

B.C. Ethics Harmonization Initiative Introductory Workshop


Report on Proceedings

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Morris J. Wosk Centre for Dialogue
Vancouver, B.C.



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Table of Contents

1.	Executive Summary	i
2.	Introduction.....	3
2.1	Terminology.....	4
3.	Approaches to Research Ethics Review	5
3.1	Enhancing Quality of Efficiency through Collaborative Approaches to Ethics Review	5
3.2	The Experience of the Alberta Research Ethics Community Consensus Initiative (ARECCI).....	8
3.3	Ethics and Research: the Québec Context and the New Mechanism for Multi-centre Projects.....	10
3.4	National Perspectives	11
4.	Promoting and Advancing the Approach.....	13
4.1	Group Activities and Discussion Summaries	15
4.1.1	<i>Approach 1: Status Quo</i>	15
4.1.2	<i>Approach 2: Common Tools and Processes</i>	17
4.1.3	<i>Approach 3: Reciprocity</i>	18
4.1.4	<i>Approach 4: Provincial or Centralized</i>	20
5.	Summary Remarks	21
5.1	Reflections	21
5.2	Summary of Comments from Closing Plenary	23
5.2.1	<i>Emerging Themes</i>	23
5.2.2	<i>Preferred approach</i>	25
5.2.3	<i>Desire for action</i>	25
5.2.4	<i>The Future Role of MSFHR in Ethics Harmonization</i>	26
5.3	Closing Remarks	26
5.4	Next Steps	27
Appendix A	About the Michael Smith Foundation for Health Research.....	28
Appendix B	About the B.C. Ethics Harmonization Initiative.....	29
Appendix C	Summary of Workshop Participation	33
Appendix D	List of Workshop Participants.....	34
Appendix E	British Columbia REBs.....	39

1. Executive Summary

On November 19, 2007 in Vancouver, the Michael Smith Foundation for Health Research (MSFHR) convened an invitational workshop involving researchers, VPs or Directors of Research, and Chairs or Managers of Research Ethics Boards (REBs) from key BC health research institutions and organizations. This workshop was a key component of the BC Ethics Harmonization Initiative (BCEHI), a process facilitated by MSFHR to develop 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. Invitees to this workshop represented a variety of stakeholders and were uniquely qualified to discuss the options that range from adoption of harmonized core guidelines and institutional review reciprocity to a coordinated, shared, provincial ethics review mechanism.

To inform the BCEHI and the discussions at the workshop, MSFHR prepared three background documents:

- The Ethics Review Process in British Columbia: An Environmental Scan
- Investigator Experience with Research Ethics Boards in British Columbia: Survey Report
- Harmonization of the Ethics Review Process: An Environmental Scan

MSFHR presented the results of the environmental scans and investigator survey. Expert speakers from Alberta, Québec, Health Canada and the US-based Office for Human Research Protections shared their views and experiences with harmonizing ethics review, providing a national and international context.

Participants also worked in small groups to discuss issues, barriers and options for a variety of approaches to provincial coordination:

- Status Quo
- Common Tools and Processes
- Reciprocity
- Provincial or Centralized

Each group reported back to the workshop participants, including their suggestions for next steps for action. The workshop closed with a general discussion about what had been shared and learned throughout the day and how the work of the BCEHI could continue.

Several major themes emerged throughout the course of discussions and presentations:

- More information is required to better inform further work
- Leadership and trust are critical to achieving success with the BCEHI
- Common information technology systems and forms are required, at a minimum

Workshop participants concurred that the status quo is not an option, nor is creating one central provincial REB. Rather, the general consensus was that a hybrid of reciprocity and common tools/processes and collaboration would enable B.C. to best meet its goals for ethics review reform.

Harmonization of ethics review has been identified as a major issue for many years. The MSFHR and workshop participants expressed a desire for action and change – neither group would like to be working with the status quo five years from now. Concrete suggestions for immediate action were made and volunteers offered to begin work in a number of areas.

The MSFHR committed to preparing and releasing a report early in 2008, and expressed willingness to support stakeholder efforts and maintain the momentum for change that began in the workshop. While the options and opinions vary on the matter of ethics review harmonization, a commitment to protecting human research subjects while advancing knowledge underpins the objectives of everyone involved.



2. Introduction

The Michael Smith Foundation for Health Research (MSFHR)¹ convened an invitational workshop on November 19, 2007, involving stakeholder representatives from B.C. health research institutions and organizations, researchers from across many fields of investigation and selected representatives from other provinces.² The workshop had four objectives:

- to hear and comment on the results of the Environmental Scans and Investigator Survey;
- to learn about possible mechanisms and structures for ethics review of research involving human subjects;
- to identify strengths and weaknesses of options for improving the ethics review process as it relates to research involving human subjects; and
- to provide advice on next steps for the B.C. Ethics Harmonization Initiative.

The workshop was supported and endorsed by MSFHR's Board of Directors and Research Advisory Council, as well as the British Columbia Ministries of Advanced Education and Health. It was part of a larger project known as the B.C. Ethics Harmonization Initiative, more fully described in Appendix B.

The workshop had several components:

- presentation of summaries of research completed to date in B.C. (survey and scan);
- presentation and discussion of efforts varying approaches to reforming ethics review in other countries;
- presentations detailing various approaches to ethics review in other parts of Canada;
- work in small groups to explore key aspects of options for reform of ethics review processes in B.C.; and
- presentations to summarize the findings of the small group discussions.

This report provides a summary of each of these components, following the sequence in which they occurred on November 19, 2007.

¹ More information about the Michael Smith Foundation for Health Research is available in Appendix A.

² Details regarding attendees are provided in Appendix C and Appendix D.

2.1 Terminology

Please note that when discussing topics of ethics review and harmonization, terminology is not always clearly defined and agreed upon by all stakeholders and observers. The following is a brief guide to the use of key terminology in this report:

Reform: Refers to any attempt to change the ethics review system with the goal of improvement (irrespective of the mechanism).

Harmonization: refers to attempts to improve on the current REB system by aligning existing processes and structures and developing new ones. Streamline is used in the same context. We did not make a clear distinction between 'harmonized' and 'streamlined' given that there are no clear criteria to distinguish between the two.

Research Ethics Boards (REBs): This is the predominant term used in Canada to refer to ethics committees. In the U.S. the most common term is Institutional Review Board (IRB).

Multi-centre studies: There is variation in the literature on the use of *multi-centre* versus *multi-site* studies. Often the terms are used interchangeably but may also define two different concepts of multiple research locations versus multiple collaborative researchers. This report uses the predominant term in Canada: multi-centre describes research that is conducted at more than one location or in more than one jurisdiction (which may be an institution, regional territory, or country) and may or may not involve multiple collaborative researchers at one or more locations.

3. Approaches to Research Ethics Review

3.1 *Enhancing Quality of Efficiency through Collaborative Approaches to Ethics Review*

*Presented by: Greg Koski, PhD, MD, CPI
Harvard University, Boston MA*

Dr. Koski was the founding director of the Office for Human Research Protection (OHRP) in the United States, as the Department of Health and Human Services remodeled the country's system for protecting human research subjects. Under his leadership, OHRP developed a systems approach to human research subject protection; initiated the development of private, voluntary accreditation of human research protection programs; streamlined the federal assurance process; expanded education and outreach programs; and implemented a quality improvement program to assist those involved with human subject research evaluate and strengthen their protection programs.

Having returned to teaching and clinical practice in cardiac anaesthesia, he continues his involvement in research ethics as a member of the Institute for Health Policy at Massachusetts General Hospital. His presentation was based in his experience as an active participant in a number of ethics review, reform, or improvement initiatives in the US.



Dr. Koski began his remarks with the observation that Canadians have something in our collective psyche that steers us toward harmony, toward a willingness to work together, and that this is a great foundation for the work under way here in B.C.

He noted that his comments would be provocative. There are many perspectives on this topic and he urged participants to listen and learn from each and to not be bound by history or practice. From the research done to date, it is clear that the present state is far from perfect. He suggested that, by posing tough questions and challenging our assumptions, we can begin to envision what an effective, coordinated, value-add approach to ethics review could look like.

Dr. Koski then posed a number of these kinds of thought-provoking questions in order to frame the day's work and subsequent discussions, encouraging attendees to challenge their assumptions.

Why do we have research ethics boards?

Do we need ethics review – what would happen if we didn't have boards to review proposals? The time commitment and resources required are significant, and ultimately, virtually everything is approved. Many researchers regard them as an impediment to advancing knowledge; they don't regard the process as adding value to the research.

Developing a process and following its steps does not necessarily result in value. An administrative process could determine the risk involved in studies and investigators could be trained to respond to queries based on the level of risk involved.

Scientists fully understand that the participation of organizations and people is essential. If they were well-trained and educated in ethics, would we need REBs?

Where is the board when the research is being done, especially when there is an adverse event or other incident?

Everyone involved in health research – investigators, REBs, funding agencies, institutions – agrees that ‘we must protect human subjects’.

Why do we protect human subjects?

Research is generally voluntary and participants are motivated by a variety of factors, ranging from compensation to altruism to improving science and/or care.

Dr. Koski challenged participants to consider who has the ultimate responsibility for protecting human subjects: the investigators, the REBs or the institutions? Who has the obligation to ensure research is ethical: the investigators, the REBs or the institutions? Are these, in fact, shared obligations?

To date, there is no indication that the amount of effort expended in reviewing protocols is truly related to the risks that are involved. Most health research has very little risk.

Are the REBs preventing harm to human subjects or the institutions they represent? In Dr. Koski’s view, an effective REB bears a responsibility to science and society, as well as to research participants. Its work must be conducted in a manner consistent with all of these responsibilities.

Why is the ethics review process so slow?

Dr. Koski asserted that this perception is the single biggest complaint of investigators anywhere: in Canada, in the United States and around the world.

Most REBs do not have the financial or intellectual resources to do the work required of them. Many REBs are being asked to attempt to oversee or administer other aspects of research ethics involving human subjects that may not be appropriate or within their scope of duties, such as training investigators in ethical scientific practice or re-writing research protocols.

Ethics review is often viewed as an adjunct administrative step, one that is not integral to the scientific process. This mindset leads to the fragmented and sometimes antagonistic relationship between REBs and the investigators, which can slow down the review.

REBs are at the core of any human research protection program, but they are only one aspect of these programs.

A systems approach:

Dr. Koski champions a system approach to ensure that needs of researchers, boards, institutions, stakeholders, research sponsors and others are met. Multiple components must work together with a system or process view to ensure adequate investment, well-defined roles and goals and, above all, a clear understanding of what the research ethics review process is designed to support.

He argued that a well-defined system can support a variety of research ethics models, including different models to suit different research requirements. He presented a systems model (see figure 1 below) to illustrate such a comprehensive context.



Figure 1: A systems view of ethics review

He further argued that the chosen approach to collaborative review must be optimized for the research and venue. It is likely that one model is not going to meet the needs of all parties in B.C. However, the province is in the position to review various models and create a hybrid or combination model to optimize an approach for B.C.

Any model or combination of models requires a leadership commitment to work together. Collaborative models require that the partners be prepared to give up some autonomy and trust their colleagues. Dr. Koski also acknowledged that working together can result in outcomes that might not

happen otherwise, such as dramatically reducing the timeframe for review and the administrative paperwork required by investigators.

Clearly articulated descriptions of responsibilities and authority are absolutely essential in any new model being proposed. In fact, responsibility, accountability, and liability are inseparable.

Liability issues become manageable if the focus is to look after those issues affected by errors or incidents, rather than on laying blame. The focus should be on preventing harm in the first place. If the entire research process or system is committed to preventing harm as well as advancing science, and there is trust in that commitment, liability discussions may become more straightforward.

Collaborative models around the world are benefiting from accreditation and professional certifications. These form the basis for trust between institutions and REBs as they are non-regulatory and provide external validation of a base level of quality and consistency.

3.2 The Experience of the Alberta Research Ethics Community Consensus Initiative (ARECCI)

*Presented by: Ms. Linda Barrett-Smith
Manager, Research Ethics Initiatives
Alberta Heritage Foundation for Medical Research (AHFMR)
www.ahfmr.ab.ca/arecci*

The Alberta Research Ethics Community Consensus Initiative (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. As its administrative leader, Ms. Barrett-Smith spoke to lessons learned by this collaborative since it was founded in 2003.

She noted that much of the early work of ARECCI focused on stakeholders' discussions to determine what constitutes research (as opposed to quality improvement or program evaluation activities) for the purposes of ethics review. Amongst Alberta hospitals and health authorities, there was an increasing sense that a wide range of projects would benefit from ethics review. At the same time, some projects were going to an REB unnecessarily, adding to an already demanding workload. Whether projects are labeled as quality improvement or program evaluation, it was agreed that they pose some of the same risks to human subjects as projects that are labeled as research. Thus the ARECCI initiative worked to reach consensus on which projects require ethics review and why.

Now in phase three of its work, the ARECCI partners have focused on how to determine the appropriate type, level and process for ethics review of knowledge-generating activities that involve

people or their health information. Whether a project is considered to be research or non-research, ethics risks need to be identified and dealt with prior to implementation and counter-measures built into the project to help minimize or mitigate those risks.

To date, ARECCI has produced a document describing underlying principles and concepts “Protecting People While Increasing Knowledge” (Dec 2005); developed and tested its recommendations and three ethics screening tools; and expanded its group of collaborators.



Phase three of ARECCI's work has a capacity-building focus. Ethics screening tools, with interpretive guidelines, have been automated and are being pilot tested. An approach has been developed for ethics review of “non-research” projects such as program evaluation (PE) and quality improvement (QI). Discussion papers on review of higher risk QI and PE projects are in development and ethics review education packages are in the planning stages. This phase will also feature a major national meeting: ARECCI will host the conference “*Protecting People While Increasing Knowledge: Ethics in Health Research, Evaluation and Quality Improvement*” in Calgary in May 2008.

Ms. Barrett-Smith informed the conference that, after four years, ARECCI offers these lessons learned that may benefit the B.C. discussion:

- clarifying the scope of work is essential for staying focused and moving forward;
- field testing is key to increasing the numbers of people and organizations involved;
- working together and respecting the variety of perspectives (academic vs. clinical, rural vs. urban, population health vs. biomedical) takes time;
- building trust takes time, deal with the misperceptions and politics at the beginning;
- this is a long-term and phased process. In addition to its complexity, the people involved have full time responsibilities;
- the process needs a catalyst and secretariat-type support;
- develop momentum through participatory approaches and shared leadership from various stakeholder groups;
- a pragmatic focus on practical decision support tools & guidelines that respect the overall context; and
- an emphasis on integration into existing structures where possible to minimize additional bureaucracy.

3.3 Ethics and Research: the Québec Context and the New Mechanism for Multi-centre Projects

Presented by: Mr. Claude Dussault

*Associate General Director, Evaluation, Research and External Affairs
Ministère de la Santé et des Services sociaux
www.ethique.msss.gouv.qc.ca*

Mr. Dussault provided insights for the workshop on efforts made in Québec to streamline and coordinate ethics review processes for a complex and diverse health research system. In contrast to the collaborative Alberta example provided by Ms. Barrett Smith, the Québec situation features a government-led initiative that is being implemented with an April 2008 target date for a new approach.

Mr. Dussault began his presentation by outlining the nature and complexity of the Québec health research landscape. Currently in Québec, there are 74 REBs affiliated with hospitals, clinics or other institutions under the jurisdiction of the Ministère de la Santé et des Services sociaux (MSSS).³ Projects that must participate in ethics review are:



- all clinical trials;
- all projects involving minors (<18) or disabled adults; and
- all projects taking place in an institution within the Health & Social Services Network.⁴

Under the leadership of the MSSS, Québec is making changes to its approach to ethics review for multi-centre research projects. These changes arose out of the recommendations of an independent inquiry in 2006, which identified a number of issues with the existing ethics review system.

Mr. Dussault reported that Québec's challenges with its process for ethics review in multi-centre research projects are similar to those identified in other jurisdictions, including

- delays and unnecessary costs (multiple ethics reviews),
- different and sometimes contradictory requests from REBs,
- multiple consent forms (for the same project),

³ Mr. Dussault also noted that there are other REBs in Québec that fall outside the Ministry's jurisdiction. These are including university-based and private REBs, bringing the total number of REBs in the province to more than 100.

⁴ Health and Social Services is integrated under unified administration and is mainly funded by the Government of Québec. There are 322 institutions, of which 299 are public. The Québec health care system is divided into three levels: central, regional and local. At the central level, MSSS establishes orientations, allocates resources, and assess results of the network. More information available at: <http://www.msss.gouv.qc.ca/en/reseau/services.php>

- de-motivated researchers,
- unequal treatment of research subjects, and
- loss of credibility for the overall ethics review process and requirements.

A new centralized hybrid model has been developed to improve multi-centre reviews. This new process is expected to be in use in all MSSS organizations by April 2008. This process will only apply to multi-centre projects based in the province. Each project determines one principal investigator; his or her REB is the principal REB.

Each local REB will have three weeks to conduct a preliminary review in an expedited manner. The principal REB will undertake a full review and must take into account comments provided by the local REBs. The principal REB will render its decision and send it to each local REB.

The local REB will have two weeks to approve or reject the decision by the principal REB. This step was included as a way of dealing with the potential liability issues, in that the local REB has taken responsibility for the decision of the principal REB. The key aspect of the reform is that the local REB cannot request additional modifications at this point; it must simply decide to accept or reject the principal REB decision. The principal REB will then issue its final decision and specify to the PI which institutions have concurred.

Based on a cost framework developed for Québec, Mr. Dussault noted projections that this new process will cost less than 40 per cent of the duplicative full review system currently in place.

3.4 National Perspectives

*Presented by: Peter Monette, PhD
Senior Policy Analyst,
Health Canada*

Dr. Peter Monette, as a Senior Policy Analyst at Health Canada, directs the Secretariat of the Sponsors' Table for Human Research Participant Protection in Canada.⁵ Dr. Monette indicated that his remarks were his personal and did not necessarily represent Health Canada or the Government of Canada.

He described recent developments at the national level in Canada, namely the work of a coalition of jurisdictions working on recommendations for ethics review reform. This group, the Sponsor's Table, is comprised of organizations that share a common interest in promoting research involving humans that meets the highest standards in excellence and ethics. At the present time, the Sponsor's Table members include:

⁵ For more information, please visit www.hrppc-pphrc.ca.

- Alberta Ministry of Health and Wellness,
- The Association of Canadian Academic Healthcare Organizations,
- The Association of Faculties of Medicine of Canada,
- The Association of Universities and Colleges of Canada,
- Canada's Research-Based Pharmaceutical Companies,
- The Canadian Federation for the Humanities and Social Sciences,
- The Canadian Institutes of Health Research,
- Fond de la recherche en santé du Québec,
- Health Canada,
- Health Charities Coalition of Canada (since June 2007)
- The Michael Smith Foundation for Health Research (since August 2007)
- Research Canada (since June 2007)
- The Natural Sciences and Engineering Research Council,
- The Social Sciences and Humanities Research Council, and
- The Royal College of Physicians and Surgeons of Canada.



In 2007, the Sponsor's Table struck an Experts Committee to provide expert advice on developing 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. A draft report is available and feedback was invited from stakeholders across Canada. The key recommendation in the draft report is to create a Canadian Council for the Protection of Human Research Participants, which is intended to focus on three areas of activity: policy, education and accreditation.

The report and its recommendations will go to Sponsors' Table in the spring 2008 for approval.

Dr. Monette emphasized that there is a good deal of interest in accreditation as part of the solution to harmonizing ethics review. The Experts Committee has determined that accreditation must be part of a broader approach that includes education and policy work. It is not a stand-alone solution.

Dr. Monette echoed the comments of earlier speakers when he identified some of the key challenges in determining the best approach for ethics review at a national level, including:

- insufficient value placed on human research participant protection. It factors low on the priority lists of many involved in research, below funding and resources, control and the research process itself. This culture is changing but it requires a leadership commitment to shift significantly.
- balancing the needs of various research sectors. Health research uses social science methodologies, but clinical research concerns push the agenda.
- co-ordinated leadership is required from all sectors and all levels of government to ensure a national approach to ethics review is developed. Provincial efforts are needed but eventually, we cannot find ourselves with different approaches across the country.

4. Promoting and Advancing the Approach

Options for new models of ethics review in B.C. vary widely. Through the BCEHI efforts conducted earlier in 2007, four potential approaches towards REB harmonization were determined:

- maintain the status quo;
- develop common processes and tools for use by all REBs;
- create reciprocity agreements between REBs; and
- a centralized provincial approach with one ethics review mechanism.



Following the morning presentations, the majority of time during the November 19th workshop was then devoted to exploring various aspects or characteristics of these general approaches. It was stressed that no one approach was being promoted or was anticipated to be adopted, and further, that several characteristics to reform were present or shared across the approaches. To facilitate individual input and cross-fertilization of ideas from various sectors and perspectives, participants were organized into small groups. The challenge for the discussion was to determine the essential features for the best possible research ethics review system model for British Columbia.

Table 1 on the next page summarizes some of the key characteristics of these approaches and their (sometimes common) characteristics.

Summary Table: Characteristics of Approaches to System Harmonization				
Approach:	Status Quo	Common Tools and Processes	Reciprocity	Provincial or centralized
Characteristic:				
Number of Research Ethics Boards	23 – or more - ⁶ independent, organization or institution-based REBs	23 independent, organization or institution-based Research Ethics Boards	23 – or fewer – independent, organization or institution-based REBs	Single, province-wide REB
Constitution/ governance	Each REB constituted according to Tri-Council Policy Statement for research involving human subjects and local institutional policies	Each REB constituted according to Tri-Council Policy Statement for research involving human subjects and local institutional policies	Each REB constituted according to Tri-Council Policy Statement for research involving human subjects and local institutional policies as well as inter-institutional memoranda of agreement.	Central REB constituted according to Tri-Council Policy Statement for research involving human subjects
Basis of review	Each REB adheres to and interprets recognized international and national guidelines, codes of ethics or policy statements	REBs agree to a common interpretation of international and national guidelines, codes of ethics or policy statements and use a common set of tools and processes	For single site studies, each REB adheres to and interprets recognized international and national guidelines, codes of ethics or policy statements	All proposals for research involving human subjects submitted to a single centralized REB
Multi-centre process	Research proposals involving multiple sites are reviewed and, where acceptable, approved by each site-based REB	<not specified – presumably would be facilitated via use of common tools and processes, reducing duplication of effort>	REBs agree to designate a lead organization or institution for multi-centre research and to accept and be bound by the decision of that lead REB	All proposals for research involving human subjects submitted to a single centralized REB

Table 1: Approaches to Harmonization

⁶ There were 23 Research Ethics Boards identified in B.C. that currently review research involving human subjects, representing 21 institutions; they are listed in Appendix E.

4.1 *Group Activities and Discussion Summaries*

For the first group activity, participants were divided into eight subsets of about 15 people each. Each group was asked to discuss the merits and limitations of one of the four approaches to REB harmonization; each approach was discussed in the morning sessions by two of these groups.



In the afternoon, the morning groups merged into four larger groups of approximately 30 people. These larger gatherings brought together the two groups that had spent time in the morning discussing each of the four approaches to ethics review. They shared their thoughts and developed a presentation to share with their counterparts, highlighting the key characteristics of their assigned approach. They also focused on identifying merits, limitations, initial steps for implementation, and some objectives or measures of success that might be tracked if that particular approach was pursued in B.C.

Each group selected a presenter to share the discussion and findings with the larger group. Where more than one opinion or set of ideas was evident, each was presented in the plenary session.

Following the second group gatherings, participants reconvened in plenary session to hear presentations from each of the four larger groups summarizing their discussions. The following section reflects these brief presentations.

4.1.1 **Approach 1: Status Quo**

Characteristics:

- In BC, there are 23 independent, organization or institution-based Research Ethics Boards.⁷
- Each REB constituted according to Tri-Council Policy Statement for research involving human subjects.
- Each REB adheres to and interprets recognized international and national guidelines, codes of ethics or policy statements.
- Research proposals involving multiple sites are reviewed and, where acceptable, approved by each site-based REB.

The merits of maintaining the status quo are the autonomy of the REBs, the opportunity for education and training as new members are recruited and the local focus and expertise of these boards.

⁷ There were 23 Research Ethics Boards identified in B.C. that currently review research involving human subjects, representing 21 institutions; they are listed in Appendix E.

Existing boards are autonomous within their organizations: they make their own decisions in the context that is appropriate for the organization or community. These boards provide the opportunity for board members to learn as they go through the process and participate in ethics reviews. The present structure has board members that understand their own institutions, their communities, and any special features to be found therein, such as special populations or unique geographic context.

Diversity is a key advantage in the current REB structure, at the board level, and across the province. Many of the larger current boards have quite diverse expertise among members. With 23 REBs in the province, there is diversity between the boards, such that some can develop niche or specialized expertise in certain areas.

With 23 REBs, the provincial workload is shared among many boards. Fewer boards mean more work for all.

Several limitations to the status quo were identified, including inconsistency in decision-making, costs and delays in approvals, and inefficient use of member expertise, especially with multi-site reviews.

For the status quo to be sustainable, decision making must become standardized and efficient if it is to improve consistency and quality and reduce costs and delay. More information about the details of the status quo would create an understanding of where the primary issues are and how to resolve them. Accreditation and certification of boards would further improve quality and mean more efficient use of board member time on reviews.

The status quo would benefit from greater cooperation and trust between the REBs and between REB members and the investigators.

If the status quo is to be maintained, there are some improvements that could be made to better meet the needs of investigators, organizations, and the community.

- Standards and measurements of success need to be established, including stakeholder satisfaction, turn-around time and education or training of members and investigators.
- More robust communication between boards and the investigators who require approvals.
- Enhanced communication and collaboration between REBs to increase cooperation, transparency and trust.
- Establish a complete current state description, building on work to date by MSFHR.

The next step to reviewing and improving the status quo is for the organizational sponsors of REBs to come together to review information, describe measures of success and develop avenues to drive the further development of the current system.

4.1.2 Approach 2: Common Tools and Processes

Characteristics:

- In BC, there would be 23 independent, organization or institution-based Research Ethics Boards.
- Each REB constituted according to Tri-Council Policy Statement for research involving human subjects.
- All REBs agree to a common interpretation of international and national guidelines, codes of ethics or policy statements and use a common set of tools and processes for ethics review.

Common tools and processes will lead to greater efficiency in the ethics review process. This approach can lead to developing more sophisticated tools for sharing the administration of this process. It also helps the relationships and trust develop that are necessary for further cooperation and integration.

Recognizing that there is some sharing of tools and processes, this group agreed that there are still some 'quick wins' available. Through careful analysis and some initial steps, there are relationships in place that would enable early discussions and perhaps a pilot project or proof of concept.

Increasing efficiency could lead to B.C. being viewed as a more desirable home for health research, and will increase our ability to attract more multi-site investigation.

It will be challenging to create common tools and processes while still maintaining the unique local needs that stem either from communities, geography, or specialty.

Multi-site studies with multiple investigators are the most complex for review and the tools to support this aspect of research will require the most effort.

Many institutions and REBs have invested in their tools, particularly information technology systems. Common IT tools are an obvious solution; some organizations may see their investment in ethics review shift or disappear completely.

The challenges in establishing common tools and processes could be managed by creating a list of priorities, agreed to by the REBs and with input from investigators. It would be important to determine – from the investigator's perspective – whether consistency or speed is more critical. One may have to be compromised up to improve the other, at least in the early days.

Implementation would begin with creating an inventory of forms and other materials that are in use. It is possible that they are more similar than is realized, collecting essentially the same information but perhaps ordered differently. With the inventory, it may be possible to identify some obvious or early 'wins' – tools that can be created and put in place quickly.

Using pilot projects to test and then refine tools and processes was also proposed as a way to gain agreement, especially if any REBs will be significantly affected by changes.

A neutral third party to guide and maintain momentum would be helpful; perhaps this could be a continuing role for MSFHR.

Leadership and sponsorship are important element in creating and implementing common tools. REB chairs have to lead this, and in order to do so, they should meet regularly to share a common understanding of the goals for the initiative.

As there was a good deal of overlap between the ideas generated by the common tools and the status quo groups, perhaps discussion could begin quickly on ways for REBs to work together.

4.1.3 Approach 3: Reciprocity

Characteristics:

- In BC there would be 23 – or fewer – independent, organization or institution-based Research Ethics Boards.
- Each REB constituted according to Tri-Council Policy Statement for research involving human subjects.
- REBs agree to designate a lead organization or institution for multi-site research projects and to accept and be bound by the decision of that lead REB's decision.

The two morning discussion groups approached the topic of reciprocal agreements or reciprocity from quite different perspectives.

One group determined that they could not discuss this approach as they felt more information and a more fulsome definition of reciprocity were required. This group redefined reciprocal model as one where institutions, not just REBs, accept each other's reviews without just 'rubber stamping' them. This requires formal agreements outlining responsibilities, liabilities, and accountabilities between institutions. These agreements have to be at the institution level due to the potential impacts on policies, funding, and practices regarding research management.

As well, any reciprocal agreement must allow the opportunity for the local board to take into account local concerns through a review of its own (administrative or operational) and not simply to accept unconditionally the conclusions of a primary board. This will require agreement between the institutions. A number of suggestions were made about information that needs to be collected before reciprocal agreements could proceed.

The second group considered the definition of reciprocity as presented by the MSFHR. Working toward reciprocal agreements between institutions and their REBs has many advantages identified by the participants. This approach will reduce workload and redundancy as studies are being

reviewed by one REB, rather than multiple boards. REBs can be more responsive to investigators as a result.

Reciprocal agreements will build a stronger community of REBs as they work more closely together through exchange of information and workload. This can lead to increased trust and a movement toward common standards and other shared items that are part of the ethics review process. Boards can develop specific areas of expertise, upon which other boards can rely for review.

Reciprocity could lead to a common understanding and agreement around the province about the role of REBs. At present, REBs have different purviews – the scope of their work varies from confining themselves to the ethics and science of the studies they review to also managing resource allocation and other activities within the realm of research. With reciprocal agreements, a common agreement on the purpose and function of REBs would have to be in place.

With one board of record or lead board for reviews, there are a number of challenges to be managed.

- Lead boards may be perceived as having a lack of understanding and sensitivity to local context.
- REBs that are not the lead in their jurisdictions may sense a loss of control and power. How do we ensure that all boards have an appropriate amount of work and aren't seen as redundant?
- Hidden duplication can start to develop, where a hidden process or bureaucracy exists, imposing additional conditions or constraints on a study that has already been approved by the board of record.
- Institutional conflicts of interest can arise where there are advantages to being the institution with the board of record for large, multi-site trials. The ethics review process has to be distinct from politics and funding discussions.
- If any of the above develops, there is a potential for an increasing lack of trust.
- Liability issues are complex and will require leadership and legal input to resolve.
- Local resistance by some boards can sabotage the process if those boards continue on their own path and ignore new processes.

If reciprocal agreements are put into place, there are several expected benefits.

- Greater satisfaction and fewer complaints from study participants, investigators and research administrators.
- Fewer investigations by Privacy Commissioner.
- More accredited sites and REBs in place to support ethics review.
- Fewer review processes for multi-site studies.

- More collaborative discussions between REBs.
- Increase in reciprocity agreements between REBs and organizations.
- More studies completed, more study participants recruited.

4.1.4 Approach 4: Provincial or Centralized

Characteristics:

- Single, province-wide REB constituted according to Tri-Council Policy Statement for research involving human subjects.
- All proposals for research involving human subjects submitted to a single centralized REB.

This group dismissed the definition as provided, as they didn't believe that there would be agreement to proceed with this kind of centralized ethics review structure. With daunting logistics and the question of how this would be funded, the group determined that a centralized service and resource organization would be more reasonable and preferable. It was noted that this is really a combination of what the Common Tools and Process and the Reciprocity groups found during their discussions.

The key features of this approach create common forms within an IT system along with standards in the province for issues such as the role of students, what requires ethics review and what does not, and post-review follow-up. This approach would provide a venue for human research subjects' interaction – where information would be available, questions answered and questions and comments would be addressed. This centralized organization would also take the lead in education programs and materials for REB members.

In essence, the presentation was not promoting a move to one REB, but to enhance the role and function of the existing REBs through centrally-managed processes and administration.

This approach could lead to B.C. becoming a more attractive location for research. B.C. has significant resources such as databases that can be leveraged with this kind of approach as well. Any developments to improve the ethics review process have to be built with quality, effectiveness and scalability in mind as all participants are interested in creating an environment to support more high-quality research.

In order to proceed with this approach to ethics review, several steps need to be taken: The problem that is being addressed needs to be clearly defined, including the size and scope (for example, what is the data related to multi-centre trials?) and detailed information gathering, building on the work already completed, is required.

Governments and institutional leaders must be strongly committed with their support and resources to implement new processes. These leaders have to be prepared to work collaboratively across institutions and regions.

A key element to garner support and commitment would be a fully-developed business case with data to support these initiatives.

A scalable, flexible system that meets the objective of human subject protection will have its success measured by:

- an increase in the amount and quality of research;
- standardized turnaround for applications - there was some discussion about whether to aim to be the shortest in Canada or set a timeframe based on best practices;
- an increased understanding of, and input from, human subjects involved in health research;
- an increase in researcher satisfaction with ethics review; and
- an on-going dialogue with all REBs.

The next steps toward developing this approach would be to clearly define the scope of the problem, confirm a champion and a commitment from the research community leadership and government and develop a business case.

5. Summary Remarks

5.1 Reflections

*Presented by: Greg Koski, PhD, MD, CPI
Harvard University, Boston MA*

Following the presentations by each of the participant groups, guest speaker Dr. Greg Koski was invited to reflect on what he had heard as he listened in on the day's discussions.

Once again in these closing remarks, Dr. Koski highlighted the common goal shared by of institutions, REBs, and investigators – that of highest quality research that protects human subjects. He again challenged participants that their decisions for any future next steps should be based on this fundamental driver of changes to ethics review processes in B.C.

He proposed that REBs and investigators each need a better understanding of what ethics review means to the other. Investigators believe that REBs are skilled at activities that the researchers don't find important to the ethics review or research process, while researchers may at times seem cavalier or less concerned about ethics than the board members would like them to be.

Better education of investigators and better education of REB members about the role and function of each other in the ethics review system will improve communication and understanding of the various roles involved in research and research ethics.

Dr. Koski challenged REBs to be more engaged with the research community. They must reach out and involve them in reviews and discussions. Why wouldn't an REB have the investigator present when the proposal is being discussed? It would save time and increase the REB members' understanding of the project.

He was also critical of researchers not actively championing the need to protect human subjects. In general, researchers have been slow to speak publicly about this very critical aspect of their work. In addition to proactively championing this need, they can also be more engaged in the process by providing additional information quickly, responding to questions promptly, etc.



REBs and investigators are on the same side and both groups can therefore collaborate to enhance the process.

The ethics review process itself needs to be clearly defined and understood. Dr. Koski commented on the prevalent opinion heard throughout the day that ethics review is seen as additional work without any added value, implying that few in the academic or research realm value the process or the work of the REBs. In his view, service on REBs should be viewed as fundamental in terms of what people contribute to the academic mission of the institution. It is an integral part of the science, not an administrative process to be adhered to. He called upon leaders to change this view both within their institutions and among their stakeholders.

A clear understanding of and visible support for the role of REBs will also allow focus, leading to greater efficiency and perhaps more resources and support, which will in turn lead to faster reviews. Dr. Koski stated that the idea that speed comes at the price of quality is incorrect. People and processes can be quick and efficient when they have a clear mandate, a lack of distractions and tools and processes to support the work. REBs must focus on ethics reviews, not administrative or performance or financial reviews. Too often, these reviews are “muddled together”, delaying the results.

According to Dr. Koski, REBs are rarely sued, and never successfully. He noted a high level of concern among researchers about “getting into trouble” and an ensuing focus on non-compliance and liability. This mindset is counter-productive overall. The goal of the ethics review process, and therefore of REBs and investigators alike, is to prevent harm to human subjects. Working from a more narrow perspective such as reducing an organization's liability or protecting individual projects is not in keeping with the overall goal of high quality research that protects the people involved.

He was adamant that trust and leadership are key ingredients to moving beyond this mindset, such that if boards, investigators and institutions were to work more closely together, then perhaps “we could get over this”.

IT systems supporting ethics review offer great opportunities that as yet, seem under-appreciated or under-explored in B.C. Mention was made, for example, of a system or tool that UBC has developed – why hasn’t this been offered by UBC or demanded by the other REBs?

IT systems “can do wonders” for adding efficiency for REBs and researchers. Simple web-based forms can be used by everyone. Systems that alert REBs and researchers in real-time about adverse events are available and will go a long way toward creating the efficiency that this province really needs.

Dr. Koski pointed out that harmonization efforts are underway across Canada. While the workshop group has heard some examples, it will be important for B.C. to understand all national activities, as national approaches may also be part of the solution. The energy that currently surrounds this work in B.C. can be captured and shared across the country to promote responsible high quality research.

The recurring request for more data has to be fulfilled. More detail about specific REB costs is a key piece of information. Evaluating performance of REBs based on provincial standards will also better describe the current state. It will be helpful to know where processes work and where the gaps or major delays occur. Dr. Koski suggested tracking protocols through time and motion studies to provide data about the actual challenges.

In concluding his remarks, Dr Koski encouraged everyone to engage human research participants in the process. Very little was discussed throughout the day about how to determine the attitudes of the people with the most at stake in this process. Their perspectives will differ from other stakeholders, yet are essential for developing the best model for the province.

5.2 Summary of Comments from Closing Plenary

The workshop provided the opportunity to start a conversation with a broad group of people and to identify the challenges and issues that we must grapple with. It was an energetic day with many people learning and sharing with each other.

5.2.1 Emerging Themes

Participants were invited to put forward ideas and suggestions that would assist in maintaining momentum of the ethics harmonization initiative. Concrete suggestions and action steps were proposed, and are summarized here according to several major themes that emerged:

Information requirements to inform further work

- REBs and researchers across B.C. should have a better understanding of the perspectives of those community members who volunteer as human subjects in research projects. Meaningful dialogue has to begin with the people most affected by health research studies and trials.
- Clear descriptions of where the problems are: where does the process get stuck or not work efficiently?
- What are the current budgets and resources available to support the existing REBs?
- More detail about the extent of multi-site studies that are underway. What specifically would improve ethics review for this kind of research? What are the key issues with the current process?
- What are the current relationships that exist? There are examples of agreements and trust in place, for example, the University of Victoria and the Vancouver Island Health Authority each have their own REBs and a shared REB for research conducted in both organizations.
- A business case is required to articulate the scope of the effort required, the projected outcomes, and how it will be supported.
- An inventory of the kinds of education and training that is currently used by various REBs with their members or with researchers.

Leadership

To make changes to the current approach to ethics review, leadership is required. Who are the most appropriate leaders? Are there leaders? If there is consensus to move forward on ethics review reform, then identifying and gaining the commitment of institutional leaders is a critical next step. This message has to be conveyed by participants to their institutions.

Many suggested that REBs should come together to work on the issues and questions arising from the workshop. Dr. Koski challenged participants to think more broadly and to include others involved in research and ethics. One aspect of leadership is to involve stakeholders, in order to enhance understanding of the variety of perspectives and information sharing. Information becomes the basis for education and dialogue, as happened during the workshop.

Ethics review stakeholders can include researchers, REB members, institution representatives, industry representatives, geographic region representatives, human subjects, and others.

The solutions have to be driven by institutional leaders, with input from a variety of stakeholders. This requires a logical sequence of activity, as well as agreement about who else should be included.

Trust

The most common suggestion for building trust was to work together, thereby creating and building relationships. Given that there are some relationships and shared processes in place, a degree of inter-institutional trust is already present in the REB system. It was noted that this workshop also contributed to increasing the level of trust.

Common IT system and forms

Regardless of the model or approach to ethics review in B.C., common forms and communication system are required, and must be supported by a shared IT application. UBC has developed a system that can be shared and used by others. An important aspect of leveraging one system for use by multiple institutions is the look of the system vis-à-vis logos and names. It was suggested that the UBC system could be rebranded as a B.C. system.

5.2.2 Preferred approach

Workshop participants concurred that the status quo is not an option, nor is creating one central provincial REB. Rather, the general consensus was that a hybrid of reciprocity and common tools/processes and collaboration (which may include reciprocity) would enable B.C. to best meet its goals for ethics review reform.

There was recognition that perhaps not all types of research need to have ethics review handled in the same way. Perhaps a matrix approach can be developed such that low risk studies have one approach and multi-centre studies are handled differently. Reciprocity may work best among certain kinds of institutions or for certain kinds of studies, but perhaps not as a common approach for the whole province. These specific needs must be further explored.

5.2.3 Desire for action

Ethics review has been identified as a major issue for many years. The MSFHR and workshop participants expressed a desire for action and change – neither would like to be working with the status quo five years from now.

Suggestions for immediate action include:

- Strike an institutional leadership committee to endorse and move the discussion forward.
- Issue-specific working groups involving all stakeholders. While agreeing that there is major work to do at a leadership level, groups that come together to focus on specific issues can work quickly, achieving some early wins or gains. There is an opportunity to identify 'low-hanging fruit' or early wins. Issue-specific task forces can determine what kind of data or information is required to prepare the discussion.

- Inviting three to four institutions to work together on a common form and process for multi-centre research. It could be tested and improved, with others joining the process as they choose.

Other specific points include:

- UBC session on How to Review a Biomedical Protocol in the spring will be made available to all.
- The Canadian Association of REBs (CAREB) would be a useful resource for learning more about educating members of REBs. Southwestern Ontario's approach is quite comprehensive and might be a good model for B.C. to follow (i.e. regional ethics workshops focused on education and networking).

5.2.4 The Future Role of MSFHR in Ethics Harmonization

Although many workshop participants called on MSFHR to continue to facilitate processes for harmonization of ethics review in B.C., the Foundation's CEO Dr. Aubrey Tingle stressed that such a mandate cannot be accorded to MSFHR by itself. He challenged the leaders of those B.C. institutions that sponsor human subject research to endorse efforts for reform at the highest level, championing the effort and setting the bar for system reform. The Foundation will continue to emphasize that it is the institutions engaged in the REB process that must lead further activity. If such leadership is provided, the Foundation will then be ready and willing to provide a forum and facilitation support for future initiatives.

5.3 Closing Remarks

*Presented by: Martin Schechter, OBC, MD, FRCS, FCAHS
Chief Scientific Officer and
B.C. Ethics Harmonization Initiative Project Sponsor
The Michael Smith Foundation for Health Research*

Dr. Schechter closed the workshop with comments from the perspective of a researcher and referring to the four recurring themes outlined by the BC Ethics Harmonization Initiative (please see Appendix B):

- Information technology: common tools can provide a platform or foundation from which place for more collaboration to grow. There was general agreement throughout the day that building a common system in B.C. was a possibility.
- Accreditation: common standards and external validation build trust as everyone is committed to a specific level of practice.
- Trust: with the emphasis on a system for protecting human research participants and advancing knowledge, trust can increase between REBs and researchers. REB members have to learn more about science and how researchers achieve their goals. Often, rapid

implementation of research can allow severely ill patients to access experimental, state of the art – or life-saving – therapies. Conversely, researchers must learn the value of the ethics review process and how to maximize their role in this process.

- Leadership: leaders from all areas of the research ethics enterprise are participants in this workshop. Changes will not take place if leaders are not supportive and actively championing the effort. By default, we will continue with the status quo. Therefore, significant effort is required or five years from now we will still be talking about reforming ethics review.



5.4 Next Steps

A report of proceedings will be prepared, and the Stakeholder Task Force will meet again to review the report and ensure that options for next steps - as described throughout the workshop – are well articulated. The report will be published in late January for broad circulation to the research community, both provincially and nationally. Participants were also welcomed to contact Task Force members or MSFHR staff directly to make their views known.

Appendix A About the Michael Smith Foundation for Health Research

The Michael Smith Foundation for Health Research (MSFHR) is the provincial support agency for health research in British Columbia. Established by the B.C. government in 2001, MSFHR is an independent, third-party organization that works to develop B.C. as a leading force in health research, supporting improvements to health, health care and economic opportunity. We focus on:

- Supporting people by attracting the best and creating an environment where they can excel;
- Working across academic, health and government systems to foster collaborations that enhance health research productivity, competitiveness, and impact;
- Building partnerships within B.C. and across Canada to leverage B.C.'s health research potential and create better returns on research investment;
- Demonstrating fairness, accountability and transparency in all our activities.

MSFHR was named to honour Nobel Laureate Dr. Michael Smith (1932-2000), a pre-eminent B.C. scientist with a long-standing personal commitment to ensuring support for researchers throughout their careers, and who believed that B.C. could and should be a leading centre for health research.

Our Mission

MSFHR leads, partners and serves as a catalyst to build British Columbia's capacity for excellence in clinical, biomedical, health services and population health research.

Our Vision

MSFHR:

- works to create a vibrant and sustainable British Columbian health research environment that is recognized for excellence and:
 - has the human resources, infrastructure and research space to compete effectively for national and international funding across all sectors;
 - anticipates and responds to B.C. health needs; and
 - builds the B.C. economy;
- networks for critical mass across Western Canada, nationally and internationally.

Our Role

As British Columbia's provincially mandated health research organization, MSFHR builds B.C.'s capacity for excellence in health research by:

- leading, partnering and serving as a catalyst to advance provincial, inter-provincial and national initiatives that expand health research support and opportunities;
- working with health research stakeholders to identify, prioritize and respond to provincial priorities; and
- delivering innovative programs to address the key building blocks of a vibrant, sustainable research effort.

For further information about the Foundation and its activities, please visit the MSFHR website at <http://www.msfhr.org/sub-about.htm>

Appendix B About the B.C. Ethics Harmonization Initiative

Scope of the Initiative

There have been many attempts in many countries to create the most accessible, effective, efficient, uniform ethics review system. As yet, no single system has emerged as the most likely to succeed with reform in a way that meets all stakeholders' goals and expectations. The 'ideal' system typically envisioned is one accessible to researchers *and* highly protective of subjects who participate in health research activity.

With such an ideal in mind, 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. Over the past year, a number of organizations have launched separate and, to date, uncoordinated initiatives in an attempt to address concerns at least with respect to their own institutional context.

While many agree that there is a clear need for a provincial approach to ethics review, it is not clear what potential 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, the Michael Smith Foundation for Health Research agreed to facilitate a process to explore options in greater depth. The Foundation struck a Stakeholder Task Force to provide advice and feedback, and make recommendations to MSFHR as requested, on topics relating to the B.C. Ethics Harmonization Initiative (BCEHI). Based on feedback from the Stakeholder Task Force, the scope of the initiative is:

1. Environmental Scanning – a three stage process:
 - a) *B.C. Research Ethics Board (REB) Scan*: description of mechanisms and structures for ethics review of research involving human subjects in the academic institutions, health authorities and communities of British Columbia, including identification of the issues and barriers related to ethics review that exist in the provincial health research environment (May to July, 2007).
The report is available at: http://www.msfr.org/docs/BC_Scan.pdf
 - b) *Harmonization Scan*: description of processes and structures adopted in other jurisdictions, particularly across Canada but also including selected other countries such as England and Australia (May to July, 2007).
The report is available at: http://www.msfr.org/docs/Harmonization_Scan.pdf

- c) *B.C. Investigator Survey*: survey of B.C. researchers to identify and prioritize the key barriers/areas of concern with respect to quality, access, consistency, efficiency and capacity for ethics review of research involving human subjects (August to October, 2007).

The report is available at:

http://www.msfhr.org/docs/Investigator_Survey.pdf

2. Workshop – a gathering of stakeholder representatives (VPs or Directors of Research, Chairs & Managers of REBs and investigators) from key B.C. health research institutions and organizations to receive the results of the environmental scans, hear from expert speakers, and discuss options for a coordinated response in meeting the need for a provincial approach to ethics approval (November 2007). The proceedings of that workshop are outlined in this report.

Dimensions of an REB

In the course of research relating to the ethics review process in British Columbia, MSFHR repeatedly encountered certain topics that were expressed as key to consideration of any potential improvements in the provincial system. Keeping in mind the overarching goal of protecting the interests of human subjects involved in research, the Research Ethics Board approval process may be considered along the following dimensions: Access, Quality, Efficiency, Capacity and Consistency. For the purposes of discussion at the November 19 provincial workshop, these dimensions were defined as follows:

Access:

This dimension relates to the perception that information is readily available to applicants in order that they may

- know to which REB to apply and how;
- have the skills and knowledge to prepare a high quality application;
- develop a clear sense of the REB processes, timelines, and decision rules;
- know how they can improve their chances of a successful outcome; and
- know when they can expect a decision from the REB.

Capacity:

This dimension relates to the perception that the REB has

- sufficient expertise to assess applications across a spectrum of health research;
- sufficient frequency of meetings to respond in a timely manner;
- continuing access to sufficient numbers of willing and qualified board members to manage the demand for ethics review; and
- resources to manage the ethics review process effectively.

Consistency:

This dimension relates to the perception that

- the REB subscribes to a recognized standard of quality process, output and outcome;
- the ethics review process is of uniform quality across the province; and

- that the same application would receive comparable review and outcome from any B.C. institution's REB.

Efficiency:

This dimension relates to the perception that REB processes are

- clear;
- straightforward;
- concluded in a timely manner; and that
- REB application activities are not unnecessarily duplicated.

Quality:

This dimension relates to the perception that REB decisions are

- fair;
- well-informed;
- clearly justified to applicants;
- consistent with regulatory and legal obligations of all responsible parties
- include annual recertification of ethics approval through the course of the approved research; and
- include site monitoring for compliance through the course of the approved research.

Recurring Themes

Based on the findings of the environmental scan of ethics review processes in other jurisdictions across Canada and around the world, MSFHR's research also identified four overarching themes that repeatedly are identified by stakeholders as important contributing factors to successful ethics review reform. The recurrence of these themes and the priority assigned to them by the research community in multiple jurisdictions suggests that any process to develop new models for ethics review must attend to the following:

- Leadership
- Trust
- Accreditation
- Common IT systems or tools

In addition, research indicates that, to be successful, any initiative to enhance processes for ethics review must address the review system context, including:

- The realities of the system to be served, in the light of contemporary international standards
- The increasing volume of collaborative and multi-site studies requiring review
- Opportunities for efficiency and interactive communication offered by electronic systems
- The need for evidence-based mechanisms to monitor and assure performance quality

Stakeholder Task Force

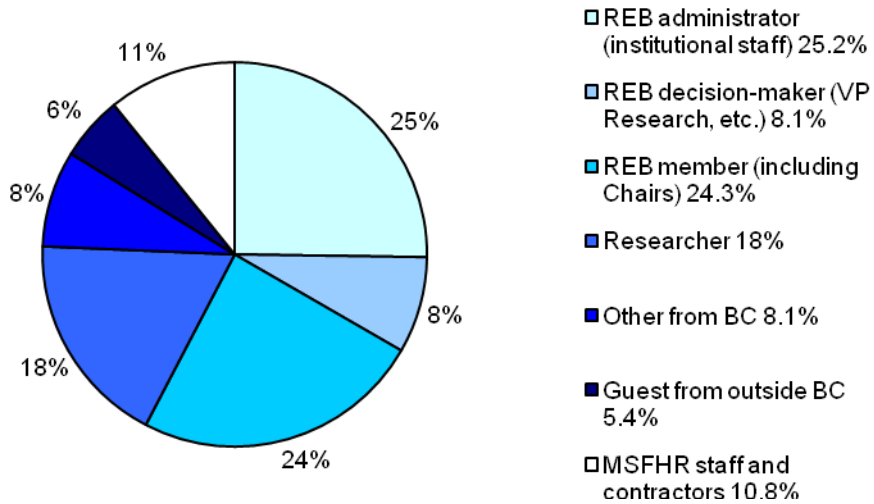
To support the B.C. Ethics Harmonization Initiative, in early 2007 MSFHR struck a Stakeholder Task Force. The purpose of this provincial group was to provide advice and feedback, and make recommendations to MSFHR as requested, on topics relating to the Initiative. Their duties included reviewing and advising on the initiative's research activities; planning for the workshop; and overseeing production of this final report including its recommendations.

Members of the Task Force were:

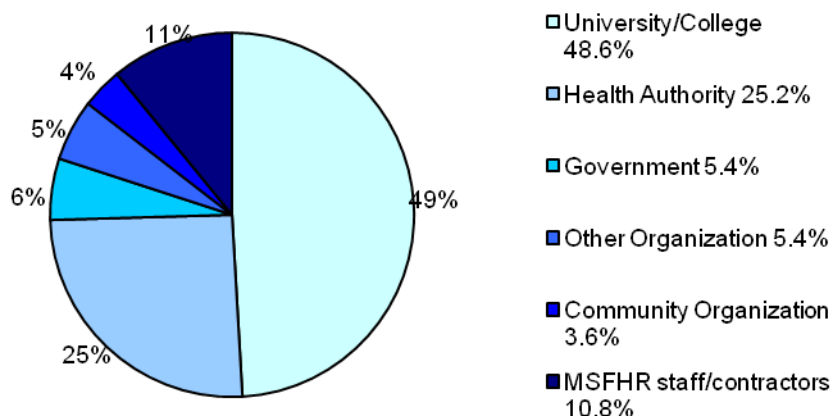
- Dr. Anne Marie Broemeling
Director, Information Support and Research, Interior Health Authority
- Dr. George Browman
Chair, Research Ethics Board, BC Cancer Agency
- Dr. Joe Connors
Vice-Chair, Research Ethics Board, BC Cancer Agency
- Ms. Eva Cheung Robinson
Program Director, Vancouver Foundation
- Ms. Laurel Evans
Associate Director of Research Ethics, UBC
- Dr. Sarah Hartley
Society & Ethics Advisor, Genome BC
- Ms. Joan Higgs
Society & Ethics Advisor, Genome BC
- Ms. Valerie Hunter
Program Director, Vancouver Foundation
- Dr. Richard Keeler
Associate Vice-President of Research, University of Victoria
- Dr. Yvonne Lefebvre
VP Research & Academic Affairs, Providence Health Care
- Dr. Linda Peritz
Associate Director, Vancouver Coastal Health Research Institute
- Dr. Deborah Poff
University of Northern BC; Board Member and Chair, Research Ethics Board, BC Medical Services Foundation (Vancouver Foundation)
- Mr. Brent Sauder
Assistant Deputy Minister, B.C. Ministry of Advanced Education
- Ms. Elisabeth Wagner
Executive Director, Strategic Policy and Research, Ministry of Health
- Ms. Leanne Warren
Director of Research, Strategic Policy and Research, Ministry of Health
- Dr. Hal Weinberg
Director of Research Ethics, SFU

Appendix C Summary of Workshop Participation

Workshop Attendees by Role



Workshop Attendees by Affiliation



Appendix D List of Workshop Participants

Lastname	Firstname	Primary Organization or Institution
Adam	Shelin	University of British Columbia
Allan	Grant	Kwantlen University-College
Audy	Sonya	Ministère de la santé et des services sociaux, QC
Bachand	Richard	Vancouver Island Health Authority
Barrett-Smith	Linda	Alberta Heritage Foundation for Medical Research
Bayne	Lillian	Consultant
Bearder	Vivienne	Providence Health Care
Bellward	Gail	University of British Columbia
Blum	Susan	Saskatchewan Health Research Foundation
Brealey	Ken	University-College of the Fraser Valley
Breden	Felix	Simon Fraser University
Brickell	Tracey	B.C. Mental Health and Addiction Services
Brinkman	Jacqui	Providence Health Care Research Institute
Brooks-Wilson	Angela	BC Cancer Agency
Browman	George	BC Cancer Agency
Buchan	Alison	University of British Columbia
Cairns	John	University of British Columbia
Chan	Laurie	University of Northern British Columbia
Chockalingam	Arun	Simon Fraser University
Christensen	Erling	Community-Based Research Centre Research Ethics Board
Chunick	Susan	Fraser Health
Conley	Tracy	BC Centre for Disease Control
Connors	Joseph	BC Cancer Agency
Coward	Patricia	Michael Smith Foundation for Health Research
Cox	Susan	University of British Columbia

Lastname	Firstname	Primary Organization or Institution
Dastur	Farhad	Kwantlen University-College
Domene	Jose	Trinity Western University
Dupuis	Jennifer	University of Northern British Columbia
Dussault	Claude	Ministère de la santé et des services sociaux, QC
Evans	Laurel	University of British Columbia
Evans	Patricia	Michael Smith Foundation for Health Research
Evans	Helen	Michael Smith Foundation for Health Research
Fedoroff	Ingrid	Providence Health Care
Ferguson	Ann	Interior Health
Foulkes	Marc	Fraser Health
Friedman	Jan	University of British Columbia Children's & Women's Health Centre
Funk	Sue	Trinity Western University
Gallagher	Elaine	University of Victoria
Goldt	Erika	Michael Smith Foundation for Health Research
Graf	Cherry	Michael Smith Foundation for Health Research
Hampe	Tanis	Northern Health
Hegele	Richard	Providence Health Care
Higgs	Joan	Genome BC
Hood	Jane	B.C. Mental Health and Addictions Research Network
Hoppins	Colleen	Royal Roads University
Hunt	Rodney	Simon Fraser University
Hunter	Theresa	Vancouver Island Health Authority
Johnston	Suzanne	Northern Health
Joschko	Michael	Vancouver Island Health Authority
Junker	Anne	Child and Family Research Institute
Keeler	Richard	University of Victoria
Kilty	Craig	B.C. Transplant Society

Lastname	Firstname	Primary Organization or Institution
Kirk	Martin	University of British Columbia
Kmetic	Andrew	University of Victoria
Koski	Greg	Harvard University
Krebs	Debbie	University of Northern British Columbia
Lam	Eugenie	University of Victoria
Lefebvre	Yvonne	Providence Health Care
Levin	Adeera	B.C. Renal Agency
Levine	Marc	University of British Columbia Children and Women's Hospital
Levy	Adrian	University of British Columbia
Lin Hsieh	Cynthia	University of British Columbia
Lo Ah Kee	Karen	University of British Columbia
Lynam	Judith	University of British Columbia
Macleod	Stuart	Provincial Health Services Authority
McArthur	Dawn	Child and Family Research Institute
McGeachie	Paul	Camosun College
McKerrow	Ron	Provincial Health Services Authority
Monette	Peter	Health Canada
Morris	Veronica	Vancouver Island Health Authority
Murphy	Tim	Michael Smith Foundation for Health Research
Nair	Pradeep	University of British Columbia
Ogden	Russel	Community-Based Research Centre Research Ethics Board
Oldendorff	Gitta	Michael Smith Foundation for Health Research
O'Neil	John	Simon Fraser University
Peritz	Linda	Vancouver Coastal Health Research Institute
Perry	Cilla	Canadian Blood Services
Peterson	Christine	Thompson Rivers University

Lastname	Firstname	Primary Organization or Institution
Poff	Deborah	Vancouver Foundation BC Medical Services Foundation
Ralph	Barb	Simon Fraser University
Rintoul	Allison	Child and Family Research Institute
Roe	Gordon	Community-Based Research Centre Research Ethics Board
Roth	Eric	University of Victoria
Russell	John	Langara College
Sauder	Brent	Ministry of Advanced Education
Sawatzky	Bonita	University of British Columbia B.C. Children's Hospital
Sawatzky-Girling	Brenda	Canadian Interprofessional Health Collaborative
Scarrow	Gayle	Michael Smith Foundation for Health Research
Schauber	Karen	University of British Columbia
Schechter	Martin	Michael Smith Foundation for Health Research
Schuckel	Victoria	Ministry of Health
Shields	Bonnie	BC Cancer Agency
Skrapek	Erin	University of British Columbia
Smith	Sharlene	Michael Smith Foundation for Health Research
Streat	Norman	The BC Institute of Technology
Sullivan	Bill	University of British Columbia
Sullivan	Lana	Vancouver Coastal Health Research Institute
Tait	Patricia	Vancouver Coastal Health Research Institute
Thompson	Shirley	University of British Columbia
Tingle	Aubrey	Michael Smith Foundation for Health Research
Todd	Angela	Michael Smith Foundation for Health Research
Tom	Freda	Vancouver Coastal Health Authority
Toronchuk	Judith	Trinity Western University
Toward	Jeffrey	University of British Columbia

Lastname	Firstname	Primary Organization or Institution
Van Bibber	Marilyn	University of Northern BC
Van Wagoner	Nancy	Thompson Rivers University
Vojnovic	Sandra	B.C. Transplant Society
Wagner	Elisabeth	Ministry of Health
Wagner	Shannon	University of Northern British Columbia
Ward	Heather	Malaspina University-College
Warren	Leanne	Ministry of Health
Weinberg	Hal	Simon Fraser University

Appendix E British Columbia REBs⁸

Organization/ Institution	Type	REB established
1. BC Cancer Agency	Health Services Academic	2003
2. BC Institute of Technology	Academic	1999
3. Camosun College	Academic	2006
4. Canadian Blood Services (B.C.)	Health Services (national NGO)	2001
5. Community-Based REB	Community	1999
6. Fraser Health	Health Services	2004
7. Interior Health	Health Services	2005
8. Kwantlen University College	Academic	2002
9. Malaspina University-College	Academic	2002
10. Northern Health	Health Services	2007
11. Providence Health Care	Health Services	1996
12. Royal Roads University	Academic	2000
13. Simon Fraser University	Academic	1996
14. Thompson Rivers University	Academic	2001
15. Trinity Western University	Academic	1995
16. University College of the Fraser Valley	Academic	2002
17. University of British Columbia	Academic	Clinical: 1983 Behavioural: 1976
18. University of Northern BC	Academic	1994
19. University of Victoria	Academic	1999
20. The Vancouver Foundation	Community	2004
21. Vancouver Island Health Authority	Health Services	Clinical: 1987 Health: 2006

⁸ REBs identified in British Columbia that currently review research involving human subjects.



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