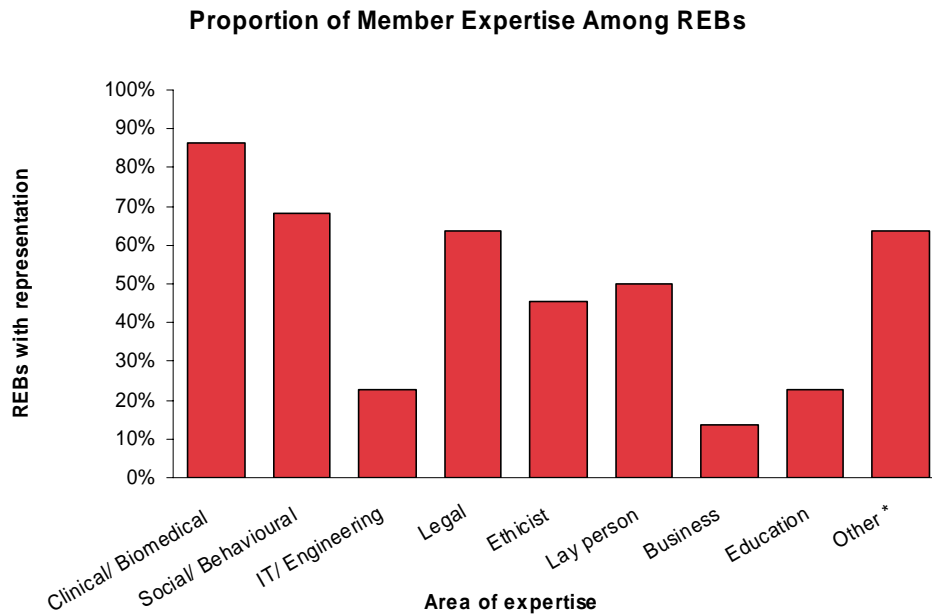


Figure 9 Expertise Represented on REBs

While the TCPS suggests that REB membership should include a person knowledgeable in the legal issues relevant to the field of research at issue, it precludes an REB's use of their respective institution's own lawyer in this role. All of the REBs surveyed included categorization of the expertise of REB members in their responses to our survey; 64% reported having a lawyer or legal expert on their Board. Seven large Boards that reviewed clinical or biomedical research reported having two or three lawyers or legal experts on the Board.

Figures 10 and 11 describe the affiliation of REB members and how it is represented among REBs. Survey results show that, of the total REB members in British Columbia, more than 200 (71%) are affiliated with the governing institution.

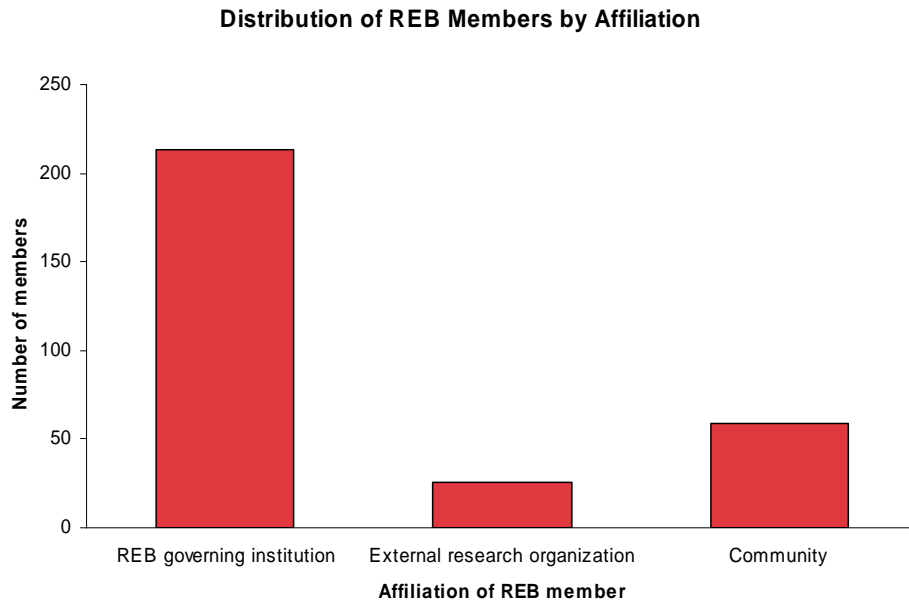


Figure 10 Affiliations Represented on REBs

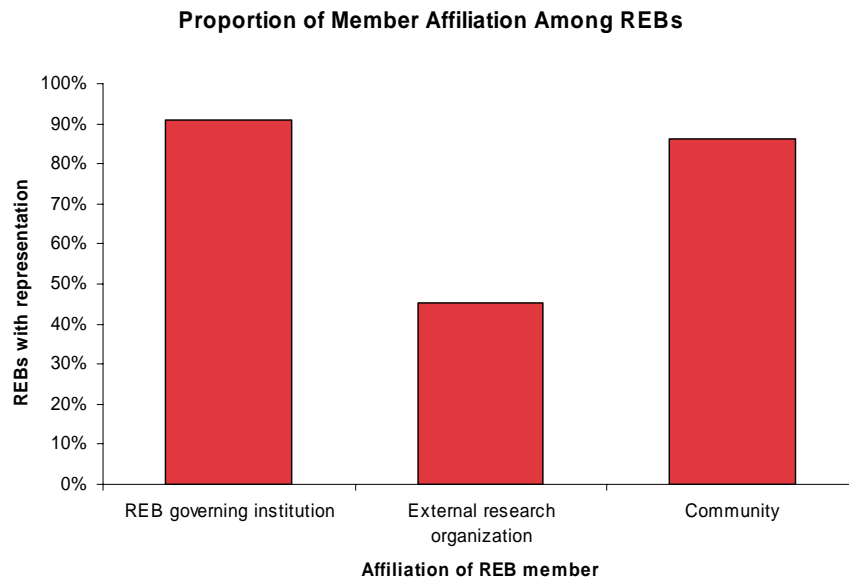


Figure 11 Affiliation of REB Members

With respect to the requirement for member training for their service on REBs, the majority of B.C. REBs reported that training is provided to their members. Fifty percent of REBs reported having at least one ‘lay member’ serving on the Board, and 64% have at least one ethicist. Commonly, new members must complete the TCPS tutorial and receive orientation and procedural training from the REB office administration. Seventeen REBs indicated that new Board members must complete some form of training before they begin their first term. Ten REBs provided additional details regarding the type of training received. Three of the REBs reported that they also offer mentoring by established Board members. Fifteen REBs also indicated that they encourage the continuing education of Board members, but the amount of support and compensation available in order for the members to take advantage of this opportunity was not reported.

Maintaining the required level of community membership was reported by most Boards to be a continuing challenge. Figure 12 shows that in general, B.C. REBs meet the TCPS expectation “that the number of community representatives should increase in proportion to the size of the Board”, and that this is particularly true for the larger Boards. Only three REBs reported no current community representatives as members.³³

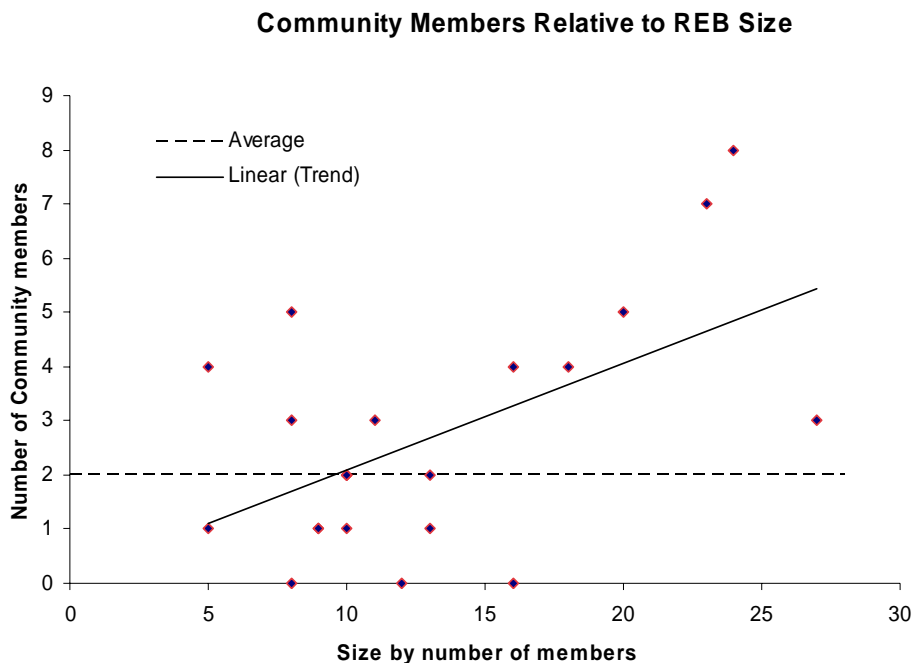


Figure 12 Community Representation by REB Size

Survey respondents reported that the vast majority of REB members are not paid for their REB service. Of 21 REBs respondents, 11 reported providing remuneration of any kind. Twelve of the

³³ Please note that REBs reporting participation of “community members” were not necessarily reporting “lay” membership. Some REB members categorized as community members had specific expertise (e.g. legal).

Boards provide reimbursement to all members for REB associated expenses. Only a small percentage of REB members were reported to receive compensation beyond in kind support such as initial training and continuing education, and reimbursement of travel expenses. Five Boards compensate Chairs and Vice or Associate Chairs through annual monetary payments, three through course release time and two through both monetary payment and course release time. Three REBs pay special members such as an ethicists or lawyers.

Voluntary turnover (defined as that which occurs when a member leaves before the end of his or her term) is a constant concern to many of our respondents. Even in the start-up phase turnover may be a problem. Each year, among REBs old enough³⁴ to reasonably estimate annual turnover, the average annual rate of voluntary turnover in membership is 16% with a range from 4% to 33%. With an average number of 14 members per Board, a 16% voluntary turnover rate translates into the loss of two to three REB members per year over and above those who have completed their terms. Members' terms of service are typically two or three years. To achieve a steady state of ethics experience most Boards stagger terms and allow members to serve an unlimited number of terms, although several Boards will restrict the number of consecutive terms.

There is great variability in the way members are recruited, nominated, approved and appointed. The criteria for selection of new members include understanding of ethical principles, scientific expertise, diverse representation and reliability of attendance to ensure a quorum. Research administrators generally develop lists based on referrals from current or former members, collegial nominations and Web-based solicitation. Recruiting techniques were reported to sometimes include offers of non-monetary incentives such as course release.

The following comments are representative of respondents' views expressed in interviews regarding the difficulty of recruiting and retaining members, maintaining a balance of scientific expertise and community representation and satisfying quorum requirements for meetings:

- *Volume of work discourages volunteers.*
- *Recruitment is a recurring issue due to commitment of time required.*
- *Professionals manage many competing demands and have no downtime.*
- *Recruiting new members is difficult for all university committees.*
- *It's very difficult to find people who want to volunteer for this.*
- *The majority of applications we receive fall within our Board members' expertise, but if they do not we obtain advice from elsewhere.*

³⁴ Please see Figure 2, section 2.3.1, for information on the range in ages of B.C. REBs.

Each REB was asked to report on the issues they face in the course of their work. Member recruitment was by far the most prominent issue and also reported as the most recurring issue: an issue that requires continual attention. Other issues ranked in prominence and recurrence were workload, duplication of effort, access to the review process, and quality of review (Figure 13).

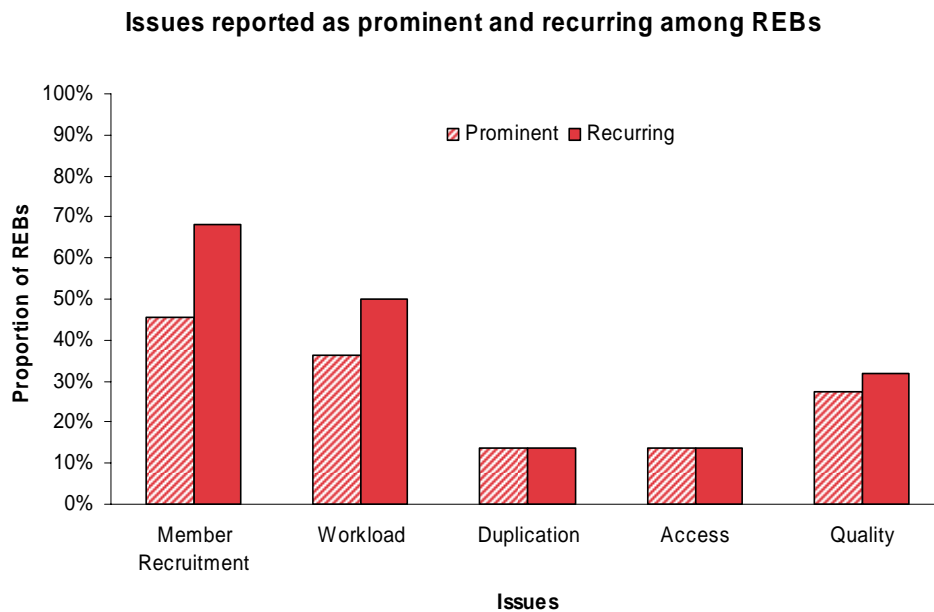


Figure 13 Prominent and Recurring Issues Identified by REBs

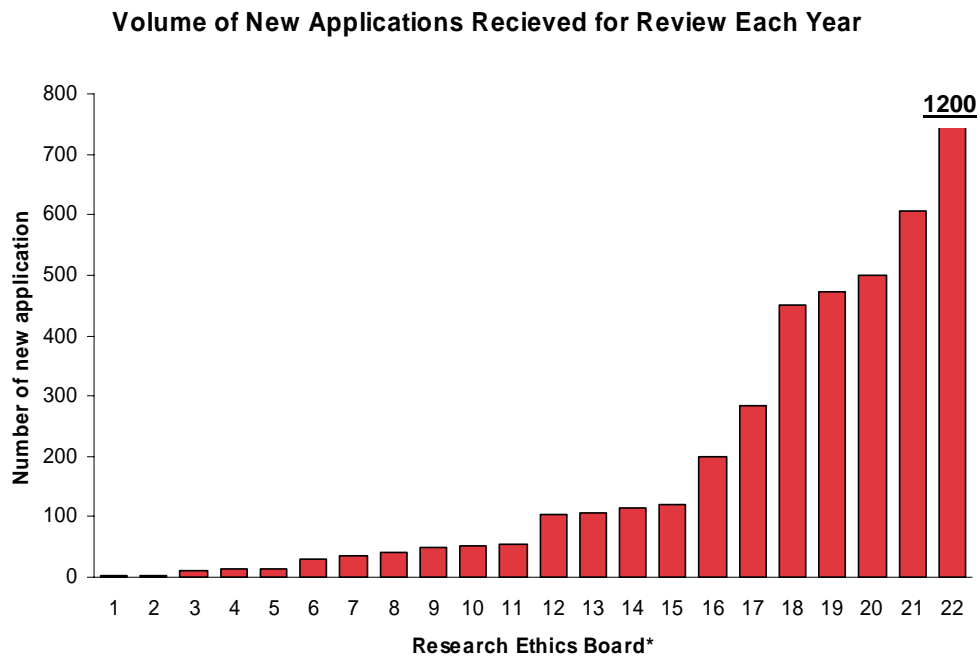
3.1.6 Manageable Workloads

TCPS: Requires REBs to cover as broad a range of research as is consistent with manageable workloads and discourages a multiplicity of REBs with small workloads within the same institution.³⁵

As noted above, workload was second only to member recruitment as the most prominent and recurring issue cited by B.C. REBs participating in this scan (see Figure 13). There are variations in experience, however. Survey data reveal significant variances between REBs in the volume of applications each Board receives for review, and the level of ongoing approved research subject to periodic review. REBs reported that 4,465 new applications for research ethics reviewed were

³⁵ TCPS Sec.1, B3, Art. 1.4

submitted to them in 2006.³⁶ The range of new applications received by an individual REB is three to 1200 (with one significant outlier: 21 of the 22 REBs received numbers of applications ranging from three to 605). The average number of applications received for review was 203.



*Assigned numbers are arbitrary; each represents one REB.

Figure 14 Volume of New Protocols per Year

The next phase of our analysis attempted to estimate the total review workload associated with these new applications. In addition to new protocols, ongoing protocols must also be reviewed for either amendments submitted, or renewals of ethics approval. Based on data submitted by REB respondents for 2006, an estimated 6,473 amendments (with a range of zero to 2080 per REB) and 2,655 renewals (with a range of zero to 836 per REB) are reviewed by B.C. REBs per year. This brings the total number of protocols reviewed each year to an estimated 13,593.³⁷

³⁶ REBs were asked to report figures for the last full year, which was for 2006 in almost all cases. If REBs were not able to report for 2006, they were asked to provide the average number per based on the most recent data available. See Appendix D.

³⁷ It is possible that amendments for new protocols are reviewed within the same year they are initially submitted and approved, possibly leading to some degree of duplication in this estimate.

While REBs reported a total of 4,465 new applications received for ethics review last year, revisions required to new protocols by the REBs result in the REB members reviewing a new protocol more than one time before approval. Not every REB member may review every protocol.³⁸ We also asked REBs to report the average number of times a new protocol is revised prior to approval (not including a possible administrative review which often occurs to ensure that an application contains the required forms, signatures, etc.) The average number of revisions before approval across REBs was two. If we take into consideration the number of times an REB must review a new protocol as well as the number of amendments and ongoing renewals they must review each year, we calculate that 17,559 protocol reviews are done each year.

Respondents noted that their concerns relating to variable quality of reviews across organizations were directly related to the variation in REB workload volumes – in their opinions, smaller organizations' REBs did not always garner enough experience with reviewing to provide the same quality of review as available from more experienced REBs who process higher volumes. Conversely, some respondents to our survey were of the opinion that large volumes of review work contributed to less time for thorough review of individual applications.

REBs in the start-up phase generally reported that they do not have workload issues. As noted previously, our scan found a great variation in age of the REBs that responded to the survey (as seen in Figure 2, section 2.3.1).³⁹ It is important to note that several of the newer Boards (established between 2004 and 2007) reported that although they review a smaller number of protocols, they have seen a noticeable increase in the number of new protocols each year. These Boards project that they will have a greater workload under the same resources in the future. There are several possible reasons suggested by our scan contributors including that the academic faculty are oriented towards teaching more than research; research interests do not require human subjects; and/or the bulk of human subjects research qualifies for expedited review.

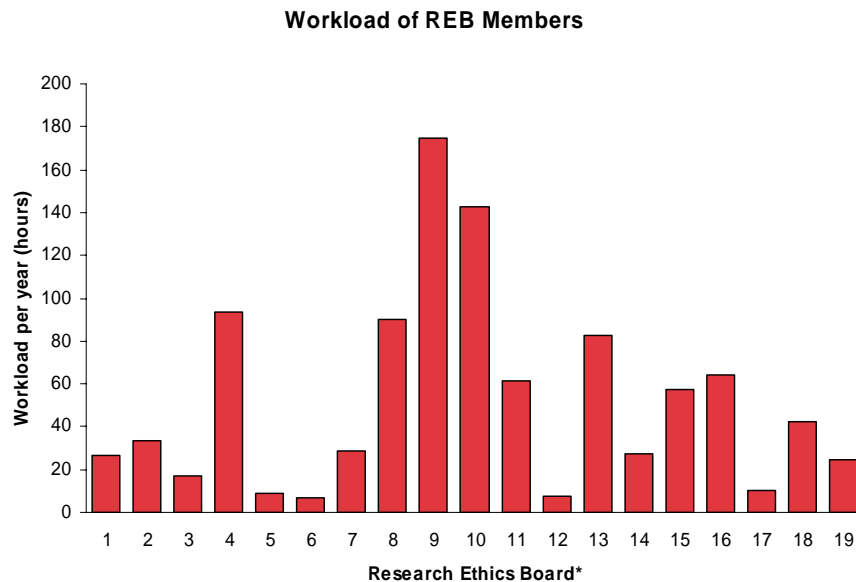
Calculation of the estimated workload of REB members must also take into account not only the time spent in review meetings, but also the effort required to review documentation and prepare for the meetings.⁴⁰ Appendix D describes our methodology for calculating estimates of this additional workload; the results are summarized in Figure 15 below, which illustrates the estimated member workload per year in hours, by Board. It is important to note that there is a wide range of workloads not only for the average member across all Boards, but also likely among members within a Board. Additionally, estimated workload per member does not take into account the additional specific duties of a Chair or Vice-Chair. The average member workload may greatly underestimate the average workload of a Chair or Vice-Chair due to the considerable amount of time they work over and above the commitment of an average member.

³⁸ Practices vary among REBs (see section 3.2.1)

³⁹ Please note that some “new” REBs (i.e. those established since 2004) may have been created to replace predecessor bodies established under earlier administrative structures. For example, some Health Authority REBs have taken on the role previously fulfilled by individual hospital REBs within their respective geographic areas.

⁴⁰ A MSFHR follow-up questionnaire (Appendix A, pg.59) asked about REB member preparation time.

Our total estimated workload calculations for REB members take into consideration the time spent in REB meetings per year; the average time spent in preparation for meetings; and the meeting attendance rate. Appendix D provides further details regarding how these estimates were calculated. Further details about meeting length and frequency can be seen in section 3.2.3. The estimates of REB member workload discussed related to REB members review activities only, and therefore do not include additional hours spent by REB members and chairs who are involved in other aspects of REB operations. Also excluded is any REB-related workload undertaken by institutional and administrative staff. Overall, these estimates can be considered to be highly conservative.



**Assigned numbers are arbitrary; each represents one REB.*

Figure 15 Estimated REB Member Workload

Keeping in mind the considerable individual variations described above, we estimate that the average B.C. REB member spends 50 hours on REB activities each year (with a range across Boards of 7 to 175 hours), for a provincial total of 17,048 hours. This equates to 2,273 days of work, or an FTE equivalent of 7.8. While this reflects an average REB member, workloads for Chairs would be significantly higher due to a much higher number of responsibilities and duties performed.

We estimate that 14 REBs have per member workloads less than the mean workload of 50 hours per year, while eight REBs' members have an estimated workload greater than 50 hours per year. Figure 16 shows how incidence of reporting workload and recruitment as a prominent or recurring issues is related to the estimated workload of an REB. REBs that have an average member workload greater than the average 50 hours per year reported recruitment and workload as issues more frequently than REBs with an average member workload less than 50 hours per year.

Relationship of Average Member Hours with Reporting of Issues		
Workload \ Issue	Recruitment	Workload
Average member workload is less than 50 hours per year	57%	43%
Average member workload is greater than 50 hours per year	88%	63%

Figure 16 REB Issues Relative to Estimated Member Workload

In general, Boards that review fewer new protocols per year have lower workloads. REBs that consider health services research and clinical trials usually review a larger number of protocols and report struggling with heavy workloads that challenge members and staff and frustrate investigators anxious to commence or continue important work. The following comments are representative:

- *Heavy workload is a recurring problem.*
- *We have a very large workload.*
- *Sometimes there are more applications than available reviewers with needed expertise.*
- *Job descriptions do not allocate time to review REB applications and attend meetings.*
- *Even minimal risk reviews take time and resources.*
- *Turnaround time for applications is negatively affected by the volume of work.*
- *From time to time submissions exceed full board capacity.*
- *Members contribute a significant amount of uncompensated time.*
- *Review of material prior to meetings is time-consuming.*
- *Workload interferes with continuing education requirements.*

3.1.7 Specific Areas of Research

TCPS: *Suggests large institutions may find it necessary to create more than one REB with each Board having the appropriate expertise to cover specific areas of research.*⁴¹

Two B.C. institutions with the combination of broad research interests and high volume of human subjects research have divided their institutional review duties across more than one Board. Historically, UBC had a single Board which was replaced by separate behavioural (BREB) and clinical (CREB) boards. In the spring of 2007 CREB, BREB, Providence Health Care and the B.C. Cancer Agency⁴² entered into an agreement designed to alleviate the burden of redundant reviews. As a result of this agreement the initial review conducted by any of the four Boards will be honoured by the other three in most cases. The Board that reviews and approves a protocol becomes responsible for subsequent supervision as well (see Appendix B, “One Board of Record” agreement).

The Vancouver Island Health Authority (VIHA) has also divided ethics review between two REBs. The long-standing Research Review and Ethical Approval Committee (established 1988) was formally divided in 2006 into the Clinical REB to review clinical trial and biomedical research and the Health REB to review social and behavioural research. In addition, VIHA has collaborated with the University of Victoria (UVic) in 2005 to establish a Joint Research Ethics Sub-committee. This joint committee reviews minimal risk research for UVic researchers who will be recruiting from or conducting research within the auspices of VIHA. The committee is co-chaired by one UVic and one VIHA REB member.

TCPS: Encourages open lines of communication.⁴³

Our conversations indicated that respondents believe the importance of providing assistance to applicants prior to the submission of applications cannot be overestimated.

We found wide variation in the use of existing information technology for applications, expedited review, communication with researchers and communication among members prior to full Board sessions. Customized information technology to facilitate communication is available but not in place owing to lack of funding. Many Boards were too small to see this as problematic and others mentioned the cost of a dedicated system as prohibitive.

⁴¹ TCPS Sec.1, B3, Art. 1.4

⁴² Providence Health Care and the BC Cancer Agency REBs are designated UBC-REBs, even though Providence is a Health Authority and BC Cancer Agency is under the jurisdiction of the PHSA. Vancouver Coastal Health does not have its own REB and defers protocols to be conducted at hospitals under its jurisdiction to CREB. Negotiations are underway for Canadian Blood Services, which is physically located at UBC, to be the 5th REB to join this group. UBC has a REB for animal research which uses the RISE system.

⁴³ TCPS Sec.2, D1, Art. 2.4 (c)

The only complete online system of application for researchers located in BC that was reported to us is the UBC RISE (Researcher Information Services) system, serving the UBC CREB, BREB, B.C. Cancer Agency, and Providence Health Care REBs.⁴⁴ The RISE interactive system used by UBC Boards allows the Chair and Manager of each UBC REB with an interest in a proposal to view the application and submit any questions or concerns to the Chair of the reviewing REB.

Several other REBs provide the option to submit applications electronically. Five REBs currently provide online information to direct researchers in the process of completing applications for multi-centre studies.

A few REBs reported that providing materials for education of the general public on ethical issues and ethics process was a branch of their responsibilities. We found 12 REBs that provide links to educational information on ethical principles and standards on their websites. Four of these provided information only on the TCPS and tutorial, while three provided additional information on subjects such as ICH-GCP, PRE, and CIHR. Five REBs provided a more extensive catalogue of information. Examples of this information include the Declaration of Helsinki, U.S. Food and Drug Regulations, FOIPPA and PIPEDA (Canadian privacy protection legislation), HIPPA (U.S. health insurance protection legislation), and references to SSHRC, NCEHR, and the Canadian Bioethics Society.

In general, Among respondents to our survey there was general consensus that, in principle, a uniform technological system could be useful. The actual details and nature of that system were, however, not addressed in any detail. In the short run many respondents predicted informational and educational advantages to a network for all B.C. Boards and some envisioned long-term harmonization of such resources.

- *We provide the researchers with the ability to track their submission throughout the review, and approval process from anywhere that internet access is available.*
- *We may not do a good job of communicating about ethics review.*
- *At the moment we don't have too many opportunities to share information, except perhaps when we meet at national conferences.*

3.1.8 Liability Prevention and Coverage

TCPS: Requires REBs to determine whether an application provides for a “comprehensible description of reasonably foreseeable harms and benefits” to be given to prospective subjects or authorized third parties.⁴⁵

REBs are typically insured for liability under general policies carried by an institution or organization. Six of the REBs surveyed were unsure of whom their insurance provider is, and a few others

⁴⁴ <http://rise.ubc.ca/rise/>

⁴⁵ TCPS Sec.1, B2, Art. 1.3

provided delayed answers because they did not know at the time that the survey was conducted. The Canadian University Reciprocal Insurance Exchange (CURIE) covers Provincial academic institutions and the BC Health Care Protection Program insures Health Authorities. Community-based REBs are covered under private insurance companies, while one of the REBs surveyed, the Canadian Blood Services, is self-insured. The REBs interviewed did not report any experiences with legal actions in British Columbia with respect to REB deliberations, much less any finding of culpability. Overall, there is a sense of concern that an adverse event could result in legal liability but no personal experience to that effect.⁴⁶

TCPS: Requires an REB member knowledgeable in the relevant law for biomedical research and advises the presence of a member knowledgeable in the relevant law for other areas of research⁴⁷ but prohibits the use of an institution's legal counsel.

Member recruitment was the most frequently reported issue among REBs (Figure 12). Ten REBs reported it as a leading problem, and 15 reported that it is an ongoing issue. Larger REBs more frequently report it as a problem than smaller REBs (see section 3.1.6).

Only one REB reported biomedical studies as a specific focus of the research they reviewed and at the same time also reported that their REB does have relevant legal representation. Although there were no other REBs that reported biomedical research as a specific focus area of review, we identified at least 11 REBs that may review biomedical research from time to time.

Of these, all have legal representation on the Board, therefore fulfilling the TCPS requirement. Overall, there are 14 REBs that have legal representation and 11 of these reported that this fulfills requirements under the REB Terms of Reference.⁴⁸ For REBs without resources to pay legal fees, a lack of legal representation may be related to difficulties in recruitment that arise from general resource limitations and/or the relatively high opportunity cost accruing to lawyers who volunteer their time for REB service.

3.2 Procedure

3.2.1 Levels of Review

TCPS: Suggests three levels of review: 1) departmental, 2) expedited and 3) full REB.⁴⁹

⁴⁶ A sampling of the U.S. experience with litigation can be found at <http://www.sskrplaw.com/gene/index.html>.

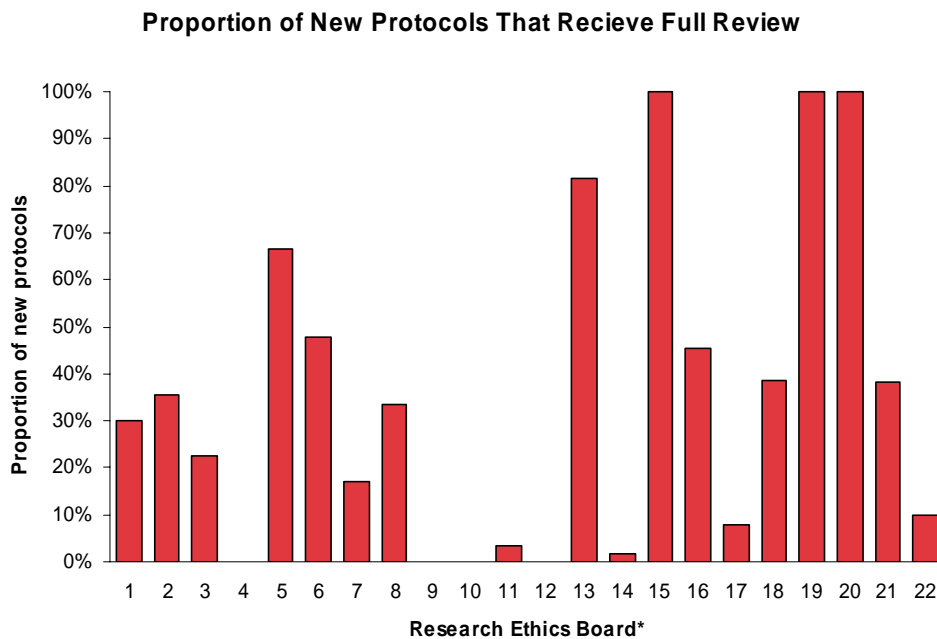
⁴⁷ TCPS Sec.1, Par. D1, Art. 1.6

⁴⁸ These 11 stated that their Terms of Reference or Standard Operating Procedures mandates that the Board must have one member with appropriate legal expertise at all times.

⁴⁹ TCPS Sec.1, Par. D1, Art. 1.6

While the TCPS provides criteria for these three levels of review, in practice there is discrepancy which appears to relate to be a function of volume, resources and experience. Four Boards reported that 100% of submissions met the criteria for expedited review, while three reported that all applications received full Board review. No analysis was undertaken to determine the rationale for these variations.

Across the province, approximately 30% of all protocols are reviewed by full Board. However, on average, any given Board typically undertakes a full review of approximately 40% of the protocols submitted to that Board. Figure 17 shows the variability of proportion of protocols that receive full Board review among REBs. There does not appear to be a strong relationship between the number of new protocols that an REB receives each year and the proportion of protocols that receive full review. Smaller Boards are not necessarily more likely to review more protocols by full Board and larger Boards are not necessarily more likely to expedite reviews of more protocols compared to smaller boards.



**REBs are presented randomly; assigned numbers are arbitrary.*

Figure 17 Proportion of Protocols that Receive Full Board Review

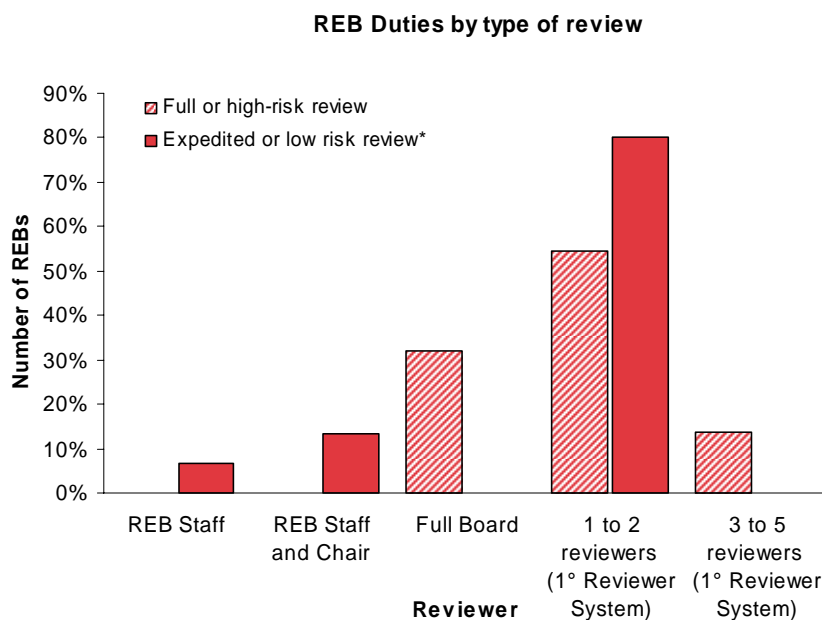
Independent student research in connection with course work (not part of a faculty project) is evaluated by professors and, in some cases, by department heads as well. Where department heads review the project, the institutional policy will govern whether the student still needs to submit an application to the REB.

3.2.2 Proportionate Review

TCPS: Instructs REBs to allocate resources in proportion to the “potentially invasive or harmful” nature of proposed or ongoing research⁵⁰ and reserves the “most intensive scrutiny” to the “most ethically challenging” research.⁵¹

According to the data provided by respondents to our survey, approximately 1 332 applications received full REB review in 2007 by a total of 18 REBs. For both expedited and full or high risk reviews, the most common approach reported by B.C. REBs is the primary reviewer system, involving one to two primary reviewers undertaking in-depth reviews. Appointing a primary and secondary reviewer (to provide in-depth coverage and make a presentation at the Board meeting where the submission is scheduled to be discussed) is the most common type of review for both full and expedited review (Figure 18). Often the primary or one of the secondary reviewers is the Chair (however this was not reported in our data). Sometimes expedited review is conducted by the Chair or staff member without full Board involvement.

In highly complex matters an additional outside consultant may be hired to provide scientific or regulatory expertise. Respondents uniformly acknowledged the potential need for outside expertise to augment members’ knowledge.



**Based on 15 survey respondents*

Figure 18 Duties by Review Type

⁵⁰ TCPS Sec.1, Par. D1, Art. 1.6

⁵¹ TCPS Sec.1, Par. D4, Art. 1.9

Some Boards that serve individual institutions commented that their ethics reviews rely on members knowledgeable of local demographic characteristics. Two REBs reported that they require at least one member based on their geographical representation. Similarly with respect to Aboriginal populations, some REBs reported that they have more experience in this area compared with other Boards.

Lack of funds for administrative staff, difficulty in recruiting members (particularly members with relevant expertise) and sheer volume of submissions were three often-cited obstacles to efficient handling of the kind of research that warrants full board review.

3.2.3 Face-to-Face Review

TCPS: Requires face-to-face review of proposed research except proposals that meet the criteria for expedited review.⁵²

The number of meetings per year and length of meeting times for a given REB was found to be correlated with the volume of applications received for review, the complexity of the science involved in the submitted protocols, and the perceived level of risk to human subjects. The majority of proposals that require full board review relate to clinical trials. These were reported to consume REB time disproportionately, and often stretch REB resources. Behavioural and health services research involving potential psychological risks, vulnerable populations and/or sensitive data may also require special skill and engender intense deliberation.

Applications for clinical trials of new drugs and medical devices or new uses for approved drugs rarely meet the requirements for expedited review. To accommodate both the volume and degree of difficulty, the REBs that typically review these kinds of applications were found to schedule as many as two meetings each month (total of 22-23 meetings per year).

Survey responses revealed that the average length of one B.C. REB meeting is 2.3 hours, with a range of 1.5 to 4.5 hours. The average number of meetings held per year is ten, with a range of two to 23. The distribution of meeting frequency can be seen in Figure 19 on the next page. Considering the number of meetings per year, the estimated preparation time required, the average attendance and length of each meeting, we project that the average REB member spends approximately 50 hours on REB-related activities each year, with a range of seven to 75 hours per member across all Boards.⁵³ Again, there is a large spectrum of workloads for the average REB member across Boards, as well as among members within a Board. In particular, the workload is underestimated for Chairs and Vice-Chairs when considering their additional duties (see section 3.1.6).

⁵² TCPS Sec.1, Par. D3, Art. 1.8

⁵³ Appendix D provides details of MSFHR's methodology in calculating these workload estimates.

Respondents reported that typically REB meetings tend to follow an agenda, often distributed to members prior to the meetings, and minutes are always recorded. During meetings the tone of proceedings was reported to range from informal to formal. In the opinion of respondents, the general lack of shared or common templates contributes to delays in approvals and inconsistent requests for modifications when applications are reviewed by multiple institutions.

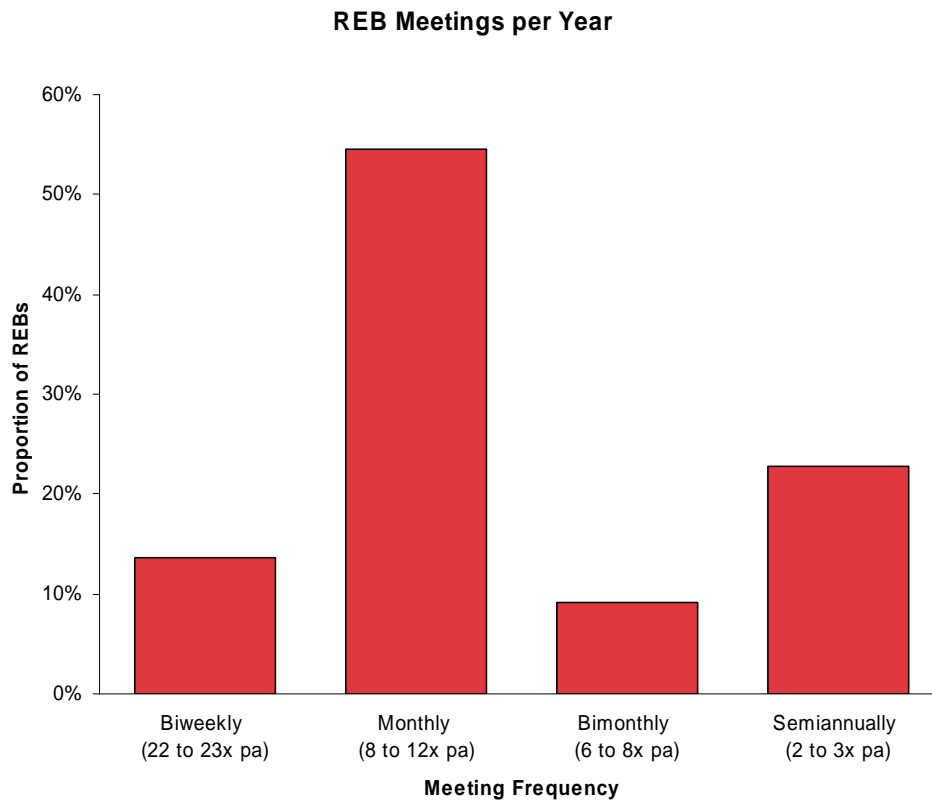


Figure 19 Meeting Frequency

3.2.4 Researcher Access

TCPS: Requires REBS to accommodate “reasonable requests from researchers to participate in discussions about their proposals.”⁵⁴

Prohibits researchers from being present when members make decisions.

Most respondents agreed that, if applications are properly screened and corrections made in the time between submission and meeting, there is generally no need for the researcher to attend the REB meeting when their application is discussed. But where there are complex issues of a scientific

⁵⁴ TCPS Sec.1, D5, Art. 1.10

or ethical nature, a Board may wish to pose questions directly to the investigator in the presence of all decision-makers.

There was a great deal of variation reported by respondents with respect to applicant-Board interface during REB meetings. REBs reported the need for more administrative resources and member expertise to interface effectively with applicants, to reduce waiting time for approvals and to enhance mutual understanding of expectations and outcomes.

In general, REB administrators and Chairs reported being aware that researchers do not always feel well-served by the application and review process. Several respondents suggested that a combination of enhanced efficiency and improved communication may be effective to build trust and open communication between researchers and REBs. Some comments about the participation of researchers in discussion of their submissions, representative of respondent views, are as follows:

- *A researcher may be invited by the REB to attend a meeting to discuss their project for an exchange of information prior to the REB discussion and vote.*
- *We provide the researchers with the ability to track their submission throughout the review and approval process from anywhere that internet access is available.*
- *Investigators may ask and be given permission to present their study at a meeting.*
- *Researchers have access to office staff, online guidance, pre-submission discussion interaction and may request to be invited to attend a Board meeting to discuss their application.*
- *Access is always an issue.*

3.2.5 Decisions and Dissents

TCPS: Requires minutes to be prepared and maintained documenting decisions, dissents and rationale.⁵⁵

Seventeen boards cited “consensus” as the basis for decision-making. When impasses are reached there is a tendency to explore the issues and call upon expert advice. Majority vote prevails when consensus cannot be reached within a reasonable timeframe. Several Boards have formalized mechanisms for decision-making in the absence of unanimity. Large-volume REBs that review clinical research have introduced specific requirements for representation among those in favour of approval. Figure 20 summarizes the three main decision-making mechanisms employed by B.C. REBs.

⁵⁵ TCPS Sec.1, Par. D3, Art. 1.8

Summary of Common Decision-Making Mechanisms	
Consensus	Seventeen Boards reported they prefer make decisions by consensus. Four Boards reported they will use majority vote if consensus fails to be reached. Several respondents indicated that REB members were willing to prolong discussions in order to achieve consensus.
Majority	Four Boards reported that majority vote was routinely accepted. Fifteen Boards reported that whether through consensus or majority, they have never failed to reach a decision during a meeting. A tie is often resolved by Chair vote.
Majority vote plus	One board reported specific modifications to the normal definition of majority, involving quorums related to member representation.

Figure 20 REB Decision-Making Mechanisms

3.2.6 Reconsideration of Research

TCPS: Requires REBs to reconsider any decision negatively impacting a research project upon the researcher’s request.⁵⁶

Requires REBs to provide an explanation of the reasons for opinions or decisions and written grounds for the decision.

Gives researchers the right to request reconsideration, “to be heard” by the REB and to rebut the stated grounds and opinions for decisions.

The MSFHR environmental scan did not gather specific information about the practical application of these provisions of the TCPS. In their Terms of Reference or Standard Operating Procedures, nine of the REBs surveyed briefly state the right of a researcher to request reconsideration and the requirement of the REB to comply. Of these, only four make reference to an established process for handling reconsideration.

Interview comments reflected a widespread agreement that researchers are entitled to reasonable access to the decision-making process and the opportunity to engage in a dialogue that enhances the quality of decisions.

⁵⁶ TCPS Sec.1, D5, Art. 1.10

3.2.7 Prior and Parallel Reviews

TCPS: Advises REBS to “normally avoid duplicating previous professional peer-review assessments unless there is a good and defined reason to do so.”

Some survey and interview respondents reported that their Boards are disposed to rely on previous peer reviews in the interest of conserving institutional resources and promoting efficient decision-making. Others expressed reluctance to cede responsibility; ambiguity about interpretation of this provision; and concerns about liability. This environmental scan did not undertake a case by case analysis to confirm anecdotal evidence of wide variability with respect to actual practices in this area.

REBs differ as to whether they consider the administrative or financial impact of research on their institution to be an appropriate field of inquiry for the REB. In many institutions, a parallel or sequential review takes place alongside the REB process with respect to the burden of research on the resources of a facility. In some cases a facility will conduct an independent review of the proposal’s burden on its resources and calculate an appropriate fee or surcharge; sometimes this review is concurrent with the REB consideration. A range of opinions was expressed amongst respondents to our scan as to whether coordination of ethics and facilities’ reviews would promote efficiency.

Review systems focusing primarily on administrative, liability and financial issues (as they relate to the health authority or hospital at which research occurs) are becoming an increasing component of approval processes for health research involving human subjects. The relationship of these processes to ethics review is sometimes unclear. In attempt to address this issue for example, the Alberta Research Ethics Community Consensus Initiative (ARECCI)⁵⁷ has noted the definitional challenges associated with research approval. Early in that initiative’s work, questions arose:

“... as to whether knowledge generating projects understood to be something other than research, such as quality improvement, quality assurance, and program evaluation, should be ethically reviewed, and if so, by whom. With the current emphasis on evidence-based practices, projects seeking to gather such evidence are being encouraged across the health system. Whether such projects are labelled as quality and evaluation, they may pose some of the same risks to human subjects as projects that are labelled as research. It needs to be made clear what needs ethics review and why. Review processes need to be transparent and consistent, whether undertaken by an REB or by another process.”⁵⁸

⁵⁷ ARECCI is a collaborative undertaking of organizations and entities who have chosen to work together to enhance the ethical oversight of certain types of knowledge generating projects in health care in Alberta (research, quality improvement, quality assurance, program evaluation). ARECCI is a joint initiative of the Alberta Heritage Foundation for Medical Research (AHFMR), Research Ethics Boards (REBs) in the province, Health Authorities, and Alberta Health and Wellness.

⁵⁸ ARECCI, 2007: <http://www.ahfmr.ab.ca/arecci/overview.php>

3.2.8 Appeal Boards

TCPS: Directs REBs to establish a system for appellate review when discussion and reconsideration fail to yield agreement.⁵⁹

Suggests that small institutions form “regional alliances, including the sharing of appeal boards.”⁶⁰

Despite their institutional independence, several academic REBs in British Columbia have entered into formal agreements to serve as appeal boards for each other. As reported by respondents to the scan, nine REBs have an agreement to share an appeal board with an REB outside of their institution (see Figure 23). Of these, three reported reciprocal agreements and two are large institutions that provide appeal board services to a smaller REB (size based on volume of protocols reviewed). Several more recently established REBs reported that they have not yet been required to use an appeal process and have therefore not explored collaborations with other REBs.

3.3 Policy

3.3.1 Fundamental Principles but Range of Values

TCPS: Expresses the belief that fundamental principles in research involving human subjects are common across the social sciences and humanities, the natural sciences and engineering and the health sciences.⁶¹

Acknowledges the “range of fundamental values upon which the research ethics enterprise is founded.”⁶²

This scan asked the REBs to discuss the frequency and intensity of reviews that include consideration of common principles such as: informed consent and absence of coercion; scientific and legal qualifications of the investigator; properly formulated scientific experimentation; and beneficence towards experiment participants was imperative. The purpose of these questions was to seek information about how a REB informs itself and deliberates on the scientific basis for the proposed use of human subjects to promote valid research objectives.

In general, responses indicate that the REBs share a strong commitment and adherence to the fundamental principles underpinning research involving human subjects. Although the fundamental

⁵⁹ TCPS Sec.1, D6, Art. 1.11 (a)

⁶⁰ TCPS Sec.1, D6, Art. 1.11 (a)

⁶¹ Goals and Rationale of the Policy, TCPS Section B

⁶² Goals and Rationale of the Policy, TCPS Section G

values upon which the research ethics enterprise is founded are shared among REBs in B.C., there is an acknowledged range of adherence and ability to accommodate these values.

In some instances REBs reported that the intensity of consideration of these principles in ethics review is commensurate with the overall level of risk. Nine REBs responded that they routinely explore whether or not the research study is based on previous knowledge so that the anticipated results justify continuation with human subjects. Other REBs stated that there has been no occasion where this situation has arisen as most research they review involves very low risk. Some also reported that they rely on the criteria and approval of Health Canada and/or other peer review bodies who have reviewed the scientific merit of the research prior to the ethics review process.

REBs that serve a single, small institution reported that they often do not review qualifications of investigators to determine whether they have the experience to undertake proposed methodologies, in some cases due to the fact that at these smaller institutions the researchers are usually well known to the REB members.

3.3.2 Scholarly vs. Ethics Review

TCPS: Acknowledges the dichotomy between “scholarly” and “ethics” review.⁶³

Accepts the need for flexibility with respect to scholarly review of biomedical research by stating “the extent of review ... will vary according to the research carried out.”

Offers four options for deciding if, when and how to conduct scholarly review.⁶⁴

When a study is assessed to present more than minimal risk, a difficult question sometimes arises for REBs: how much or how little attention should be paid to its “scholarly merit”? The flexibility built into the Tri-Council system reflects this challenge, but at the same time has been cited as a contributor to inconsistency in the approach of autonomous REBs. Alternately, others point to this inconsistency as a sign the process is working, since reasonable minds can differ on complex ethical questions.

Where the applicant is a principal investigator affiliated with an academic institution, the proposal may have been reviewed by an academic department and a sponsoring organization and the REB can accept that judgment. For example, a review committee established at Vancouver’s Children’s & Women’s Health Centre and the Research Institute functions as a permanent “scholarly” review

⁶³ TCPS Sec.1, C2, Art. 1.5

⁶⁴ Specifically, the four options offered are: “Conclude that the proposed research has already passed appropriate peer review, for example by a funding agency; Establish an ad hoc independent external peer review; Establish a permanent peer review committee reporting directly to the REB; [and] Assume complete responsibility for the scholarly merit, which would require that it have the necessary scholarly expertise in the discipline to carry out peer review of the research in question.”

committee for research to be conducted at this facility or by an investigator affiliated with the Centre or the Institute. This Committee operates in conjunction with BREB and CREB and relies on the UBC Boards for ethics review. Its mandate is “to ensure that research projects at Children’s & Women’s are appropriate with respect to ethics, methodology, patient impact and availability of Children’s & Women’s resources.”⁶⁵ MSFHR was told that such activities where they exist can slow down the ethics review process.

Across the Province we found inconsistency in the extent of peer review of non-minimal risk studies and availability of expertise, as reflected in the following comments from the scan’s respondents:

- *Intensity of study review depends on level of concern about value and design.*
- *Review includes assessment of social value and scientific value.*
- *Expert reviewers, either Board members or consultants determine if the level of risk is justified by the merit.*
- *If the study is supported by a sponsor that adequately reviews scientific merit, the REB accepts that as an adequate review and then determines if the risk is justified.*
- *Bad research is unethical.*
- *Where student research is involved the purpose of the review includes training in research methodology.*
- *Reviews include assessment of social value and scientific value.*
- *If the benefits outweigh the risks we do not judge the study design.*
- *When vulnerable populations are involved our review is more intense.*

3.3.3 Free and Informed Consent

TCPS: Defines “free and informed consent” as “the dialogue, information sharing and general process through which prospective subjects choose to participate in research”.

Recommends written consent by the subject or authorized party and requires documentation of any alternate procedure.

Each REB acknowledged that the fundamental principle of ensuring each human subject has the mental and legal capacity to understand the nature of the study and is provided with adequate knowledge to understand the risks involved is of utmost priority in ethics review. However, review of an applicant’s written explanation of a subject’s proposed role, risk of harm and potential benefit for the purpose of satisfying the requirement for “free and informed consent” was frequently mentioned

⁶⁵ Clinical Research Review Committee of Children's & Women's Health Centre and The Research Institute http://cfri.ca/research_support/hospital_research/process_procedures.asp

as time-consuming and detracting from the quality of review and consistency of requests for modifications. REBs that use informed consent templates and pre-review modification through the intervention of a skilled administrative assistant reported that this contributed to more efficient and timely review. There are 10 REBs that use informed consent templates, although one of these is only applicable for research involving special populations (e.g. children). Providence Health Care and Fraser Health also share common informed consent forms for emergency health research studies.

Some representative comments reflecting respondents views on variations in informed consent review are as follows:

- *Vulnerability of the participant population is always considered.*
- *Issues of power and authority between the researcher and subject are important.*
- *Any issues identified by reviewers are discussed at meeting.*
- *We consider whether the researcher is in a position of power or influence.*
- *We ensure that a detailed, but not complicated, consent form is provided.*
- *Almost every proposal has a weak area.*
- *Where vulnerable populations are involved we seek special assurance that potential for harm is fully understood.*
- *Comprehensive and detailed information is required.*
- *Consent forms have to be modified to reflect local site information.*
- *Agreement as to what constitutes implied consent with respect to secondary use of data would promote consistency and efficiency.*

3.3.4 Multi-centre Research

TCPS: Encourages small institutions to explore regional cooperation or alliances, including the sharing of REBs.⁶⁶

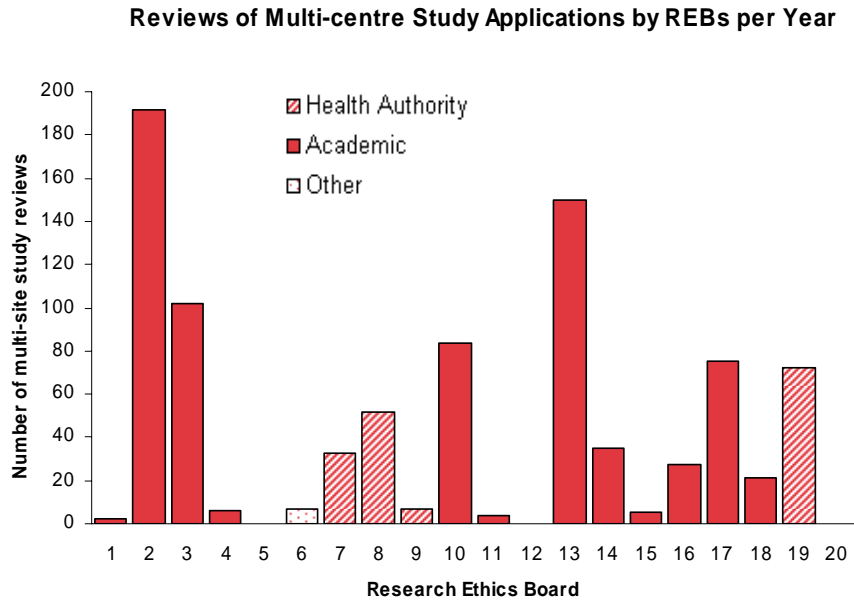
Discourages simultaneous submission of an application to more than one REB within an institution and admonishes researchers submitting an application not to seek simultaneous review by another REB, “whether inside or outside the institution.”⁶⁷

Among 20 survey respondents that responded to this category, 17 reported that they have reviewed applications for multi-centre studies (Figure 21). Of these, 10 have reviewed applications for multi-

⁶⁶ TCPS Sec.1, B3, Article 1.4 (c)

⁶⁷ TCPS Sec.1, B3, Article 1.4 (c)

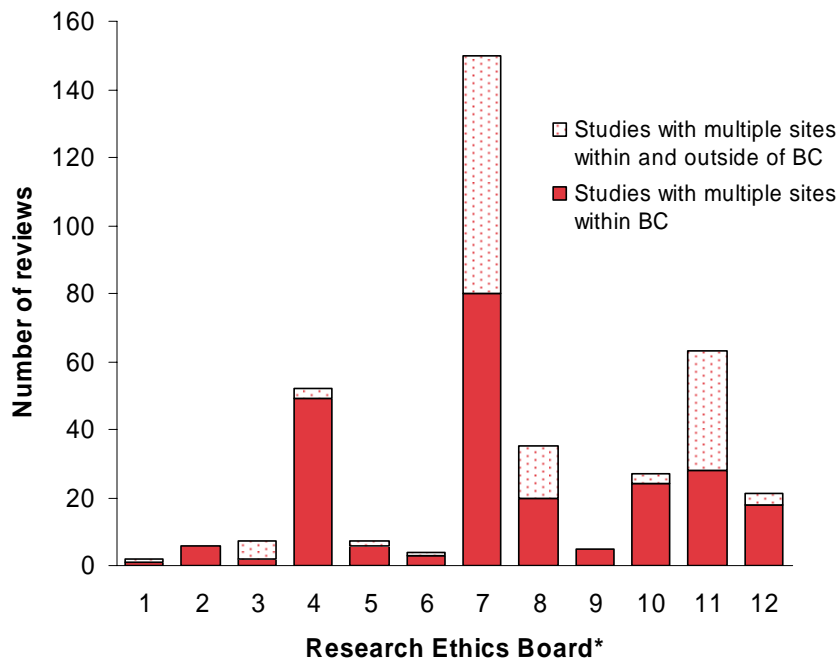
centre studies that involve sites outside of British Columbia, however, at the time of the survey, five were not able to report whether or not the multi-centre studies they reviewed had sites outside of B.C. (Figure 22).



Note: REBs presented randomly; assigned numbers are arbitrary.

Figure 21 Multi-centre Reviews

Review of Multi-centre Studies Involving Sites Within or Outside of B.C.



**REBs presented randomly; assigned numbers are arbitrary. As seen in Figure 21, only 17 review multi-centre research. Only 12 of these 17 were able to report activity by location; their responses are represented in this graph.*

Figure 22 Locations of Multi-centre Reviews

Through research and survey responses several links were found between REBs who have cooperative agreements; however, when asked about current cooperation with other institutions on the ethics review process, REBs reported an absence of cooperative agreements. Numerous reasons were given for the lack of regional cooperation. The following barriers were commonly expressed:

- ambiguity about what kind of arrangement would be consistent with the Tri-Council guidelines;
- concern about liability;
- uncertainty regarding the quality of other Boards' reviews;
- appreciation for the pedagogical value of ethics review; and
- institutional pride.

REBs also differ in their approach to proposals that require regulatory approval. For example, with respect to clinical trials of investigational drugs, some REBs require a No Objection Letter (NOL) from Health Canada prior to commencing ethics review, while others will review an application and provide an approval that is contingent upon receipt of the NOL.

REBs differ in their approach to re-review of multi-site proposals and applications that have already been approved by an academic department, a sponsor or another ethics review board. Survey respondents commented that in their view, local Boards may not have the expertise or financial resources to accommodate specialized, multi-disciplinary, international and collaborative research. Nonetheless, the perception that review quality is uneven impedes the development of reciprocal relationships which would alleviate the burden of multiple reviews.

Comments representative of our respondents' views about duplicate or parallel reviews are as follows:

- *When a project is conducted at a facility not under our jurisdiction, there will be more than one review which is cumbersome for the researcher and the sponsor.*
- *On large multi-centred grants we would like to be notified that someone from our institution is involved in a study conducted at another institution.*
- *When two or more Boards consider the same proposal from the local perspective, they often reach different conclusions on one or more aspects of the study.*
- *When we are aware that a project has been previously reviewed at another institution, we take that Board's decision into consideration, but make our own decision, based on our own perspective.*
- *When a researcher identifies on the ethics application that s/he is collaborating with someone at another institution we ask that the researcher names all the collaborators and their institutional affiliation on their application form.*
- *We request certificates of approval for collaborators.*
- *We experience double review of applications.*
- *Clinical trial Serious Adverse Events reports go to all institutions which is inefficient.*
- *A goal is to explore the acceptance of approvals from other REBs.*
- *There is duplication of review for studies conducted across Canada and elsewhere.*
- *Duplication occurs when research is in partnership with another agency or institution.*
- *We have the expertise to judge the scientific validity of proposals.*
- *With clinical trials we determine whether previous data supports advancement to human subjects and whether the protocol is scientifically sound.*
- *We do not explore the qualifications of researchers.*

- *We ask for the CV of the PI to be submitted as part of the application process.*
- *Members are personally familiar with the Principal Investigators.*
- *We require a department chair to sign off on a PI's qualifications, expertise and resources to carry out the proposed research.*
- *Methodology is carefully reviewed and qualifications to perform specific procedures are ensured.*
- *We discuss the PI's expertise in relation to the proposal.*
- *In clinical trials there is a great deal of national and international oversight which enables us to focus on local issues*

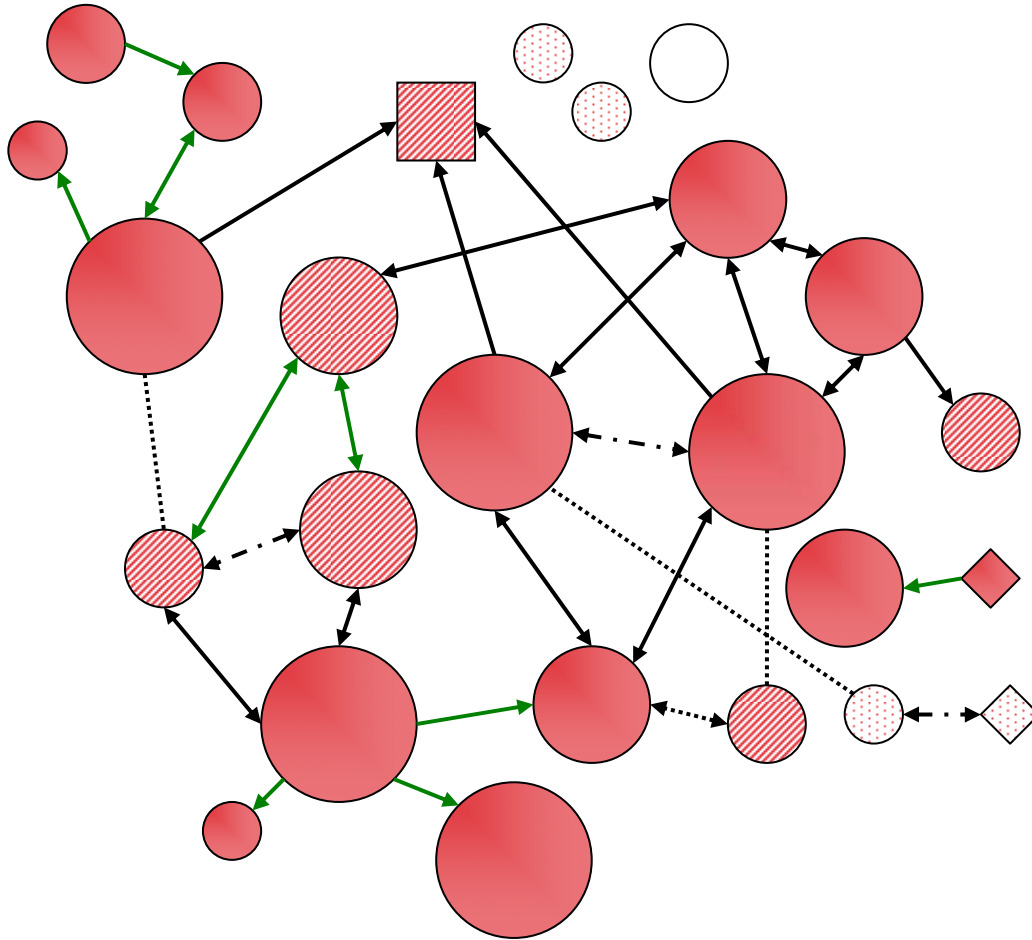
Despite independent legal, liability and oversight mechanisms for each institution hosting an REB, our analysis of the B.C. REB environment suggests the presence of a complex web of relationships and agreements amongst and between the province's research ethics boards. We found evidence of inter-dependence with another institution for all but three of the 22 REBs surveyed. Figure 23 on the next page illustrates our findings regarding these links. Arrows in the figure indicate the flow of resources. There may be additional arrangements, both existing and proposed, that are not reflected in the Figure 23.

A few of the common and significant kinds of collaboration currently active between B.C. REBs include:

- Collaboration between two or more Boards with an existing agreement to reduce duplication of effort (e.g. UBC One Board of Record; SOP for Interior Health to accept the reviews of B.C. Cancer Agency).
- Shared appeal boards (e.g. reciprocal agreement between Malaspina University-College and Royal Roads University; one way agreement where University of Victoria acts as an appeal board for Camosun College).
- Agreements to share researcher affiliation status (e.g. Agreement to allow Royal Roads University researchers to have 'affiliated investigator' status at VCH; UBC and UNBC cross-appointed medical faculty submitting 'joint' applications).
- Potential collaborations under discussion (e.g. Northern Health providing REB member expertise on local issues to UBC and receiving the advice of large institution experts).

We found institutional REBs that have operational ties to institutions outside the Province. The CBS B.C. REB operates under its national parent organization. Trinity Western University has an appeal board agreement with an institution outside of B.C. In addition, many private REBs that operate in B.C. such as WIRB (not depicted in Figure 23) operate as a division under the administration of a national or even international institution, although their REB decisions are independent. Two of these are community REBs, while one serves a Health Authority, and all three review relatively small volumes of applications compared to more collaborative REBs, however, we did not find that REB size necessarily projected the number of existing or potential collaborations.

Collaborations among Research Ethics Boards at academic institutions, health authorities and community (and other) research organizations in British Columbia.



Legend:

	-Each sphere equals one REB. Size is representative of the number of protocols reviewed by that REB each year.		-REBs within one institution.
	-Institution without REB		-Shared Appeal Boards
	-REB outside of B.C. (no data)		-Collaboration with existing agreement
	-Community/Other		-Potential collaborations under discussion
	-Health Authority governance		-Arrows indicate flow of resources
	-Academic governance		

Figure 23 Collaborations Among BC REBs

4. Safety and Efficiency: Opportunities for Improvement

In the course of reviewing the data collected through our emailed survey and in face-to-face and telephone interviews, we identified numerous strengths of the REBs currently operating in British Columbia. In accordance with the spirit of the TCPS, REBs foster an increased awareness of the social benefits of research, the scientific process, the demand for evidence-based policy and decision-making, the nature of risk as it pertains to individuals in a variety of circumstances and the ethical dilemmas inherent in research involving people as subjects. Academic review of student projects enhances the educational experience. Geographically dispersed boards have opportunities to better reflect unique characteristics of rural communities and ethnic cultures and other issues of local concern.

Along with the strengths, we found evidence of an ongoing struggle to achieve both optimal protection of human subjects as mandated by the TCPS, and efficient, timely approval of socially beneficial scientific studies. Local Boards may not have the expertise or financial resources to accommodate specialized, multi-disciplinary, international and collaborative research. With respect to the quality of reviews by their institution's REB(s), the following comments are representative of interviewee responses:

- *Inconsistent quality of review is a barrier to collaboration.*
- *We have identified errors in studies approved by others and for this reason are not inclined to accept reviews done by these sites.*
- *Quality control and consistency is an issue.*
- *We strive to make improvements on an ongoing basis.*
- *We discuss processes, policies and improvements.*
- *Quality is not a problem at our institution.*
- *We make every effort to ensure that members with the appropriate expertise are assigned as primary reviewers.*
- *If needed, we arrange an external expert review.*
- *Better quality of review would come from developing guides to provide consistency.*
- *If we need more scientific expertise we can contact an outside expert or panel of experts.*
- *New members may lack experience and training.*

Sharing basic tools was often suggested by respondents as a first step to enhancing the provincial system for ethics review: for example, a common application form and standard informed consent templates were frequently mentioned as ways to promote efficiency. Currently, a researcher

requesting ethics approval in numerous unrelated sites may have to complete as many different forms as sites. The concept of a common application form, with filters for various kinds of research and levels of review, and part of a uniform technological system, was generally reported to be appealing.

With respect to perceived barriers and opportunities for harmonization or collaboration with other REB's, the following comments are typical of what we heard from interview participants:

- *The TCPS requires us to review all protocols related to our institution.*
- *It would violate our policy to accept the decision of another REB without review.*
- *We have a duty to protect human subjects that are associated with our institution, and we would be negligent if we did not conduct our own reviews.*
- *We need a communication mechanism for multi-centre studies.*
- *Other institutions may not request the same information about collaborators or ask for documentation from each of the participating collaborators' institutions.*
- *Shared membership could be beneficial.*
- *Practical knowledge and expertise could be shared with more than one Board.*
- *Health authority staff may recognize risks that may not be apparent to University REBs.*
- *We are able to coordinate activities efficiently because our office is responsible.*
- *We would welcome the opportunity to reduce the duplication of effort.*
- *We must not lose sight of our role in advocating for the human participant.*
- *We have reviewed studies previously approved by other REBs and have had some serious concerns and different opinions.*
- *A Health Authority review committee may emphasize different aspects of a study (e.g. organizational impact or knowledge translation) than an academic REB.*
- *Harmonization would mean giving up control.*
- *If we were restructured provincially and a credible and representative REB process existed, REB members would not be expected to trust an unrelated Board's review ('someone else's' REB) because we would all be part of a system with consistent standards and procedures.*
- *Local site-specific knowledge is an absolute requirement for the conduct of clinical trials.*
- *Sites do not have the same methods for monitoring and particular populations.*
- *Communication is key for collaboration.*
- *University ethical review can be interpreted by community partners as a barrier.*

- *Standard application forms within B.C. would facilitate review of multi-site protocols.*
- *Standards and methods are inconsistent in B.C. The NCEHR 'accreditation' process is the first step in establishing consistency across Canada.*
- *Small changes may be required by one institution but not acceptable by another.*
- *We inform the researcher that for large multi-centred studies they need to communicate with their collaborators to ensure that ethical review will take place in their home institution.*
- *Under Health Canada regulation, there must be a site investigator for each site — there cannot be one PI for multi-centre studies.*
- *There is a lack of standardized forms.*
- *There are various degrees of review that may not satisfy our policies.*
- *An opportunity is the willingness to work together to minimize the number of review processes that a PI wishing to conduct research in health authorities must undertake at the current time.*

5. In Summary

British Columbia does not currently enjoy an integrated or harmonized system for ethics review of research involving human subjects. Instead, researchers, their institutions and research subjects alike rely on a constellation of boards struggling to identify and allocate limited financial, professional and community resources to fulfill the letter and spirit of the TCPS. This environmental scan confirms that capacity is limited by scarcity of human, technological and financial resources. The majority of B.C. REB members are affiliated with the institution their REB serves and in almost half of these maintaining the required level of community membership is difficult. Circumstances vary by location, size of the institution and number of protocols reviews. Appropriate expertise is not always available, both in the science related to the research under review and in the relevant area of law. In other situations there are sufficient numbers of people with health and privacy law expertise, but heavy workloads are experienced as difficult to manage and, in some cases, result in delays.

This scan identified variations in structure, procedures and policies. Some differences are inherent in the make-up of the institution served and the nature of the research typically reviewed by a particular REB. Other variations, such as disparate application forms and informed consent templates, reflect inefficiencies acknowledged by administrators, Board members and researchers alike. Collaborative, multidisciplinary and multi-centre studies are widely understood to present challenges that provide the impetus for harmonization.

Flexibility, practicality and transparency are hallmarks of the TCPS concept of efficient and effective ethics review. The TCPS expresses an intent to harmonize the ethics review process and an expectation that REBs will benefit from common procedures within a shared ethical framework.⁶⁸ The perception that review quality is uneven impedes the development of reciprocal relationships which would alleviate the burden of multiple reviews. In the course of this environmental scan respondents identified a number of opportunities for British Columbia research institutions to work towards the Tri-Council's vision of harmonization including:

- standard application forms
- shared informed consent templates
- information technology for inter-institutional communication
- province-wide continuing education in human subjects ethics
- sharing of scientific and multi-disciplinary expertise
- resources to compensate REB members
- resources to employ administrative assistance for pre-screening of applications

⁶⁸ TCPS Goals and Rationale of the Policy, Par. B, sub. par. 3

- common criteria for expedited review
- framework for deference to review of an external Board with appropriate expertise
- common policy for review of multi-site and multi-institutional collaborative proposal
- trust-building through in-person and virtual networking, and
- development of a cohesive B.C. ethics review system,

MSFHR gratefully acknowledges the time and effort contributed by the staff and leadership of the REBs who participated in the scan processes which made this report possible. Despite the demands on their time and the realities of their workload pressures, they were uniformly generous in responding to our requests for information and time. Their responses are powerful evidence of a shared dedication to ensuring the highest possible standards of ethics review, in order to provide human research subjects with the protection and respect they deserve. This dedication is a powerful base upon which to build an even stronger and more effective provincial system for the future.

Appendix A Survey Questionnaire

Introduction

The Michael Smith Foundation for Health Research (MSFHR) is facilitating a health research ethics project on behalf of B.C. health research stakeholders and at the request of the Ministry of Health and the Ministry of Advanced Education. As part of this project, we are conducting an environmental scan of ethics review mechanisms and structures across the province. Collection of this data will give B.C. its first ever overview of current practices across all B.C. health research institutions. This baseline data will support the next phase of the project when health research stakeholders come together in a forum to explore strategies for improving quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects.

MSFHR requests your assistance in completing this questionnaire to aid in a background survey of the REB activities at your institution, and to prepare for participation in an interview with the appropriate individual at your site.

Instructions for completion

- The guide consists of 6 sections. Please complete each to the best of your ability and provide additional comments where possible.
- Please complete one questionnaire for each REB at your institution.
- Where possible, provide data for a typical 12 month period, preferably one calendar year. If this is not possible, please state the start and end months of the 12 month period that was used to collect the data.
- We ask that you return the completed questionnaire electronically to MSFHR no later than **June 15th, 2007.**

Confidentiality

Information gathered through this questionnaire and the related interview will be compiled in a report to inform a larger consultative initiative. Qualitative data may be cited while maintaining strict confidence of the source, unless permission is otherwise received expressly from the individual quoted and their institution. Copies of the final report of the environmental scan will be made available to participating institutions.

MSFHR Contact Person

Please return the completed questionnaire and address questions to:

Erika Goldt, Project Assistant for the BC Ethics Harmonization Initiative
Michael Smith Foundation for Health Research
Suite 200 – 1285 W. Broadway
Vancouver, BC V6H 3X8
Phone: 604-714-6344
Email: egoldt@msfhr.org

1. REB Profile

1.1 Please provide profile information as follows:

REB name:	
Year established:	
Research focus area (if any)	
Total REB annual budget:	
Source of the REB budget:	
Who authorizes budget allocation:	
To whom does the REB report:	
Provide the names and titles for:	
Senior Administrator Responsible for Ethical Review	
REB Administrative Contact Person	
REB Committee Chair	
Who selects or appoints the Chair:	

1.2 Describe (or attach) the process for selecting or appointing the Chair.

1.3 How is your REB and its members insured? Please provide details including the name of the insurance provider.

2. REB Members

2.1 What is the total number of members?

2.2 What is the term of membership (# of years)?

- What is the maximum number of terms a member can serve?

- 2.3 Please insert the number of persons in each category presently serving on your REB as voting members. If you have non-voting ad hoc members please enter the number in parentheses (#):

	Affiliated or employed by the institution	External: Other research organization	External: Community or lay	Number required by Terms of Reference
Biomedical Science				
Behavioural Science				
Information Technology/ Engineering				
Social Services				
Legal Counsel				
Spiritual Counsel				
Other				

- 2.4 What is the criteria and process for early termination of membership?
- 2.5 What is the rate of voluntary and statutory turnover per year (%per year for each)?
- 2.6 What is the annual remuneration per member, excluding expense reimbursement?
- Are expenses reimbursed? Y/N
- 2.7 Is Continuing Education provided to members regarding ethics of human subject research? Y/N
- If yes, is this education provided before joining the REB, during a term, or both:
- 2.8 Describe (or attach) the criteria and process for:
- recruiting members
 - selection of members
- 2.9 Describe (or attach) the policies and procedures for the disclosure and management of conflicts of interest.

3. REB Meetings

- 3.1 What is the average number of REB meetings per year?
- 3.2 What is the average length of the REB meetings (hours)?
- 3.3 Does the REB adhere closely to procedural protocol (are meetings informal or strictly formal)?
- 3.4 What is the policy for finalizing a decision (e.g. requires consensus, requires majority vote) and how are disagreements or failure to reach consensus managed?

3.5 Which topics are prominent and/or recurring for your REB in the course of its work:

	Prominent Y/N	Recurring Y/N	Please Explain
Member Recruitment			
Review Workload/Capacity			
Duplication of Effort			
Access to Review Process			
Quality of Review			

4. REB Reviews

A. Protocols

4.1 What is the total number of protocols reviewed by your REB per year?

4.2 Of this overall total, how many were categorized as follows:

Type and Outcome	Number	Comments (optional)
a. New		
Approved as submitted		
Approved conditionally		
Rejected		
Exempt		
Approved as submitted		
Approved conditionally		
Rejected		
Exempt		
TOTAL		

4.3 Of this overall total,

- how many were reviewed by full committee?
- how many received expedited review?
- how many adverse reactions/unanticipated events were reviewed?

- 4.4 Is there a primary reviewer system for full committee reviews of new protocols? Y/N
How many reviewers are assigned for each protocol?
- Is there an attempt to match the primary reviewer’s expertise to the protocol’s subject matter? Y/N
- 4.5 Is a consultant or external reviewer ever brought in to provide scientific or other relevant expertise for review of a particular protocol? Y/N
- If yes, approximately how many times per year?

B. Functions

- 4.6 Please provide information regarding who undertakes the following functions for your REB. Mark an “X” in the appropriate box for each individual as applicable.

Function	REB Chair	REB Administrator	REB Staff	REB Member	Other Person (please specify)
Performs administrative review					
Determines category for review (full, expedited, exempt, etc.)					
Performs expedited review					
Performs initial review of adverse events					
Determines if a protocol is to be reviewed by full committee or expedited.					

C. Substantive Review of Research Protocols

This section seeks information about the way the REB informs itself and deliberates on the scientific basis for the proposed use of human subjects to promote valid research objectives. Thinking about a typical review process, please answer the following questions.

- 4.7 Does your REB explore whether or not the experiment is designed to yield socially beneficial results not achievable by other methods and do the likely benefits outweigh any risks? Y/N
- If Yes, please describe the process, frequency and intensity of such review.
- 4.8 Does your REB explore whether or not the experiment is based on the results of animal experimentation or other knowledge of the disease or problem so that the anticipated results justify continuation with human subjects? Y/N
- If Yes, please describe the process, frequency and intensity of such review.
- 4.9 Does your REB explore whether or not the Principal Investigator is scientifically and legally qualified (training, skill, experience) to undertake the specific research proposed and

prepared to terminate the experiment in the event he or she has reason to believe that continuation is likely to result in injury, disability or death to a subject? Y/N

- If Yes, please describe the process, frequency and intensity of such review.

4.10 Does your REB explore whether or not the experiment is designed to afford the utmost protection to subjects, including the potential for termination of the study in the event the experiment appears likely to have harmful consequences? Y/N

- If Yes, please describe the process, frequency and intensity of such review.

4.11 Does your REB consider whether each person asked to participate in the study will have the mental and legal capacity to understand the nature of the experiment and be free from undue influence or coercion of any kind? Y/N

- If Yes, please describe the frequency and intensity of such review.

4.12 Does your REB seek to determine whether the Principal Investigator will provide proposed human subjects with adequate knowledge about the experiment and all risks to which he or she will be exposed so as to assure that consent is voluntary? Y/N

- If Yes, please describe the process, frequency and intensity of such review.

4.13 Keeping in mind the issues addressed in this section, please comment on other factors that may influence the nature of your REB's ethical review of a given submission (e.g. degree of risk, workload, status of the principal investigator, other).

5. Multi-Center Activity/Harmonization

5.1 What is the total number of reviews completed per year by your REB that involve multiple research sites?

5.2 For this total, how many reviews involved REBs:

- within BC?
- outside BC?

5.3 Have there been efforts between your REB and others at harmonization/collaboration? Y/N

- If yes, please describe these efforts and the outcomes.

5.4 Given your REB's experience with review of multi-center studies, describe the opportunities and barriers to harmonization/collaboration.

6. Additional Information

Where available and appropriate, please attach the following to this questionnaire.

- REB Organizational Chart
- REB Terms of Reference and/or Recruitment Criteria
- REB Policies and Procedures (i.e., Conflict of Interest Policy)

Appendix A Survey Questionnaire Follow-up

The Michael Smith Foundation for Health Research would like to thank you once again for your contribution to our Environmental Scan of the research ethics review process at REBs across B.C. Now that we have received your completed questionnaire, a few issues have emerged that would benefit from further clarification. We would therefore like to ask you for a few final pieces of information that will help us clarify the information to verify some key numbers and to ensure we accurately report on the data.

If you do not have precise numbers for a given question, please estimate to the best of your ability. We welcome additional comments; please email any comments to the address below. If you have any difficulty responding to or interpreting any questions, please contact the address below.

1. On average, how many REB members attend the face-to-face meetings?
For example: There are 10 REB members but on average only 7 attend = 70%
2. On average, how many hours does a member of your REB spend preparing for each REB meeting?
This may include reading protocols and applications, completing and submitting reviews, etc.
3. How many brand new applications for ethics review did your REB receive last year?
These are new applications that have not been previously reviewed by the REB in any manner. This does not include requests for amendment review or recertification. If you do not have a specific number for last year, please provide the average number per year or estimate to the best of your ability.
4. For each new protocol, please estimate the average number of times it is reviewed by the REB before it receives initial approval?
For example: Application A is reviewed by the research office and then submitted to the REB for ethics review. The REB decides that a key piece of information is missing (Review #1). Application A is revised and returned but the REB decides that wording in the Informed Consent document should be revised to reflect the new information (Review #2). After revision, Application A is once more reviewed by the REB and approved (Review #3). Application A was therefore reviewed by the REB a total of 3 times.
5. How many amendments to a previously approved project were reviewed by the REB last year?
These are for projects that are ongoing but require changes after approval and therefore need an amendment reviewed and approved by the REB. If you do not have a specific number for last year, please provide the average number per year or estimate to the best of your ability.
6. How many periodic renewals of previously approved projects did the REB review last year?
A project that has already been approved may require its approval to be renewed or 'recertified' by the REB after a set period of time (e.g. once annually). How many recertifications were reviewed by your REB last year? If you do not have a specific number for last year, please provide the average number per year or estimate to the best of your ability.

Appendix B UBC: One Board of Record Letter Dated March 27, 2007

John Hepburn, FRSC
Vice President, Research
University of British Columbia
Old Administration Building – Room 224
6328 Memorial Road
Vancouver, B.C. V6T 1Z2

April 2, 2007

Dear Dr. Hepburn,

Each research project reviewed by a University of British Columbia (UBC) Research Ethics Board (REB) should have a single REB of Record. The UBC REB that initially reviews a research project normally becomes the REB of Record for the Project but occasionally a project is referred to another of the boards. Once established as the Board of Record that REB should deal with all subsequent ethical supervision of that project. This means that the investigator is only required to submit all post approval submissions to one board, regardless of whether or not the research is being conducted at another institution under a UBC research ethics board's jurisdiction.

The purpose of implementing one board of record is to avoid the requirement for multiple formal reviews of the same research project. The need to identify one of several possible boards to be the Board of Record arises when the same principal investigator is conducting research at more than one institution under the UBC REB's jurisdiction.

Although there is one Board of Record, in order to ensure that institutional specific ethics requirements are being met, the Chair and Manager of each UBC REB for the institution involved in the research have the ability, through RISE, to view the application approved by the REB of Record. If, however, the REB Chair of any institution involved in the research has questions or concerns, these can be directed to the REB Chair of the REB of Record for resolution.

The Chairs of the following UBC Research Ethics Boards agree to this process.

Dr. Gail Bellward, Chair
UBC - Clinical Research Ethics Board

Dr. George Browman, Chair
UBC – British Columbia Cancer Agency Research Ethics Board

Dr. Peter Suedfeld, Chair
UBC - Behavioural Research Ethics Board

Dr. Ingrid Fedoroff, Chair
UBC – Providence Health Care Research Ethics Board

Appendix C BC Ethics Harmonization Initiative: Task Force Members

Dr. Anne Marie Broemeling

Director, Information Support and Research
Interior Health Authority

Dr. George Browman

Research Ethics Board Chair
BC Cancer Agency

Dr. Joe Connors

Research Ethics Board Vice-Chair
BC Cancer Agency

Ms. Eva Cheung Robinson

Program Director
BC Medical Services Foundation (Vancouver
Foundation)

Ms. Laurel Evans

Associate Director of Research Services
University of British Columbia

Dr. Sarah Hartley

Society & Ethics Advisor
Genome BC

Dr. Richard Keeler

Associate Vice-President of Research
University of Victoria

Dr. Yvonne Lefebvre

Vice President of Research & Academic
Affairs
Providence Health Care

Dr. Linda Peritz

Associate Director
Vancouver Coastal Health Research Institute

Dr. Deborah Poff

Board Member and Chair, Research Ethics
Board
BC Medical Services Foundation (Vancouver
Foundation)

Mr. Brent Sauder

Assistant Deputy Minister
Ministry of Advanced Education

Ms. Patricia Tait

Coordinator of Internal Funding and Strategic
Initiatives
Vancouver Coastal Health Research Institute

Ms. Elisabeth Wagner

Executive Director
Strategic Policy and Research
Ministry of Health

Dr. Hal Weinberg

Director of Research Ethics
Simon Fraser

Appendix D Sample Workload Determination

REBs were asked to contribute data from the most recent 12 month time period available, which was 2006 in the majority of cases. If not able to do so, we asked that they report the estimated average per year.

In only a few cases where data was not provided by an REB (this included prep time for REB members, meeting attendance rates, and number of revision to new protocols prior to approval) the average of the reported REB numbers was used. This was used only used in a few cases.

For the majority of cases where data not provided, the REB was excluded from analysis and this exclusion stated in the report by noting the number of responses considered for a given question.

Following is a sample (using created data) of the process used to report calculations in the report.

Questionnaire Response Items:

A	B	C	D	E	F
Number of members	Average attendance rate per meeting	Number of meetings per year	Average meeting length (hours)	Average prep time per member per meeting (hours)	New protocols received per year
13	80%	10	2.3	3.7	203

G	H	I	J	K
Number of reviews of each new protocol before approval (exclude admin review)	Amendments received per year	Renewals reviewed per year	Proportion of protocols reviewed by full committee	Reviewers assigned to each protocol
2	294	121	40%	5

Sample Calculations:

Workload, hours per member per year:

$$\frac{(C) \times (A) \times (B) \times (D+E)}{A}$$

FTE equivalency assumptions: 8 hours per day and 290 days per year.

Total full reviews:

$$(K) \times (J) \times (F)$$

Appendix E Abbreviations and Acronyms

ACADRE	Aboriginal Capacity and Developmental Research Environments
AHFMR	Alberta Heritage Foundation for Medical Research
ARECCI	The Alberta Research Ethics Community Consensus Initiative
B.C.	British Columbia
CBS	Canadian Blood Services
CIHR	Canadian Institutes for Health Research
CREB	Clinical Research Ethics Board (University of British Columbia)
CURIE	The Canadian University Reciprocal Insurance Exchange
FOIPPA	Freedom of Information and Protection of Privacy Act
HIPPA	Health Insurance Portability and Accountability Act
ICH – GCP	International Conference on Harmonization – Good Clinical Practice
IH	Interior Health
ITH	Intertribal Health Authority
MSFHR	The Michael Smith Foundation for Health Research
NCEHR	National Council on Ethics in Human Research
NH	Northern Health
NOL	No Objection Letter
NSERC	Natural Sciences and Engineering Research Council
OCAP	Ownership, Control, Access, and Possession or Self-Determination Applied to Research
PHSA	Provincial Health Services Authority
PI	Principal Investigator
PIPEDA	Personal Information Protection and Electronic Documents Act
PRE	Interagency Advisory Panel on Research Ethics
R&D	Research and Development
REB(s)	Research Ethics Board(s)
RISe	Research Information Services
SSHRC	Social Sciences and Humanities Research Council
TCPS	Tri-Council Policy Statement for Research Involving Human Subjects
UBC	The University of British Columbia
UNBC	The University of Northern British Columbia
UVic	The University of Victoria
VCH	Vancouver Coastal Health
VIHA	Vancouver Island Health Authority



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